02.02 General Antidote

28403 ɔt be ruled out / Infant risk can

CARBOMIX GRANULES FOR SUSPENSION "NORIT" 蓋抹滅顆粒劑

Charcoal activated 50g/bot granules for susp

Dosage: 1常備品 28403

Adult
· Diarrhea: PO, 520 mg after meals or at the first sign of discomfort, Max. 4160 mg/day
· Poison ingestion: PO, 50-100 g as a single dose; may repeat every 4-6 hr.

Pediatric
· Poison ingestion: < 1 yr, PO, 1 g/kg as a single dose; may repeat every 4-6 hr.
· Poison ingestion: 1-12 yr, PO, 25-50 g as a single dose; may repeat every 4-6 hr.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Susp: 0.5g/500mL (28401), 50g/B(28403)

ADR:

COMMON
Black feces, diarrhea, vomiting, pulmonary aspiration
SERIOUS
Hypotension(rare), Electrolyte imbalance (rare), GI obstruction

NOTE: 室溫儲存

1.Each bot should be mixed with 400ml of water
2.Discard any unused suspension after 24hours
· 本品賦形劑不含阿斯巴甜

藥名相似:

外觀相似:

外觀描述: 灰色塑膠瓶，瓶身有白色標籤，內為黑色粉末

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021549

02.04A Antidote, Acetaminophen

24406 B /

ACTEIN EFFERVESCENT TABLETS 600MG 愛克痰發泡錠600毫克

Acetylcysteine 600mg Effervescent tab

Dosage: 1常備品 24406

Adult
·Mucolytic: PO, 600mg qd-bid
·Antidote for acetaminophen: PO, 140mg/kg then 70mg/kg q4h for 17 additional doses

Pediatric(≧6 yrs)
Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Eff Tab: 600mg(24406), Granules: 200mg/PK(24407), Inj: 5g/25mL(34002)

ADR:

COMMON
Decreased prothrombin time, nausea, vomiting, hypotension, diarrhea
SERIOUS
Anaphylactic reactions, bronchoconstriction

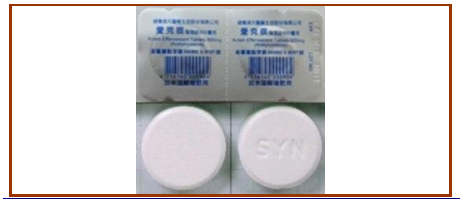
NOTE: 室溫儲存

Dissolve 1 tab in 100mL of water
含阿斯巴甜，苯酮尿症者不宜使用。

藥名相似: Eff Tab: 600mg(24406), Granules: 200mg/PK(

外觀相似:

外觀描述: 白色圓扁錠,有SYN字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045993

02.04A Antidote, Acetaminophen

24407 B /

ACTEIN GRANULES 66.7MG/GM 愛克痰顆粒 6 6 · 7 毫克/公克

Acetylcysteine(NAC) granules 200mg/3g/pack sachet

Dosage: 1常備品 24407

Adult
·Mucolytic: PO, 200 mg tid
·Antidote for acetaminophen: PO, 140 mg/kg then 70 mg/kg q4h for 17 additional doses

Pediatric
·Mucolytic: PO, 100 mg bid-qid
·Antidote for acetaminophen: PO, 140 mg/kg then 70 mg/kg q4h for 17 additional doses

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Eff Tab: 600mg(24406), Granules: 200mg/PK(24407), Inj: 300mg/3mL(34001); 5g/25mL(34002)

ADR:

COMMON
Decreased prothrombin time,nausea, vomiting,hypotension,diarrhea
SERIOUS
Anaphylactic reactions,bronchoconstriction

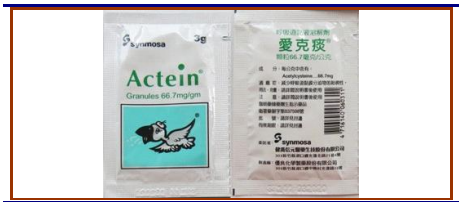
NOTE: 室溫儲存25℃以下

· 《Contraindications》Hypersensitivity to acetylcysteine ;
· 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 每包含3g顆粒粉劑,白色鋁箔包,有綠色字樣圖案



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1037598

02.04A Antidote, Acetaminophen

34002 B / Unknown(有

HIDONAC INJECTION 希那克注射劑

Acetylcysteine inj 5g/25mL bot

Dosage: 1常備品 34002

Adult
·Antidote for acetaminophen toxicity: IV, > 41 kg initial 150 mg/kg(Max.15000mg) in 200 mL of diluent (D5W, 0.45%NaCl, or SWFI) over 1 hr, then 50 mg/kg(Max.5000mg) in 500 mL of diluent over 4 hrs, then 100 mg/kg(Max.10000mg) in 1000 mL of diluent over 16 hrs.
21-40 kg initial 150 mg/kg in 100 mL of diluent over 1 hr, then 50 mg/kg in 250 mL of diluent over 4 hrs, then 100 mg/kg in 500 mL of diluent over 16 hrs.

·Pediatric
> 21 kg: Same as adult
5 - 20 kg: initial 150 mg/kg in 3 mL/kg of diluent over 1 hr, then 50 mg/kg in 7 mL/kg of diluent over 4 hrs, then 100 mg/kg in 14 mL/kg of diluent over 16 hrs.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Eff Tab: 600mg(24406), Granules: 200mg/PK(24407), Inj: 300mg/3mL(34001); 5g/25mL(34002)

ADR:

flushing, urticaria, angioedema, respiratory symptoms or hypotension

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 25mL透明注射液透明玻璃小瓶紅色鐵鋁瓶口

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024213

02.04B Antidote, Anticholinesterase/organophosphate

30002 C / Unknown(有

PAMPARA INJECTION 把母巴拉注射液

Pralidoxime chloride inj 500mg/20mL amp

Dosage: 1常備品 30002

Adult
· Anticholinesterase overdosage: IV, initial 1-2 g maintenance, 250 mg every five minutes
· Organophosphate intoxication: IV, 1-2 g in 100mL NS infused over 15-30 mins or 5% solution in SWFI over not less than 5 min; repeat same dose in 1hr if muscle weakness persists

Pediatric
· Organophosphate intoxication: IV, 25-50 mg/kg over 30min; repeat in 1-2hrs if necessary

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA, dose should be reduced

P: Inj: 500mg/20mL amp(30002)

ADR:

COMMON
Blurred vision, dizziness, headache, laryngeal spasm, hyperventilation, nausea

NOTE:

1. Establishment of an airway and atropinization must occur prior to initiating pralidoxime
2. Maximum rate of administration, (200 mg/min)
3. May induce myasthenic crisis in myasthenia gravis patients

藥名相似:

外觀相似:

外觀描述: 20mL透明注射液『棕』色安瓿，頸部有白點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1002394

02.04B Antidote, Anticholinesterase/organophosphate

31630 C / Unknown(有

ATROPINE SULFATE* INJECTION "TAI YU" "台裕"硫酸阿托品注射液

Atropine sulfate inj 1mg/1mL amp

Dosage: 1常備品 31630

Adult
IV, IM, SC, 0.4-0.6 mg 4-6 times daily
·Antidote to cholinesterase inhibitor: IV, 1-6 mg then IV or IM 2-6 mg repeated every 5-60 min until muscarinic symptoms disappear or signs of atropine toxicity appear
·Bradyarrhythmias: IV, 0.4-1 mg every 1-2 hrs as needed, Max. 2 mg
·Prophylaxis of salivation and respiratory secretions in anesthesia: IM, 0.2-0.6 mg 0.5-1 hr before surgery

Pediatric
·General dose recommendation: IM, SC, IV, 0.01 mg/kg/ dose (Max. 0.4mg/dose), may repeat q4-6h
·Cardiopulmonary resuscitations: IV, 0.02mg/kg/dose every 5 min for 2-3 doses as

needed, Max. 1 mg/dose in adolescents and 0.5 mg/dose in children; Max. total dose 2 mg in adolescents and 1 mg in children

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 1mg/1mL(31630); Oph soln: 0.5% 10mL(29242),1% 10mL(29252)

ADR:

COMMON
blurred vision, constipation, dry mouth, micturition difficulties, photophobia, tachycardia,
SERIOUS
allergic reaction, arrhythmias,coma, increased intraocular pressure, respiratory depression,

NOTE: 避光儲存25℃以下

Contraindications:
glaucoma, or a predisposition to narrow anterior chamber angle glaucoma, pyloric stenosis or prostatic hypertrophy (except in doses used for preanesthetic medication)

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液，透明玻璃安瓿，白紙『黑』字，藥名為黃底『黑』字標籤，頸部有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1014355

02.04C Antidote, Benzodiazepine

30006 **C / Unknown(有**

ANEXATE AMPOULE 安易醒注射液

Flumazenil inj 0.5mg/5mL amp

Dosage: 1常備品 30006

Adult
· Reversing the sedative effect of benzodiazepine after anesthesia: IV, 0.2mg over 15sec, further dose of 0.2mg at 1 min intervals if necessary to a cumulative dose of 1mg; If resedation, repeated the initial regimen every 20min, max. 3mg in any 1hr period
· Benzodiazepine overdose: IV, 0.2mg over 30 sec, further dose of 0.3-0.5mg at 1min intervals up to a cumulative dose of 3mg

Pediatric
· Safety and efficacy in the reversal of conscious sedation in pediatric patients below the age of 1 year have not been established
· Reversal of conscious sedation: 0.01 mg/kg (up to 0.2 mg) IV over 15 seconds; may repeat as needed every 60 seconds (max dose 0.05 mg/kg or 1 mg, whichever is lower). The mean total dose 0.65 mg (range: 0.08-1mg). Approximately one-half of patients require the maximum of five injections

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Inj: 0.5mg/5mL amp(30006)

ADR:

COMMON
agitation, dizziness, headache, increased sweating, abnormal or blurred vision, injection site pain
SERIOUS
cardiac arrhythmias , seizures

NOTE: 室溫保存

1. Most patients with a benzodiazepine overdose will respond to a cumulative dose of 1-3 mg of flumazenil, and doses beyond 3 mg do not reliably produce additional effects. On rare occasions, patients with a partial response at 3 mg may require additional titration up to a total dose of 5 mg
2. If a patient has not responded 5 minutes after receiving a cumulative dose of 5 mg of flumazenil, the major cause of sedation is likely not to be due to benzodiazepines, and additional flumazenil is likely to have no effect

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液透明安瓿，頸部有藍點及1條紫色線條和1條綠色線條

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2017124

02.04D Antidote, Paraquat

28402 **/ Unknown(有**

Fuller's Earth* 60g/box

Dosage: 1常備品 28402

Adult
· Paraquat poisoning: After stomach washout, give orally up to 1 litre of suspension (15%) plus 200 Ml of 20% mannitol in water as a purgative. Alternatively, sodium or magnesium sulphate can be used as the purgative. Repeat combined administration until Fuller's Earth appears in the stool.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Pow: 60g/box (28402)

ADR:

NDA

NOTE: 室溫儲存

Thoroughly mix contents with water making volume

up to 400ml to make a 15% suspension

藥名相似:

外觀相似:

外觀描述: 白色塑膠瓶身,上有藥名FULLER`S EARTH

02.04E Antidote, Metal poison

20003 D /

METALCAPTASE 300 滿克特３００毫克腸溶膜衣錠

D-Penicillamine 300mg FC tab

Dosage: 1常備品 20003

Adult

· Heavy metal intoxication : :PO, ac, 250mg qid
· Cystinuria:PO, ac, 2g/day, range 1-4g/day
· Rheumatoid arthritis:PO, ac, initial 125-250 mg/day, MD 500-1500mg/day
· Wilson's disease:PO, ac, initial 750mg-1.5g/day, MD up to 2g/day

Pediatric

· Cystinuria 30mg/kg/day divide qid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

1.GFR less than 50 milliliters/minute: recommend that penicillamine be avoided in these patients
2.GFR greater than 50 milliliters/minute: No dosage adjustment needed.

P:

ADR:

COMMON
anorexia, epigastric pain, nausea, vomiting myelosuppression, rash, taste disorders
SERIOUS
aplastic anemia, agranulocytosis, thrombocytopenia, glomerulopathy, renal vasculitis, Goodpasture's syndrome, myasthenia gravis, obliterative bronchiolitis, optic neuritis, peripheral sensory and motor neuropathies, tinnitus, oral lesions, pemphigus, proteinuria

NOTE: 室溫儲存

1. Patients receiving penicillamine therapy may require intake of supplemental pyridoxine
2.Wilson's disease-goal of therapy is cupriuresis of 2mg/day
3. Cystinuria-increased intake of fluids allows for lower required doses of penicillamine

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2017283

02.04E Antidote, Metal poison

27401 UK /

Succicaptal* 200mg cap 螯合拔膠囊

Succimer (DMSA) 200mg cap

Dosage: 2衛福部提供-特定解毒劑 27401

Adult

· Heavy metals poisoning (eg.Pb, Hg, As): PO, 10mg/kg q8h for 5 days, followed by 10mg/kg q12h for an additional 14days (a course of therapy lasts a total of 19 days)

Pediatric

· Lead poisoning (in pediatric patients with blood lead levels above 45 mcg/dl): 10mg/kg or 350mg/m2 q8h for 5 days, then 10/mg/kg or 350mcg/m2 q12h for 14 days

Dosing adjustments in hepatic impairment:

Administer with caution and moniter closely

Dosing adjustments in renal impairment:

Administer with caution and moniter closely

P: Cap: 200mg (27401)

ADR:

COMMON
anorexia, diarrhea, nausea, vomiting, increased LFT's, rash
SERIOUS
neutropenia

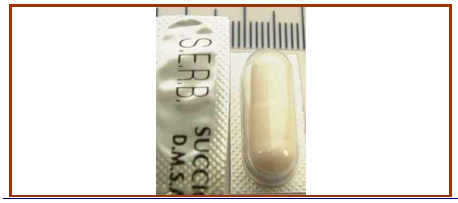
NOTE: 室溫儲存

1.Monitoring parameter : Liver function test
2.由衛生署提供特定解毒劑(本院未儲備)

藥名相似:

外觀相似:

外觀描述: 白色膠囊



02.04E Antidote, Metal poison

27402 UK /

DIMAVAL CAPSULES 螯金拔膠囊

Unithiol (DMPS) 100mg cap

Dosage: 2衛福部提供-特定解毒劑 27402

Adult

· Acute mercury poisoning: PO, ac, 1.2-2.4g/day div. Into 12 doses

· Chronic mercury poisoning: PO, ac, 100mg tid-qid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap:100mg (27402); Inj:250mg/5ml(37705)

ADR:

leukopenia, fever, headache, fatigue, nausea, dysguesia, elevated liver enzymes, bronchospasm, rash, pruritus

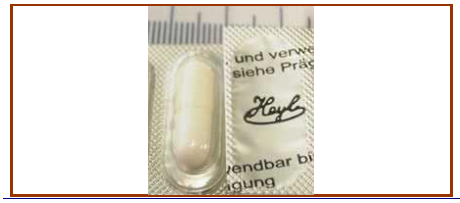
NOTE: 室溫儲存

1.Unithiol should not be taken together with mineral preparations and activated charcoal
2.Antidoxe for arsenic, lead, zinc, mercury, and chromium toxicity; not useful for cadmium removal.
3. In the case of treatment of pregnant women with DMPS, the mineral balance, especially of zinc, should be carefully monitored, It is known that zinc deficiency caused by chelating agents can have a teratogenic effect.
4.由衛生署提供特定解毒劑(本院未儲備)

藥名相似:

外觀相似:

外觀描述: 白色膠囊



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=20000002

02.04E Antidote, Metal poison

27533 B /

Exjade 125mg dispersible tablets 易解鐵可溶錠125毫克

Deferasirox 125mg tab

Dosage: 1常備品 27533

Adult
· Transfusion hemosiderosis: PO, ac, initial 20mg/kg once daily, adjust in increments of 5-10mg/kg q3-6 mons based on serum ferritin trends, Max. 30mg/kg/day

Pediatric (≥2yrs)
· Transfusion hemosiderosis: Same as adult

Dosing adjustments in hepatic impairment:

Consider dose adjustment or discontinuation for severe elevations in liver function tests

Dosing adjustments in renal impairment:

Consider dose reduction, interruption, or discontinuation with serum creatinine elevation

P: Dispersible Tab: 125mg(27533)

ADR:

COMMON
Rash, abdominal pain, diarrhea, nausea, vomiting, increased liver enzymes, headache, proteinuria, serum creatinine raised(more than 33% above baseline), cough, nasopharyngitis, fever
SERIOUS
Urticaria, drug-induced hepatitis, hearing loss

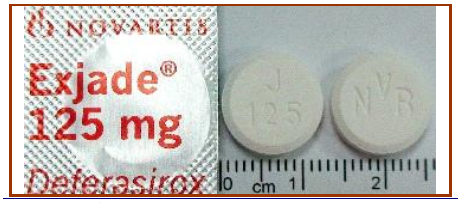
NOTE: 室溫儲存

· Tablets are dispersed by stirring in a glass of water, orange juice or apple juice (100–200 mL) until a fine suspension is obtained. Rinse residue in container with more fluid and drink
· Not mix with carbonated water or milk
· Tablets should not be chewed or swallowed whole
· 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有J125字樣；另一面有NVR字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024603

02.04E Antidote, Metal poison

27634 ɔt be ruled out / Infant risk can

Jadenu* film-coated tablets 360 mg 解鐵定膜衣錠 360 毫克

急用 Deferasirox 360mg tab

Dosage: 2急用藥 27634

Adult
· Transfusion hemosiderosis:PO,ac,initial 14mg/kg once daily, adjust in increments of 3.5-7mg/kg q3-6 mons based on serum ferritin trends, Max. 28mg/kg/day

Pediatric(≥2yrs)
· Same as adult

Dosing adjustments in hepatic impairment:

· Mild (Child-Pugh A): No dosage adjustment needed
· Moderate (Child-Pugh B): Reduce initial dose by 50% and monitor closely
· Severe (Child-Pugh C): Avoid use

Dosing adjustments in renal impairment:

Consider dose reduction, interruption, or discontinuation with serum creatinine elevation

P: P Tab: 360mg(27634), 125mg(27533, 發泡錠)

ADR:

COMMON
Rash, abdominal pain, diarrhea, nausea, vomiting, serum creatinine raised
SERIOUS
Drug reaction with eosinophilia and systemic symptoms, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, dehydration, gastrointestinal hemorrhage, gastrointestinal perforation, gastrointestinal ulcer, acute pancreatitis, agranulocytosis, anemia, neutropenia, thrombocytopenia, liver failure, anaphylaxis, hypersensitivity reaction, encephalopathy, acute

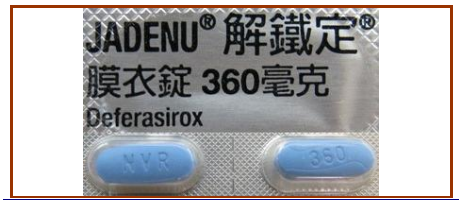
renal failure, Fanconi syndrome, glomerulonephritis, renal tubular disorder, acute tubular necrosis, angioedema

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 藍色橢圓錠，一面有360字樣；另一面有NVR字樣



02.04E Antidote, Metal poison

30001 **C / Unknown(有**

DESFERAL VIALS 500MG 除鐵能凍晶注射劑500毫克

Deferoxamine mesylate(desferrioxamin) 500mg /vial

Dosage: 1常備品 30001

Adult
· Acute iron intoxication: IM, Slow IV infusion, 1g; to be followed by 0.5g q4h for 2 doses then 0.5g q4-12h as needed; Max. 6g/day
· Chronic iron overload:IM, 0.5-1 g/day; SC infusion,1-2 g/day; Slow IV infusion, 2g for 1 unit of blood transfusion
· Chronic iron overload:SC infusion over 8-24 hr, 1-2 g (20-40 mg/kg/day)

Pediatric
safety and effectiveness have not been determined in children under the age of 3 years
· Acute iron intoxication: IM, 50 mg/kg/dose q6h or IV infusion, 15 mg/kg/hr
· Chronic iron overload: SC infusion over 8-24 hr, 20-50 mg/kg/day

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P: Vial: 500mg (30001)

ADR:

COMMON
injection site pain
SERIOUS
allergic reaction, auditory neurotoxicity, hypotension, impaired cardiac function, shock, tachycardia, mucormycosis, ocular effects

NOTE: 室溫保存

Contraindicated in patients with severe renal disease or anuria since the chelated compound is excreted primarily by the kidney

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『紅』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2011917

02.04E Antidote, Metal poison

37704 **B / Unknown(有**

Ca-EDTA 0.5g/10mL amp 注射劑

Edetate Calcium Disodium(Ca-EDTA) 0.5g/10mL amp

Dosage: 2衛福部提供-特定解毒劑 37704

Adult
Lead poisoning: IV, IM, 1g bid or 50 to 75 mg/kg/day for 5 days, followed by a 2-day interruption, with a repeated course of therapy if necessary.

Pediatric
Lead poisoning: IV, IM, 1000 to 1500 mg/m2/day for 3 to 5 days, followed by a 2-day interruption, with a repeated course of therapy if necessary.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

A.Srcr < 2mg/mL: 1g /m2 /day for 5 days
Srcr 2 to 3 mg/dL : 500mg/m2 /day for 5 days
Srcr 3 to 4 mg/dL : 500mg/m2 /dose, q48h, for 3 days
Srcr > 4 mg/dL : 500mg/m2 once weekly
B. It should not be administered to patients during periods of anuria.
C. Reduced doses of 500 mg q12h have been used in adults with azotemia; the dose was given following each 12-hour period of peritoneal dialysis

P: Amp: 0.5g/10mL (37704)

ADR:

Nausea, vomiting, salivation, bradycardia, convulsions

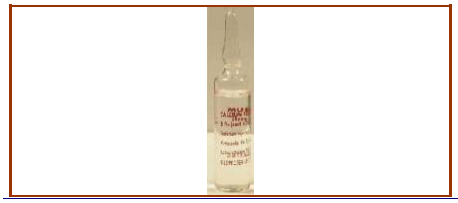
NOTE:

1.Each amp dilutes to 250ml NS or D5W for IV infusion over 1hr in asymptomatic patients, 2 hrs in symptomatic patients.
2.由衛生署提供特定解毒劑(本院未儲備)

藥名相似:

外觀相似:

外觀描述:



02.04E Antidote, Metal poison

37705 **UK / Unknown(有**

Dimaval* 250mg amp 注射劑

Unithiol (DMPS) 250mg /5mL amp

Dosage: 2衛福部提供 -特定解毒劑 37705

Adult
· Acute mercury poisoning: IV, 1amp q3-4h on 1st day, q4-6h on 2nd day, q6-8h on 3rd day, q8-12h on 4th day, and qd or switch to the oral dosage form (300mg tid) on the subsequent day; PO, ac, 1.2-2.4g/day div. Into 12 doses
· Chronic mercury poisoning: PO,ac,100mg tid-qid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

use with caution

Dosing adjustments in renal impairment:

use with caution

P: Cap:100mg(27402); Inj: 250mg/5ml(37705)

ADR:

leukopenia, fever, headache, fatigue, nausea, dysgeusia, elevated liver enzymes , bronchospasm, rash, pruritus

NOTE:

1.Unithiol should not be taken together with mineral preparations and activated charcoal
2.Antidoxe for arsenic, lead, zinc, mercury, and chromium toxicity; not useful for cadmium removal.
3. In the case of treatment of pregnant women with DMPS, the mineral balance, especially of zinc, should be carefully monitored, It is known that zinc deficiency caused by chelating agents can have a teratogenic effect.
4.由衛生署提供特定解毒劑(本院未儲備)

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=20000003

02.04F Antidote, Methemoglobinemia

37702 C /

Methylene Blue Injection 10mg/mL "Astar" "安星"甲烯藍注射液10毫克/毫升

Methylthioninium Chloride 1% 100mg/10mL vial 甲烯藍注射液

Dosage: 1常備品 37702

Adult:
· Antidote for drug-induced methemoglobinemia : Slow IV, low dose 1-2mg/kg (0.1-0.2 ml/kg of 1 % solution) may be repeated in 1hr if necessary. Max. 4mg/kg.

Pediatric
>3 months : Same as adult
<3 months : Slow IV over 5 minutes , 0.3-0.5mg/kg (0.03-0.05ml/kg of 1 % solution) may be repeated in 1 hr if necessary

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

·In patients with renal impairment, severe: dosage adjustment should be considered.

P: Inj:1% 100mg/10mL amp(37702), 0.7% 5ml/vial (38565); Soln: 0.01% 20ml/vial (33400)

ADR:

COMMON
dizziness, headache, mental confusion
abdominal pain, diarrhea, nausea, vomiting
hypertension, hypotension, sweating, vision color changes (blue tinge)
SERIOUS
arrhythmias, hemolytic anemia , methemoglobinemia

NOTE: 室溫避光儲存

1.Urine and fecal discoloration (blue-green)
2.Administration in G-6-PD patients can result in hemolysis
3.Rapid IV injection or large dose can produce methemoglobinemia

藥名相似:

外觀相似:

外觀描述: 藍色溶液、『藍』蓋玻璃小瓶

02.04G Antidote, Cyanide

37703 C / Unknown(有

NITHIODOTE* 氰化物解毒包

Sodium nitrite 300mg/10mL & Sodium thiosulfate 12.5g/50mL vial

Dosage: 2衛福部提供 -特定解毒劑 37703

Adult
· Treatment of cyanide poisoning: Slow IV, sodium nitrite 300mg at the rate of 2.5-5 mL/min followed immediately by sodium thiosulfate 12.5g over 10-20 mins. Treatment may be repeated at one-half the original dose of both drugs if signs of poisoning reappear

Pediatric
· Treatment of cyanide poisoning: Slow IV, sodium nitrite 6mg/kg(0.2mL/kg) at the rate of 2.5-5 mL/min; Max. 300mg followed immediately by sodium thiosulfate 250mg/kg(1mL/kg) over 10-20 mins; Max. 12.5g. Treatment may be repeated at one-half the original dose of both drugs if signs of poisoning reappear

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: NITHIODOTE* (sodium nitrite & sodium thiosulfate) (37703); Cyanokit (Hydroxocobalamin) (37707)

ADR:

COMMON
Palpitations, syncope, tachycardia, confusion, disorientated, dizziness, headache, blurred vision
SERIOUS
Cardiac dysrhythmia, hypotension, methemoglobinemia, coma, seizure

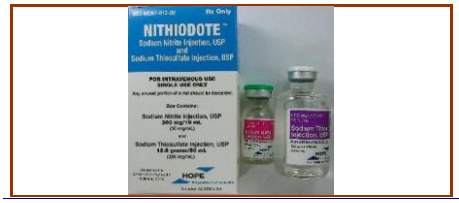
NOTE: 室溫儲存

1.Reduce the rate of infusion if significant hypotension develops .
2.Patients with G6PD deficiency are at increased risk of a hemolytic crisis with sodium nitrite administration, alternative therapeutic approaches should be considered.
3.If a decision is made to administer another cyanide antidote with NITHIODOTE*, these drugs should not be administered concurrently in the same IV line.
4.由衛生福利部全國解毒劑儲備網供應解毒劑：
氰化物暴露致生命象徵不穩定者、代謝性酸中毒、意識不清、抽搐、昏迷者應立即使用解毒劑。注意事項：
1. 心臟、腎臟衰竭或高血鈉者，需留意鈉過度負擔，引起的體液留滯作用。
2. 另sodium nitrite可用於硫化氫中毒患者。
硫化氫中毒現場使用較佳；超過一小時後使用的效果，仍無定論。

藥名相似:

外觀相似:

外觀描述: cyanide)中



02.04I Antidote, MTX

25203 **C / Infant risk can**

FOLINA TABLETS 15MG 芙琳亞錠15毫克

Calcium folinate (leucovorin calcium) 15mg tab

Dosage: 1常備品 25203

Adult
· Rescue therapy after high-dose MTX : Oral, IM, IV, 10 mg/m2 q6h on next day until MTX serum levels < 0.05 micromolar; If at 24hr following MTX administration, MTX serum levels >5 micromolar, leucovorin dosage should be increased to 100mg/m2 q3h, until MTX serum levels < 0.05 micromolar
· Counteract overdosages of folic acid antagonists: PO, 2-15mg/day for 3days or 5mg Q3days until blood counts are normal; (6mg/day are needed for patients wit platelet counts < 100,000)

Pediatric
Same as adults

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

In patients with renal insufficiency METHOTREXATE excretion may be delayed and high LEUCOVORIN doses (higher than those recommended for oral use) or prolonged administration are recommended and must be given intravenously .

P: Tab: 15mg (25203); Inj: 30mg/10ml (34839); Inj: 50mg/5mL (34838)

ADR:

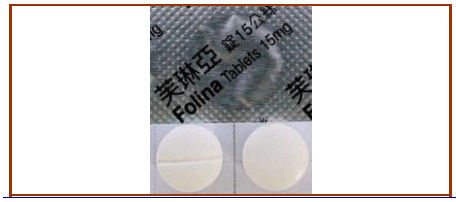
COMMON
diarrhea, nausea, stomatitis, vomiting, fatigue
SERIOUS
allergic sensitization

NOTE: 室溫儲存

藥名相似: Tab: 15mg (25203); Inj: 30mg/10ml (34839); I

外觀相似: 外盒：UFUR* Tegafur 100mg & Uracil 224mg

外觀描述: 白色圓扁錠，一面中間有刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044248

02.04I Antidote, MTX

34838 **C /**

Folina Injection 10mg/ml 芙琳亞 注射液 10毫克/毫升

Folinate calcium 50mg/5mL vial

Dosage: 1常備品 34838

Adult
· Enhance the cytotoxic effect of 5-FU in advanced colorectal cancer : slow IV, 200mg/m2/day at least over 3 min followed by an IV 5-FU dose of 370mg/m2 for 5 days, repeated at 4 wks intervals for 2 additional courses
· Rescue therapy after high-dose MTX : oral, IM, IV, 10 mg/m2 q6h on next day until MTX serum levels < 0.05 micromolar; If at 24hr following MTX administration, MTX serum levels >5 micromolar, leucovorin dosage should be increased to 100mg/m2 q3h, until MTX serum levels < 0.05 micromolar
· Counteract overdosages of folic acid antagonists: PO, 2-15mg/day for 3days or 5mg Q3days until blood counts are normal; (6mg/day are needed for patients wit platelet counts < 100,000)

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

In patients with renal insufficiency METHOTREXATE excretion may be delayed and high LEUCOVORIN doses (higher than those recommended for oral use) or prolonged administration are recommended and must be given intravenously

P: Tab: 15mg (25203); Inj: 50mg/5mL vial (34838); Inj: 30mg/10mL(34839)

ADR:

COMMON
Diarrhea, nausea, stomatitis, vomiting, fatigue
SERIOUS
Allergic sensitization

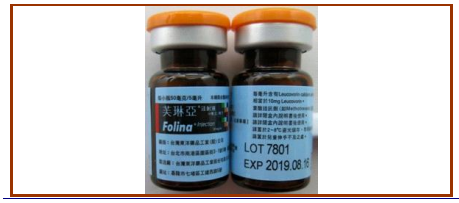
NOTE: 冰箱儲存

When doses greater than 10mg/m2 are required, formulations containing benzyl alcohol should not be used.

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液，『橘』蓋棕色玻璃小瓶



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048426

02.04J Antidote, Narcotic agonist

30005 C / Unknown(有

Naloxone Injection "G.B.L." 0.4mg/ml 解麻注射液0.4毫克/毫升

Naloxone HC1 0.4mg/1mL amp

Dosage: 1常備品 30005

Adult
· Opioid overdose: 0.4-2 mg repeat every 2-3 min as needed; if no response after 10 mg, reconsider diagnosis of opioid toxicity
· Postoperative opioid depression:IV, 0.1-0.2 mg repeat every 2-3 min as needed to desired degree of reversal; repeat doses may be needed within 1-2 hr depending on amount and type of opioid and time interval since last opioid administration
· Septic shock: 0.03-0.2 mg/kg IV bolus over 5 min; if clinical response, follow by IV infusion of 0.03-0.3 mg/kg/hr for 1-24 hr; optimal dose has not been established

Pediatric
· Opioid-induced depression: (neonates) : 0.01 mg/kg IV/IM/SC every 2-3 min to desired degree of reversal
· Opioid overdose: IV, 0.01 mg/kg then 0.1 mg/kg if needed; may give IM,SC in divided doses if IV route not available
· Postoperative opioid depression: 0.005-0.01 mg IV every 2-3min to desired degree of reversal

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Amp: 0.4mg/1mL (30005)

ADR:

SERIOUS
arrhythmias, hypertension, hypotension, ventricular fibrillation, hepatotoxicity, opiate withdrawal symptoms, pulmonary edema

NOTE: 室溫儲存

1.The use of neonatal naloxone (Narcan(R) 0.02 mg/mL) is NOT recommended since unacceptable fluid volumes are required, especially in small neonates; preparations of 0.4 mg/mL or 1 mg/mL are preferred
2. In pediatric patients, (age 17 yr and younger) naloxone should be given in a dose of 0.005-0.01 mg/kg undiluted by rapid IV push over less than 30 sec; intermittent or continuous infusions are not recommended

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液透明安瓿

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2000079

02.04K Antidote, Heparine

34931 C / Unknown(有

PROTAMINE SULPHATE LEO PHARMA 1400 ANTI-HEPARIN IU/ML SOLUTION FOR INJECTION AND INFUSION "理奧" 硫酸魚精蛋白注射液

Protamine sulfate 50mg/5mL amp

Dosage: 1常備品 34931

Adult
· Severe heparin overdose: 1mg needed to neutralize 90-115 USP units of Heparin , slow IV over 10 mins, and should not exceed 50mg in any 10 minute period; Adjust the protamine dosage depending upon the duration of time since heparin administration:1-1.5mg(Immediated), 0.5-0.75mg (30-60min), 0.25-0.375mg(>2h) to neutralize 100 USP units of Heparin

Pediatric
·Heparin: within 30 minutes since last dose of heparin therapy, 1 mg IV for every 100 units of heparin received; between 30 and 60 minutes since last dose of heparin therapy, 0.5 to 0.75 mg for every 100 units of heparin received; between 60 and 120 minutes since the last dose of heparin, 0.375 to 0.5 mg per every 100 units of heparin received; more than 120 minutes since the last dose of heparin, 0.25 to 0.375 mg per every 100 units of heparin received; MAX dose 50 mg, not exceeding 5 mg/min in a concentration of 10 mg/Ml

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

COMMON
flushing, nausea, vomiting, dyspnea
SERIOUS

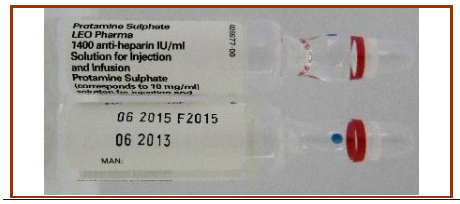
hypotension, bradycardia, anaphylaxis
anaphylactoid reactions (circulatory collapse, capillary leak, noncardiogenic pulmonary edema)

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液，頸部有藍點及1條紅線和1條白線



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2012640

02.04L Antidote, Anticholinergic Agents

37701 C / Unknown(有

Physostigmine salicylate Inj 2mg/2mL amp 水楊酸毒扁豆素注射劑

Physostigmine salicylate inj. 2mg/5mL amp

Dosage: 2衛福部提供 -特定解毒劑 37701

Adult
Anticholinergic overdose: IV, IM, 0.5-2mg (Max. IV rate 1mg/min), repeat every 20 mins until response or adverse effect occurs.

Pediatric
Anticholinergic overdose: IV, 0.01-0.03mg/kg/dose (Max. IV rate 0.5mg/min), may repeat after 5-10 mins to a Maximun total dose of 2mg or until response or adverse effect occurs.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Amp: 2mg/5mL (37701)

ADR:

COMMON
diaphoresis, diarrhea, hyperperistalsis with cramping, hypersalivation, nausea or vomiting, eye irritation, lacrimation, miosis, mydriasis
SERIOUS
arrhythmias, bradycardia, cardiac arrest, increased cardiac output, bronchospasms, shortness of breath, seizures

NOTE:

1.Have atropine on hand to control bradycardia or seizures.
2.Discontinue If excessive symptoms of salivation or emesis, frequent urination or diarrhea occur . Reduce dosage If excessive sweating or nausea occur.
3.It may induce or exacerbate seizures and cause cardiac arrest in tricyclic antidepressant overdose.
4.由衛生福利部全國解毒劑儲備網供應解毒劑：Physostigmine以治療抗乙醯膽鹼症候（anticholinergic poisoning）為主。
●可能中毒來源：
·藥物方面包括
1. 抗組織胺藥類antihistamines。
2. 抗精神病藥物類antipsychotics、antispasmodies。
3. 部分的抗巴金森症藥物anti-parkinsonism medications。
4. 含抗組織胺的助眠成藥(OTC sleep preparations)。
·植物方面包括
1. 大花曼陀羅
2. 紅花曼陀羅
3. 曼陀羅
4. 紫花曼陀羅
（有些中毒是病人誤為可食野菜或野花，有些中毒則是病人自中草藥店購買用於治療氣喘或保健）。
●Pysostigmine之使用適應症：
1. 病人有全身抽搐（seizures）。
2. 嚴重的躁動不安。
3. 昏迷伴隨呼吸衰竭。
4. 低血壓伴隨嚴重心律不整等症狀。

藥名相似:

外觀相似:

外觀描述: 棕色玻璃瓶

02.04M Antidote, Ifosfamide

30007 B / Unknown(有

UROMITEXAN INJECTION 優路保注射液

Mesna 400mg/4mL amp

Dosage: 1常備品 30007

Adult
Prophylaxis of ifosfamide or cyclophosphamide induced urothelial toxicity : IV, 20% dose of antineoplastic over 15-30 min, q4h for 3 times, beginning at the same as the antineoplastic injection

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Inj:400mg/4mL (30007)

ADR:

fatigue, headache, limb pain, nausea, diarrhea , hypotension

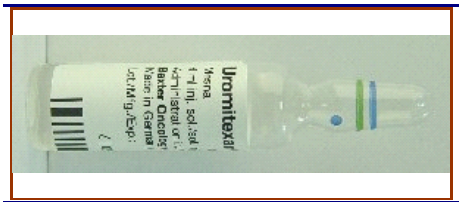
NOTE: 室溫儲存

為年長病患選定劑量應小心。Oxazaphosphorine類藥物和mesna的比例應維持不變。

藥名相似:

外觀相似:

外觀描述: 4mL透明注射液透明安瓿，頸部有藍點及1條藍色線條和1條綠色線條



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2018485

02.04O Antidote, Dabigatran

37708 **ɔt be ruled out / No report(毫**

Praxbind Solution for injection/infusion 達栓普注射液/輸注液

Idarucizumab inj 2.5g/50mL vial

Dosage: 1常備品 37708

Adult

·Drug action reversal, Dabigatran; for life-threatening or uncontrolled bleeding or when emergency surgery or procedures are required: IV,5g ; limited data support the use of an additional 5 g if coagulation parameters re-elevate in the presence of clinically relevant bleeding, or if another emergency procedure is needed.Dabigatran can be reinitiated 24 hours after administration.

·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No adjustment required

P: Inj: 2.5g/50mL vial(37708)

ADR:

NOTE: 冰箱儲存2-8℃，不可冷凍

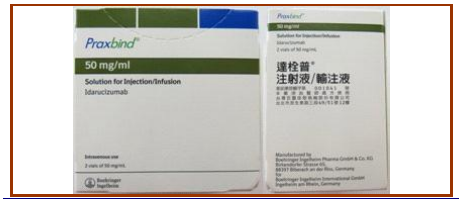
·不要與其他藥物混合,一旦溶液已經從瓶中取出,應在1小時內開始施用。不要冷凍或搖晃。

·附形劑含4g山梨醇，對遺傳性果糖不耐症的病人，曾有低血糖、低磷酸鹽血症、代謝性酸中毒、尿酸增加、急性肝衰竭及死亡案例之報告，故 對遺傳性果糖不耐症的病人，應權衡治療風險與緊急治療的效益。

藥名相似:

外觀相似:

外觀描述: 50mL透明注射液『藍』色瓶蓋安瓿



04.02 Antiallergic Agents

27220 **C / Unsafe**

ASUMALIFE CAPSULES 1MG (KETOTIFEN) 喘福膠囊 1 公絲（可多替芬）

Ketotifen fumarate 1mg cap

Dosage: 1常備品 27220

Adult
·Antiallergic, Mast cell stabilizer: PO, 1-2 mg bid; Max. 4 mg/day

Pediatric
·Antiallergic, Mast cell stabilizer: PO, 0.5-2 mg bid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: 1mg(27220)

ADR:

COMMON
Flu syndrome, pharyngitis, headache, rhinitis

NOTE: 室溫儲存

·《Contraindications》hypersensitivity to ketotifen products or benzoate compounds；
·Asthma prophylaxis : for 10wks
·The metabolism of ketotifen in children is significantly faster than in adults, thus the milligram/kilogram dose may be higher in some children to achieve optimal results. The total dose, however, remains lower in children than in adults.

藥名相似: Cap: 1mg(27220)

外觀相似: Ketoprofen 50mg Cap (22842)

外觀描述: 黃色膠囊，印有ASC字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1030467

04.04A First Generation Antihistamines

20402 **B / Infant risk can**

PILIAN TABLETS "Y.S." 佩你安 錠

Cyproheptadine HCl 4mg tab

Dosage: 1常備品 20402

Adult
·Antihistaminic: PO, initial, 4 mg tid, Max. 0.5mg/kg/day
·Appetite stimulant: PO, 4 mg tid-qid
·Migraine headache: PO, 4 mg bid-qid; Max. 32 mg/day

Pediatric
·Antihistaminic
2-6 yrs: PO, 2 mg bid-tid; Max.12 mg/day
7-14 yrs: PO, 4 mg bid-tid; Max.16 mg/day

Dosing adjustments in hepatic impairment:

Dosage adjustment required.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 4mg(20402); Sol: 0.4mg/mL, 120mL/Bot(28409)

ADR:

CNS depression, dry mouth, drowsiness, increased appetite, weight gain, nausea, vomiting, diarrhea, abdominal discomfort

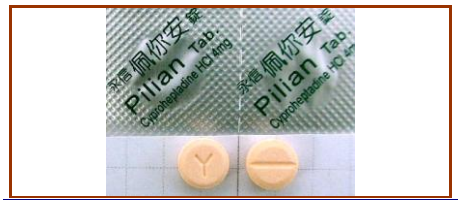
NOTE: 室溫儲存

·《Contraindications》Angle-closure glaucoma; Bladder neck obstruction; Elderly, debilitated patients; Hypersensitivity to cyproheptadine and other drugs of similar chemical structure; MAOI therapy; Newborn or premature infants; Nursing mothers; Pyloroduodenal obstruction; Stenosing peptic ulcer; Symptomatic prostatic hypertrophy；
·新生兒、早產兒、哺乳婦女為仿單禁忌。
·小孩或嬰兒服用過量，會造成嗜睡、中樞神經抑制、痙攣、和死亡。
·老年人服用本品容易造成眩暈、鎮靜和低血壓，應注意。

藥名相似:

外觀相似: Captopril 25mg Tab (22469)

外觀描述: 淡橘色圓扁錠,一面有一刻痕,另一面有 Y 字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1004737

04.04A First Generation Antihistamines

20410 **ɔt be ruled out / Infant risk can**

SUZIN CAPSULES 10MG (FLUNARIZINE) "STANDARD" "生達" 舒腦膠囊１０毫克（服納利林）

Flunarizine 10mg cap

Dosage: 1常備品 20410

Adult
·Vertigo: PO, 20 mg tid
·Peripheral vascular disease: PO, 10-20 mg qd hs
·Epilepsy: PO, LD, 30 mg qid for 6 days, plus an additional incremental dose 5 mg each day until 150 mg; MD, 10 mg tid
·Migraine prophylaxis: PO, 5-10 mg qd hs

Pediatric
·Migraine headache: PO, initial 5 mg qd, 5-10 mg qd

Dosing adjustments in hepatic impairment:

Initial dose, 5 mg qd hs. Since the drug in extensively metabolized in the liver.

Dosing adjustments in renal impairment:

No dosage adjustment needed.Only small amounts of flunarizine are excreted unchanged in the urine.

P: Cap: 10mg(20410)

ADR:

Sedation, drowsiness, extrapyramidal reactions(akathisia, orofacial dyskinesia, acute torticollis and facial tremor), weight gain, gingival hyperplasia

NOTE: 室溫儲存

Contraindications:Depression (history); Extrapyramidal symptoms (pre-existing)

藥名相似:

外觀相似:

外觀描述: 藍色/白色膠囊,有"STD"及"521"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1029575

04.04A First Generation Antihistamines

20411 **B / Infant risk can**

DEX-CTM TABLETS 2MG 特息敏錠2毫克

Dexchlorpheniramine maleate 2mg tab

Dosage: 1常備品 20411

Adult(>12yrs)
·Allergic rhinitis, common cold: PO, 2mg q 4-6 h

Pediatric
·Allergic rhinitis, common cold (2-5 yrs): PO, 0.5mg q 4-6 h
·Allergic rhinitis, common cold (6-11 yrs): PO, 1mg q 4-6 h

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab:2mg(20411); Inj: 5mg/1mL amp(30402)

ADR:

COMMON
Diarrhea, Epigastric discomfort, Nausea, Vomiting, Xerostomia, Somnolence, Nasal mucosa dry.

NOTE: 室溫儲存

·65歲以上、服用其他綜合感冒藥、鎮咳祛痰藥、鎮暈藥、鼻炎藥或抗過敏藥等的病人，應注意監測副作用是否發生。

藥名相似:

外觀相似:

外觀描述: 粉紅色圓扁錠，一面有刻痕)

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1027040

04.04A First Generation Antihistamines

20414 /

MEQUITAZINE TABLETS 5MG "U-CHU" 過敏美奎錠 5 公絲〝五洲〞

Mequitazine 5mg tab

Dosage: 1常備品 20414

Adult
·Relief of allergic conditions or antihistamine: PO, 5mg bid

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 5mg(20414)

ADR:

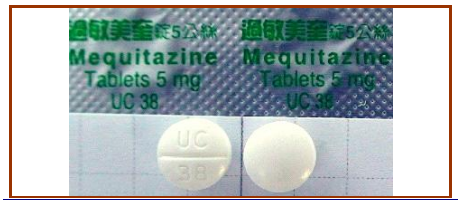
Drowsiness, sedation

NOTE: 室溫儲存

藥名相似: Tab: 5mg(20414)

外觀相似: Domtoo*10mg Tab (25013)

外觀描述: 白色圓扁錠，有UC 38字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044115

04.04A First Generation Antihistamines

22063 **C / Unsafe**

CABIDRIN FILM COATED TABLETS "JOHNSON" "強生" 過敏寧膜衣錠

Carbinoxamine maleate 2.5mg[C] & Pseudoephedrine HCl 60mg[b2] tab

Dosage: 1常備品 22063

Adult
·Relief of nasal congestion, running nose, or orther allergies: PO, 1 tab tid-qid

Pediatric (≧12yrs)
Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Dosage adjustment required.

P: Tab:(22063)

ADR:

COMMON
anxiety, restlessness, nervousness, hypertension, tachycardia, insomnia
SERIOUS
atrial fibrillation, myocardial infarction, premature ventricular contractions

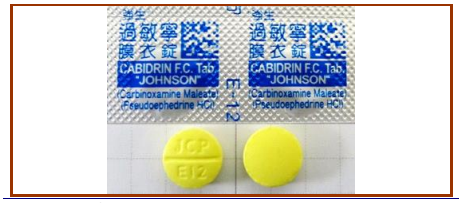
NOTE: 室溫儲存

Use of other preparations of carbinoxamine in fixed combination with pseudoephedrine is not recommended for children younger than 1 mon of age.

藥名相似:

外觀相似:

外觀描述: 黃色錠劑，中間有刻痕及"JCP. E12"字樣)



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1018444

04.04A First Generation Antihistamines

22978 C / Infant risk can

VISTARIL CAPSULES 維泰寧膠囊

Hydroxyzine HCl 25mg cap

Dosage: 1常備品 22978

Adult
·Anxiety: PO, 50-100mg qid
·Pruritus: PO, 25mg tid-qid
·Premedication for procedure; Adjunct: PO, 50-100mg

Pediatric
<6yrs
·Anxiety, Pruritus: PO, 50mg day in div.doses
·Premedication for procedure; Adjunct: PO, 0.6 mg/kg
>6yrs
·Anxiety, Pruritus: PO, 50-100mg/day in div.doses
·Premedication for procedure; Adjunct: PO, 0.6 mg/kg

Dosing adjustments in hepatic impairment:

Dosage adjustment required.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Cap: 25mg(22978)

ADR:

COMMON
Xerostomia, headache, somnolence
SERIOUS
Prolonged QT interval, Torsades de pointes, Acute generalized exanthematous pustulosis(AGEP)

NOTE: 室溫儲存

藥名相似: Cap: 25mg(22978)

外觀相似:

外觀描述: 淺綠/深綠色膠囊，有Pfizer及VIS-25字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12003354

04.04A First Generation Antihistamines

24861 ɔt be ruled out / Infant risk is

Meclizine HCl Tablets 25mg "F.Y." 美克旅鎮錠25毫克

Meclizine HCl 25mg tab

Dosage: 1常備品 24861

Adult
·Motion sickness: PO, 25-50 mg 1hr before travel, repeated in 24hrs if necessary
·Antivertigo: PO, 25-100 mg daily in div.doses

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Dosage adjustment required.

Dosing adjustments in renal impairment:

NDA

P: Tab: 25mg(24861)

ADR:

Drowsiness, sedation, xerostomia

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，另一面有FY T069字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12004781

04.04A First Generation Antihistamines

28408 / Unsafe

CYPROH SOLUTION 0.4MG/ML "KOJAR" (CYPROHEPTADINE HYDROCHLORIDE) "國嘉 " 喜普液 0.4毫克/毫升

Cyproheptadine HCl syr 0.4mg/mL, 60mL/bot

Dosage: 1常備品 28408

Adult
·Antihistaminic: PO, initial, 4 mg tid, Max. 0.5mg/kg/day
·Appetite stimulant: PO, 4 mg tid-qid
·Migraine headache: PO, 4 mg bid-qid; Max.32 mg/day

Pediatric
·Antihistaminic
2-6 yrs: PO, 2 mg bid-tid; Max.12 mg/day
7-14 yrs: PO, 4 mg bid-tid; Max.16 mg/day

Dosing adjustments in hepatic impairment:

Dosage adjustment required.

Dosing adjustments in renal impairment:

NDA

P: Tab: 4mg(20402); Sol: 0.4mg/mL, 120mL/Bot(28409)

ADR:

COMMON
Increased appetite, Weight gain, Abdominal discomfort, Diarrhea, Nausea, Vomiting, Xerostomia, Central nervous system depression, Somnolence; Thick sputum, Bronchial.
SERIOUS

Hepatitis.

NOTE: 室溫儲存

·《Contraindications》Angle-closure glaucoma; Bladder neck obstruction; Elderly, debilitated patients; Hypersensitivity to cyproheptadine and other drugs of similar chemical structure; MAOI therapy; Newborn or premature infants; Nursing mothers; Pyloroduodenal obstruction; Stenosing peptic ulcer; Symptomatic prostatic hypertrophy；
·新生兒、早產兒、哺乳婦女為仿單禁忌。
·小孩或嬰兒服用過量，會造成嗜睡、中樞神經抑制、痙攣、和死亡。
·老年人服用本品容易造成眩暈、鎮靜和低血壓，應注意。
·本品賦形劑不含阿斯巴甜
·香料為百香果香料，無香草成份。

藥名相似:

外觀相似:

外觀描述: 60mL半透明塑膠瓶，微橘色液體，白色上蓋

04.04A First Generation Antihistamines

28604 **/ Unknown(有**

SECORINE SYRUP "CENTER" "晟德"息咳寧糖漿

Chlorpheniramine maleate 0.1mg/mL [B], dl-Methylephedrine HCl 1mg/mL, Guaifenesin 5mg/mL [C] syrup, 120mL/bot

Dosage: 1常備品 28604

Adult
·Cough/rhinitis/expectoration: PO, 10mL tid-qid

Pediatric
·Cough/rhinitis/expectoration: PO, 5mL tid-qid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Syr: 120mL/bot(28604)

ADR:

NOTE: 室溫儲存

·《Contraindications》曾因本藥成分引起過敏的人。苯酮尿症的人，因本藥含阿斯巴甜(Aspartame)賦形劑；
·含阿斯巴甜，苯酮尿症者不宜使用。(0.8mg/mL)
·柑橘口味：香料為橘子香精(精油)，不含香草成份。
(2018.06.22 晟德 賴藥師提供)

藥名相似:

外觀相似:

外觀描述: 120mL塑膠瓶，淡紅色澄清液體

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1040833

04.04A First Generation Antihistamines

30401 **B / Unsafe**

BENAMINE INJECTION 30MG/ML (DIPHENHYDRAMINE HCL) "VPP" "榮民" 去敏注射液 3 0 毫克/毫升 (鹽酸二苯胺明)

Diphenhydramine HCl inj 30mg/1mL amp

Dosage: 1常備品 30401

Adult
·Antiemetic, antihistaminic: IM,IV, 10-50 mg q2-3h; Max. 400 mg/day

Pediatric
·Antiemetic, antihistaminic: IM,IV, 5 mg/kg/day or 150 mg/m2/day divided in 4 doses; Max. 300 mg/day

Dosing adjustments in hepatic impairment:

Dosage adjustment required.

Dosing adjustments in renal impairment:

GFR >50 mL/min, increase dosing interval to q6h
GFR 10-50 mL/min, increase dosing interval to q6-12h
GFR<10 mL/min, increase dosing interval to q12-18h

P: Inj: 30mg/1mL Amp(30401)

ADR:

NOTE: 室溫儲存

Not recommended in infants or neonates, due to potential CNS effects

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液，褐色安瓿頸部有灰點，白底黑字標籤有條碼

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1022588

04.04A First Generation Antihistamines

30402 **C / Unsafe**

CHLORPHENIRAMINE MALEATE INJECTION 5MG "S.T." 縮水蘋果酸氯芬尼拉明針 5 公絲

Chlorpheniramine 5mg/1mL amp

Dosage: 1常備品 30402

Adult
·Antihistaminic: IM, IV, SC, 5-20 mg/day; Max. 40 mg/day

Pediatric(>6yrs)
·Antihistaminic: SC, 87.5 mcg/kg or 2.5 mg/m(2) 4

times daily

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 5mg/1mL amp(30402); Tab: 2mg(20411)

ADR:

COMMON
drowsiness, diarrhea, constipation, nausea, vomiting

NOTE:

Each 1ml amp contain benzyl alcohol 10mg.

藥名相似:

外觀相似:

外觀描述: 1mL注射液透明安瓿，頸部有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1203002

04.04B Second Generation Antihistamines

20399 **C / Infant risk can**

DESORA* 5mg tab 治敏樂膜衣錠

Desloratadine 5mg tab

Dosage: 1常備品 20399

Adult
·Seasonal/Perennial allergic rhinitis, chronic idiopathic urticaria: PO, 5mg qd

Pediatric
·Seasonal/Perennial allergic rhinitis, chronic idiopathic urticaria:
6-11 mon: PO, 1mg qd
12 mon-5 yrs: PO, 1.25mg qd
6-11 yrs: PO, 2.5mg qd
≧12 yrs: PO, 5mg qd

Dosing adjustments in hepatic impairment:

Adults and children 12 yrs and older: 5mg qod

Dosing adjustments in renal impairment:

Adults and children 12 yrs and older: 5mg qod

P: Tab: 5mg(20399)

ADR:

COMMON
Xerostomia, myalgia, dizziness, somnolence, pharyngitis, fatigue, influenza-like illness
SERIOUS
Increased liver enzymes (rare)

NOTE: 室溫儲存

藥名相似: Tab: 5mg(20399)

外觀相似:

外觀描述: 藍色圓扁錠，一面有"YS"及"D5"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1051197

04.04B Second Generation Antihistamines

20409 **C / Infant risk is**

ALLEGRA 60MG TABLETS 艾來 6 0 公絲錠劑

Fexofenadine HCl 60mg tab

Dosage: 1常備品 20409

Adult
·Chronic idiopathic urticaria: PO, 60 mg bid
·Seasonal allergic rhinitis:PO, 60 mg bid or 180 mg qd

Pediatric
·Chronic idiopathic urticaria(6mon-2 yrs): PO, 15mg bid
·Chronic idiopathic urticaria, seasonal allergic rhinitis(2 -11yrs):PO, 30 mg bid

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

Clcr < 80 mL/min:
· >12yrs:initial,60 mg qd
· 2-11 yrs:initial,30 mg qd
· 6mon-<2yrs:initial,15 mg qd

P: Tab:60mg(20409)

ADR:

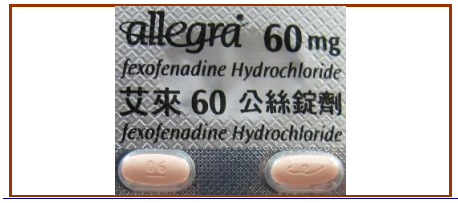
Dizziness, drowsiness, fatigue, dysmenorrhea, dyspepsia, headache, otitis media, upper respiratory tract infection ,
viral infection (cold, flu)

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 粉橘色長橢圓形錠，一面有06字樣，另一面有E字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023016

04.04B Second Generation Antihistamines

20418 **ɔt be ruled out / Infant risk has**

Estimin F.C. Tablets 5mg ” Kingdom” (Ebatine) “景德 ” 宜敏亭膜衣錠 5 毫克

Ebastine 5mg tab

Dosage: 1常備品 20418

Adult
·Allergic rhinitis: PO, 10-20mg qd

Pediatric

·Seasonal allergic rhinitis(2-15yrs): PO, 2.5-20mg qd
·Perennial allergic rhinitis(12-17yrs): PO, 5-20mg qd

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Dosage adjustment required.

P: Tab: 5mg(20418)

ADR:

headache, somnolence, dry mouth, nausea, increased appetite, and diarrhea.

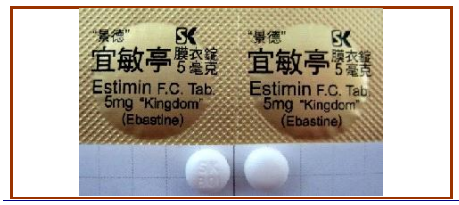
NOTE: 室溫儲存

Ebastine is a prodrug, metabolized to active metabolite, carebastine.

藥名相似: Tab: 5mg(20418)

外觀相似:

外觀描述: 白色圓形錠，一面有SK 801字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049700

04.04B Second Generation Antihistamines

20419 **B / Infant risk can**

XYZAL FILM-COATED TABLETS 5MG 驅異樂膜衣錠 5 毫克

Levocetirizine 5mg tab

Dosage: 1常備品 20419

Adult
·Allergic conditions(allergic rhinitis, chronic urticaria): PO, 5mg qd (in the evening).

Pediatric
·Allergic conditions(allergic rhinitis, chronic urticaria):PO, 6mon-5yrs,1.25mg qd (in the evening).
6-11yrs, 2.5mg qd (in the evening).

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Adult and children(>12yrs):
Clcr 50-80 mL/min: 2.5mg qd
Clcr 30-50 mL/min: 2.5mg qod
Clcr 10-30 mL/min: 2.5mg q3-4d
Clcr <10 mL/min,hemodialysis: Contraindicated
Children(6mon-11yrs)with renal impairment: Contraindicated

P: Tab: 5mg(20419)

ADR:

COMMON
Constipation, Diarrhea, Painful teething, Xerostomia, Somnolence, Nasopharyngitis, Pharyngitis, Fatigue.
SERIOUS
Urinary retention

NOTE: 室溫儲存

·Contraindications: Hypersensitivity to levocetirizine, cetirizine, or any component of the product, Hemodialysis patients, Severe renal insufficiency(CrCl< 10 mL/min), Renally impaired pediatric patients.
·仿單警語
1.藥品可能使痙攣加劇，有癲癇及抽搐風險病人應慎用。
2.皮膚過敏測試前，應有3天藥品清除期，以免受抗組織胺藥品影響。
3.戒斷症狀：停止治療可能發生搔癢症狀；重新開始使用前，應先消除搔癢症狀。

藥名相似:

外觀相似:

外觀描述: 白色長橢圓形錠，有"Y"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023792

04.04B Second Generation Antihistamines

22057 **C /**

HIROS* S.R.M. CAPSULES "EVEREST" "永勝"喜洛緩釋微粒膠囊

Cetirizine 5mg & Pseudoephedrine 120mg SRM tab

Dosage: 1常備品 22057

Adult
·Allergic rhinitis: PO, 1 tab bid

Pediatric
·Allergic rhinitis(≧12yrs): PO, 1 tab bid

Dosing adjustments in hepatic impairment:

1 tab qd

Dosing adjustments in renal impairment:

1 tab qd

P: Tab: HIROS*(22057); Soln: cetirizine 60mg/60mL Bot(28413)

ADR:

COMMON
Xerostomia, dizziness, insomnia, somnolence, anxiety, restlessness, fatigue

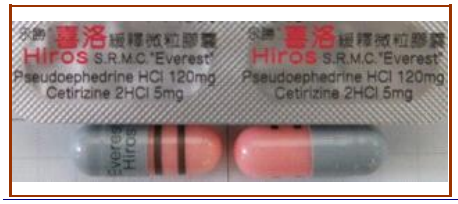
NOTE: 室溫儲存

·Swallow whole; do not crush, break or chew

藥名相似:

外觀相似:

外觀描述: 『粉紅/灰』色膠囊，粉紅色上有平行雙線條紋，灰色上有"Everest Hiros"字樣



04.04B Second Generation Antihistamines

22075 B / Infant risk is

LORAPSEUDO* 24H SR F.C. TABLETS 10/240MG "CYH" 莫鼻卡24小時持續性膜衣錠

Loratadine 10mg[B] & Pseudoephedrine sulfate 240mg [b2] tab

Dosage: 1常備品 22075

Adult
·Asthma, seasonal allergic rhinitis: PO,1 tab QD

Pediatric
·Safety and efficacy have not been established in patients less than 12 years old

Dosing adjustments in hepatic impairment:

Not recommended.

Dosing adjustments in renal impairment:

GFR ≦30 mL/min: PO, 1 tab qod

P: Tab: 10mg/240mg LoraPseudo(22075)

ADR:

dizziness, headache, nervousness
dry mouth, fatigue, insomnia, somnolence

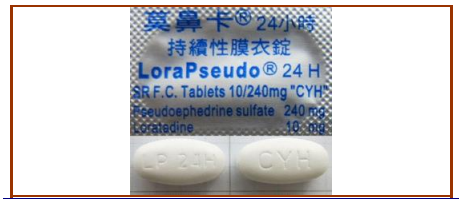
NOTE: 室溫儲存25℃以下

1.Patients receiving Finska-LP should be advised to consult a clinician before initiating therapy if they have heart disease, hypertension, thyroid disease, diabetes mellitus, or difficulty in urination resulting from enlargement of the prostate
2.Swallow whole; do not crush or chew
3.<重要警訊>■每日限1粒■，現有藥品之Pseudoephedrine含量為每顆240mg。

藥名相似:

外觀相似:

外觀描述: 白長橢圓錠，一面有"LP 24H"字樣，另一面有"CYH"字樣



04.04B Second Generation Antihistamines

28413 B / Unknown(有

CETIRIZINE ORAL SOLUTION 1MG/ML "CENTER" "晟德" 勝克敏液1毫克/毫升

Cetirizine HCl soln 60mg/60mL/bot

Dosage: 1常備品 28413

Adult
·Allergic rhinitis, chronic urticaria: PO, 5-10 mg qd

Pediatric
·Allergic rhinitis, chronic urticaria
6-11 mon: PO, 2.5 mg qd
12-23 mon: PO, 2.5 mg bid, Max. 5 mg/day
2-5 yrs: PO, 2.5-5 mg qd or 2.5 mg bid
>6yrs: PO, 5-10 mg qd

Dosing adjustments in hepatic impairment:

>6yrs: 5 mg qd

Dosing adjustments in renal impairment:

>6yrs
Clcr 11-31 mL/min: 5 mg qd

P: Soln: 60mg/60ml(28413)

ADR:

Dry mouth, fatigue, headache, somnolence

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to cetirizine hydrochloride or any of its ingredients, levocetirizine, or hydroxyzine；
·本品賦形劑不含阿斯巴甜

藥名相似: Soln: 60mg/60ml(28413)

外觀相似:

外觀描述: 60cc白色塑膠瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044023

06.02 Anthelmintics

20802 C / Infant risk can

CONQUER TABLETS "YUNG SHIN" "永信"疳克錠

Mebendazole 100mg tab

Dosage: 1常備品 20802

Adult
· Pinworms: PO, 100mg as a single dose; may need to repeat after 2 wks
· Whipworms, hookworms, roundworms: PO, 100mg bid for 3 days; may need to repeat if patient is not cured within 3-4 wks
· Capillariasis: PO, 200mg bid for 20 days

Pediatric
· Same as adults

Dosing adjustments in hepatic impairment:

Dosage adjustment required.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 100mg(20802)

ADR:

COMMON
Abdominal pain, constipation, diarrhea, headache, rash
SERIOUS
Hepatitis, seizures

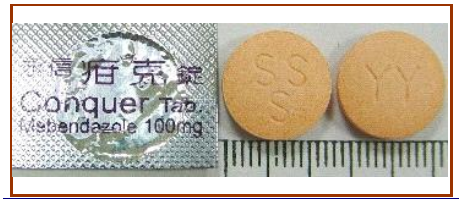
NOTE: 室溫儲存

· Treatment (for pinworms) should include family members in close contact with patient.
· May be taken without regard to meals; fasting/purging is not required.

藥名相似:

外觀相似:

外觀描述: 橘色圓扁錠，一面有"YY"，另一面"SSS"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1011644

06.02 Anthelmintics

20805 B / Unsafe

KAICIDE TABLETS 600MG (PRAZIQUANTEL) 凱光錠 ６００毫克（帕芝奎）

Praziquantel 600mg tab

Dosage: 1常備品 20805

Adult
· Schistosomiasis: PO, 20mg/kg 3 times for 1 day (at 4-6 hrs intervals) or 40mg/kg as a single dose or in 2 equally divided doses
· Clonorchiasis/opisthorchiasis: PO, 25mg/kg 3 times for 1 day (at 4-6 hrs intervals)
· Cysticercosis: PO, 50-100mg/kg/day divided q8h for 30 days
· Tapeworms: PO, 5-10mg/kg as a single dose (25mg/kg for Hymenolepis nana)
· Flukes: PO, 25mg/kg/dose q8h for 1-2 days

Pediatric(≧4 yrs)
· Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 600mg(20805)

ADR:

COMMON
Malaise, headache, dizziness, abdominal pain
SERIOUS
Cardiac dysrhythmia, heart block, seizure

NOTE: 室溫儲存

· Take with food ; do not chew tablets because of bitter taste.

藥名相似:

外觀相似:

外觀描述: 白色長橢圓扁錠，有KDPC字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1029833

06.02 Anthelmintics

27578 C / Caution

Stromectol Tablets 3 mg 絲每妥錠3毫克

急用Ivermectin 3mg tab

Dosage: 2急用藥 27578

Adult
· Scabies: PO, 0.2mg/kg as a single dose, may require a repeat dose in 10-14 days; 0.2mg/kg qd on days 1, 15 and 29 for the treatment of severe or crusted(Norwegian) scabies
· Strongyloidiasis: PO, 0.2mg/kg as a single dose or daily on two consecutive days
· Onchocerciasis: PO, 0.15mg/kg as a single dose; retreatment interval between 3 and 12 mons
· Mansonella infections: PO, 0.15mg/kg as a single dose for the treatment of Mansonella streptocerca; 0.2mg/kg as a single dose for the treatment of Mansonella ozzardi
· Wuchereria infections: PO, 0.15-0.4mg/kg as a single dose

Pediatric (≧15kg)
· Scabies, Strongyloidiasis, Onchocerciasis: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 3mg(27578, 專案進口)(27956, 疾管局提供)

ADR:

COMMON
Pruritus, dizziness
SERIOUS

Mazzotti reaction, seizure

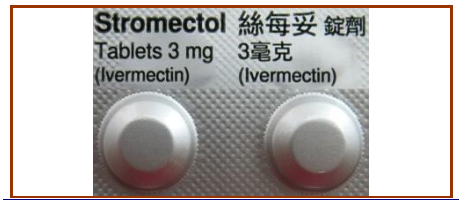
NOTE: 室溫儲存30°C以下

· Take on an empty stomach
· 限皮膚科醫師使用於疥瘡病患

藥名相似:

外觀相似:

外觀描述: 白色紙盒,內為鋁箔包裝上有黑色"STROMECTOL 3mg"字樣



06.02 Anthelmintics

27956 **C / Caution**

疾管局Stromectol* 3mg tab 疾管局提供用於糞小桿線蟲或血絲蟲感染

疾管局Ivermectin 3mg tab

Dosage: 2衛福部提供 27956

Adult
· Scabies: PO, 0.2mg/kg as a single dose, may require a repeat dose in 10-14 days; 0.2mg/kg qd on days 1, 15 and 29 for the treatment of severe or crusted(Norwegian) scabies
· Strongyloidiasis: PO, 0.2mg/kg as a single dose or daily on two consecutive days
· Onchocerciasis: PO, 0.15mg/kg as a single dose; retreatment interval between 3 and 12 mons
· Mansonella infections: PO, 0.15mg/kg as a single dose for the treatment of Mansonella streptocerca; 0.2mg/kg as a single dose for the treatment of Mansonella ozzardi
· Wuchereria infections: PO, 0.15-0.4mg/kg as a single dose

Pediatric (≧15kg)
· Scabies, Strongyloidiasis, Onchocerciasis: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 3mg(27578, 專案進口)(27956, 疾管局提供)

ADR:

COMMON
Pruritus, dizziness
SERIOUS
Mazzotti reaction, seizure

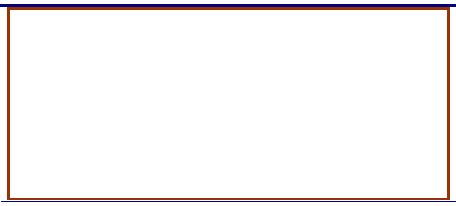
NOTE: 室溫儲存

· Take on an empty stomach

藥名相似:

外觀相似:

外觀描述:



06.02 Anthelmintics

27969 **C / Unsafe**

疾管署Zentel* 400mg tab --

疾管局Albendazole 400mg tab

Dosage: 2衛福部提供 27969

Adult
· Cutaneous larva migrans (hookworm), ascariasis (roundworm): PO, 400mg as a single dose; dose may be repeated after 3 wks if necessary
· Taeniasis (tapeworm), strongyloidiasis (treadworm): PO, 400mg qd for 3 days; dose may be repeated after 3 wks if necessary
· Enterobiasis (pinworm): PO, 400mg as a single dose; dose may be repeated after 7 days
· Giardiasis: PO, 400mg qd for 5 days
· Trichuriasis (whipworm): PO, 400mg bid for 10-15 days
· Echinococcosis (Hydatid): PO, < 60kg- 15mg/kg/day in 2 divided doses; ≧60kg- 400mg bid; Max. 800mg/day. Administer a 28-day cycle followed by a 14-day albendazole-free interval for a total of 3 cycles

Pediatric
· Cutaneous larva migrans (hookworm), ascariasis (roundworm): PO,
1-2 yrs: 200mg as a single dose; dose may be repeated after 3 wks if necessary
> 2 yrs: Same as adult
· Enterobiasis (pinworm): PO,
1-2 yrs: 200mg as a single dose; dose may be repeated after 7 days
> 2 yrs: Same as adult
· Trichuriasis (whipworm): PO, 15mg/kg/day divided in 2 doses for 10-15 days
· Taeniasis (tapeworm), strongyloidiasis(treadworm), giardiasis (> 2 yrs), Echinococcosis (Hydatid): Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 400mg(27969)

ADR:

COMMON
Abdominal pain, nausea, vomiting, headache
SERIOUS
Stevens-Johnson syndrome, agranulocytosis, aplastic anemia, granulocytopenic disorder, leukopenia, pancytopenia, thrombocytopenia, increased liver enzymes, raised intracranial pressure

NOTE: 室溫儲存30℃以下

藥名相似:

外觀相似:

外觀描述: 粉橘色橢圓錠，中央有刻痕

06.04 Antiamoebic & Antiprotozoan Agents

20832 **d / Infant risk is**

Hydroquine Film Coated Tablets 200mg "信東" 瘡寧膜衣錠 200 毫克

Hydroxychloroquine sulfate 200mg FC tab (=155mg base)

Dosage: 1常備品 20832

Adult

· Chemoprophylaxis of malaria: PO, 400mg weekly begin 2 wks before exposure; continue for 4-8 wks after leaving endemic area

· Treatment of malaria: PO, initial 800mg, followed by 400mg given at 6, 24, and 48 hours after initial dose

· Rheumatoid arthritis: PO, initial 400-600mg/day for 4-12 wks; MD 200-400mg/day

· Lupus erythematosus: PO, initial 400mg qd-bid for several wks or mons depending on the response of the patient. MD 200-400mg/day

Pediatric

· Chemoprophylaxis of malaria: PO, 6.5mg/kg weekly; should not exceed 400mg; begin 2 wks before exposure; continue for 4-8 wks after leaving endemic area

· Treatment of malaria: PO, initial 13mg/kg, followed by 6.5mg/kg given at 6, 24, and 48 hours after initial dose

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 200mg(20832) (27968, 旅專用藥)(27701,疾管署提供)

ADR:

SERIOUS
Torsades de pointes, severe hypoglycemia, agranulocytosis, aplastic anemia, thrombocytopenia, disorder of muscle, retinal disorder, hearing loss, angioedema

NOTE: 儲存25℃以下

· Take with food or milk.

· If objective improvement of rheumatoid arthritis (e.g., reduced joint swelling, increased mobility) does not occur within 6 months, hydroxychloroquine should be discontinued.

·(公文號:109000680209109.05.22)賽諾菲發函有關PLAQUENIL* 200mg(Hydroxychloroquine) tab 醫護人員溝通信函(DHPC letter)，說明於嚴重特殊傳染性肺炎(COVID-19)屬適應症外用藥(off lable)及其潛在不良事件，溝通信函訊息申明：

-使用於COVID-19屬於適應症外用法；

-已知有導致QT prolongation and subsequent arrhythmias的風險，且與使用劑量相關；其風險在併用其他會延長QT interval的藥品，如Azithromycin，會增加風險。

-近來併用其他會延長QT interval的藥品，如Azithromycin，而發生嚴重或危及生命的報告增加了。

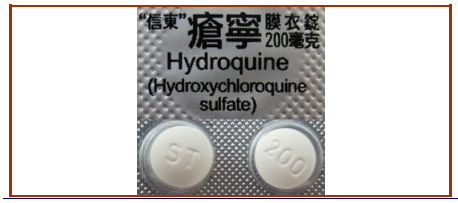
-用於COVID-19應謹慎，尤其併用其他會延長QT interval的藥品，如Azithromycin，建議在醫院進行心臟ECG監測。

-其他用藥安全訊息，如與其他藥品(Antacids, Ciclosporin, Digoxin, Praziquantel)之交互作用。

藥名相似: Tab: 200mg(20832) (27968, 旅專用藥)

外觀相似:

外觀描述: 白色圓扁錠,一面有"ST",另一面有"200"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1050142

06.04 Antiamoebic & Antiprotozoan Agents

20834 **B / Unsafe**

TOLIZOLE* CAPSULES 250MG "KOJAR"(METRONIDAZOLE) "國嘉"德利治瘧膠囊250毫克（硝基甲嘧唑乙醇）

Metronidazole 250mg cap

Dosage: 1常備品 20834

Adult

· Amebiasis: PO, 500-750mg q8h for 5-10 days

· Anaerobic bacterial infections: PO, 7.5mg/kg q6h; Max. 4g/day

· Bacterial vaginosis: PO, 500mg bid for 7 days

· Trichomoniasis: PO, 250mg q8h for 7 days or 375mg q12h for 7 days or 500mg q12h for 7 days or 2g as a single dose

· Helicobacter pylori infection: PO, 250-500mg q6-8h for 14 days

· Pseudomembranous colitis: PO, 750mg-2g/day div. q6-8h for 7-14 days

· Giardiasis: PO, 250mg q8h for 5-7 days

Pediatric

· Amebiasis: PO, 35-50mg/kg/day div. q8h for 7-10 days

· Anaerobic bacterial infections: PO, 30mg/kg/day div. q6h; Max. 4g/day

· Trichomoniasis: PO, 15mg/kg/day div. q8h for 7 days; Max. 2g/day

· Helicobacter pylori infection: PO, 15-20mg/kg/day div. q12h for 4 wks

· Pseudomembranous colitis: PO, 30-50mg/kg/day div. q6-8h for 7-10 days

· Giardiasis: PO, 15mg/kg/day div. q8h for 5-7 days; Max. 250mg/dose

Dosing adjustments in hepatic impairment:

Severe hepatic impairment: Dosage adjustment required

Dosing adjustments in renal impairment:

Mild to moderate renal impairment: No dosage adjustment needed
Severe renal impairment(Clcr<10mL/min): Administer 50% of normal dose

P: Tab: 250mg(20834); Dental gel: 25%, 0.3g/tube(29162); Vaginal gel: 0.75%, 25g/tube(29019); Topica gel: 0.75%. 15g/tube; Inj: 500mg/100mL Bot(30831)

ADR:

COMMON
Abdominal discomfort, loss of appetite, metallic taste, nausea, vomiting, Jarisch Herxheimer reaction, ataxia, dizziness, headache, peripheral neuropathy, seizure, candida infection of genital region, symptomatic cervicitis/vaginitis, vaginal discharge, disulfiram-like reaction
SERIOUS
Leukopenia, thrombocytopenia (rare), ototoxicity (rare)

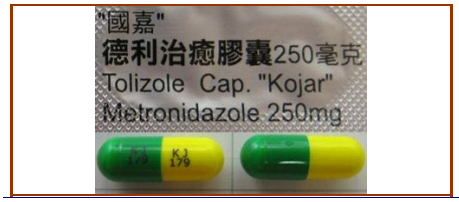
NOTE: 室溫儲存

· 《Contraindications》alcohol (or products containing propylene glycol) use during and for at least 3 days after metronidazole use (oral, Flagyl(R) IV, vaginal gel); concomitant use with or within the last 2 weeks of disulfiram (oral, Flagyl(R) IV, vaginal gel); hypersensitivity to metronidazole or any other component of the product or to other nitroimidazole agents; hypersensitivity to parabens (vaginal gel); pregnancy, first trimester, in patients being treated for trichomoniasis (immediate-release tablets, capsules) ;
· May cause darkening of urine.
· Do not take alcohol for at least 24 hours after the last dose.
· May be taken with food to minimize stomach upset.
· 廠商來文仿單變更(OA文號：乙1060011353)：在出現早期症狀如頭部搖晃感、步態障礙、意識障礙、構音障礙、四肢麻痺等情況時，應充分觀察患者的情況。若懷疑是本藥引起的腦病變，應立即停藥。此外，治療超過10天或使用1500mg/天以上的情況下，需特別注意。

藥名相似:

外觀相似:

外觀描述: 綠色/黃色 膠囊，有黑色"KJ 179"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1041025

06.04 Antiamoebic & Antiprotozoan Agents

27060 **C / Caution**

MEPHAQUIN Lactab 250 mg --

Mefloquine 250mg tab

Dosage: 1常備品 27060

Adult
·Malaria prophylaxis: PO, 250mg weekly starting 1 week before arrival in endemic area, continuing weekly during travel and for 4 weeks after leaving endemic area. The CDC suggests that prophylaxis begin 2~3 weeks prior to travel.
·Malaria treatment: PO, 1250mg as a single dose

Pediatric (≧6 mons & >5 kg)
·Malaria prophylaxis: PO, 5mg/kg weekly starting 1 week before arrival in endemic area, continuing weekly during travel and for 4 weeks after leaving endemic area. The CDC suggests that prophylaxis begin 2~3 weeks prior to travel. Max. 250mg/wk
·Malaria treatment: PO, 20-25mg/kg/day in 2 divided doses, taken 6-8 hours apart. Max. 1250mg/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 250mg(27060)

ADR:

COMMON
Bradyarrhythmia, abdominal pain, diarrhea, nausea, vomiting, coordination problem, dizziness, dream disorder, headache, insomnia, somnolence, vertigo, anxiety
SERIOUS
Prolonged QT interval, seizure, at risk for suicide, pneumonitis

NOTE: 室溫儲存

· Administer with food and with at least 240mL of water
· If vomiting occurs within 30 mins after dose, repeat another dose; If vomiting occurs within 30 to 60 mins after dose, give an additional half-dose

藥名相似:

外觀相似:

外觀描述:

06.04 Antiamoebic & Antiprotozoan Agents

27906 **UK /**

疾管局Iodoquinol 650mg tab

Dosage: 2衛福部提供 27906

Adult
·Amebic infection: PO, 630 or 650mg tid for 20 days

Pediatric
·Amebic infection: PO, 40mg/kg/day in 3 divided doses for 20 days; Max. 650mg/dose, 1.95g/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 650mg(27906)

ADR:

COMMON
Pruritus, urticaria, shivering, diarrhea, nausea, vomiting, cramp, headache, fever
SERIOUS
Peripheral neuropathy (long-term high-dose course), optic atrophy (long-term high-dose course), optic neuritis (long-term high-dose course)

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 淺黃色圓扁錠,上有DIODOQUIN字樣

06.04 Antiamoebic & Antiprotozoan Agents

27957 ɔt be ruled out / Infant risk can

疾管局HUMATIN* 250mg cap HUMATIN*膠囊

疾管局Paromomycin 250mg cap 阿米巴感染

Dosage: 2衛福部提供 27957

Adult
· Intestinal amebiasis: PO, 25-35mg/kg/day in 3 divided doses for 5-10 days.(疾管署：每日最大劑量為 3g，療程 7 日)

Pediatric
Same as adult

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Use with caution

P: Cap: 250mg(27957)

ADR:

COMMON
Abdominal cramps, diarrhea, nausea

NOTE: 室溫儲存

· 疾管署：治療阿米巴性痢疾感染時，每日最大劑量為 3g(4# tid)，療程 7 日。(2018.12)

藥名相似:

外觀相似:

外觀描述: 黃/黑色膠囊

06.04 Antiamoebic & Antiprotozoan Agents

27958 C / Infant risk is

疾管局Daraprim* 25mg tab 錠劑

疾管局Pyrimethamine 25mg tab 弓漿蟲感染

Dosage: 2衛福部提供 27958

Adult
· Toxoplasmosis: PO, LD 100mg, followed by 25-50mg daily

Pediatric
· Toxoplasmosis: PO,
< 3mons: 6.25mg qod
3-9 mons: 6.25mg qd
10 mons-2 yrs: 1mg/kg/day
3-6 yrs: Initial 2mg/kg(Max. 50mg), followed by 1mg/kg/day(Max. 25mg)
>6 yrs: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 25mg(27958)

ADR:

COMMON
Rash
SERIOUS
Stevens-Johnson syndrome(rare), leukopenia, megaloblastic anemia

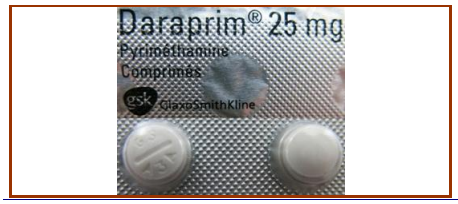
NOTE: 室溫儲存

· In the treatment of toxoplasmosis, it should be given with a sulfonamide such as sulfadiazine

藥名相似:

外觀相似:

外觀描述: 鋁箔包裝上有黑色" Daraprim"字樣



06.04 Antiamoebic & Antiprotozoan Agents

27964 C / Caution

旅專Malarone* tab 阿托奎酮與氯胍混合製劑

旅專atovaquone 250mg & proguanil 100mg tab (瘧疾)

Dosage: 2衛福部提供 27964

Adult
·Malaria prophylaxis: PO, 1 tab qd 1-2 days prior to entering endemic area, during stay and for 7 days after returning
·Malaria treatment: PO, 4 tabs qd for 3 days

Pediatric
·Malaria prophylaxis: PO, srarts 1-2 days prior to entering endemic area, during stay and for 7 days after returning. Take as a single dose, once daily.
11-20kg:atovaquone 62.5mg/proguanil 25mg
21-30kg:atovaquone 125mg/proguanil 50mg
31-40kg:atovaquone 187.5mg/proguanil 75mg
>40kg:atovaquone 250mg/proguanil 100mg
·Malaria treatment: PO, take as a single dose, once

daily for 3 consecutive days.
5-8kg:atovaquone 125mg/proguanil 50mg
9-10kg:atovaquone 187.5mg/proguanil 75mg
11-20kg: 1 tab; 21-30kg: 2 tabs; 31-40kg: 3 tabs; >40kg: same as adult

Dosing adjustments in hepatic impairment:

Mild to moderate hepatic impairment: No dosage adjustment needed

Dosing adjustments in renal impairment:

Mild to moderate renal impairment(Clcr >30mL/min): No dosage adjustment needed
Severe renal impairment(Clcr <30mL/min): Contraindicated for malaria prophylaxis; use 3-day treatment regimen only if benefit outweighs risks for greater drug exposure

P: Tab: Malarone*(27964)

ADR:

COMMON
Pruritus, abdominal pain, diarrhea, loss of appetite, nausea, vomiting, increased liver function test, asthenia, dizziness, headache, cough
SERIOUS
Erythema multiforme, Stevens-Johnson syndrome, neutropenia, pancytopenia, hepatitis, liver failure, anaphylaxis, immune hypersensitivity reaction

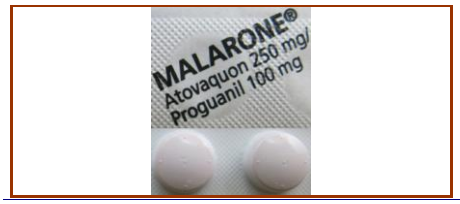
NOTE: 室溫儲存

·Do not take Malarone* for longer than 28 days
·If vomiting occurs within 1hr of administration, repeat the dose.

藥名相似:

外觀相似:

外觀描述: 磚紅色圓扁錠，一面有GX及CM3字樣



06.04 Antiamoebic & Antiprotozoan Agents

30831 **B / Unsafe**

METRONIDAZOLE FRESENIUS* 黴得挫注射液

Metronidazole inj 500mg/100mL vial

Dosage: 1常備品 30831

Adult
· Anaerobic bacterial infections: IV infusion over 1hr, initial 15mg/kg, MD 7.5mg/kg q6h for 7-10 days; Max. 4g/day

Pediatric
· Anaerobic bacterial infections: IV infusion over 1hr, initial 15mg/kg, MD 30mg/kg/day div. q6h; Max. 4g/day

Dosing adjustments in hepatic impairment:

Severe hepatic impairment: Dosage adjustment required

Dosing adjustments in renal impairment:

Mild to moderate renal impairment: No dosage adjustment needed
Severe renal impairment(Clcr<10mL/min): 50% of normal dose

P: Tab: 250mg(20834); Dental gel: 25%, 0.3g/tube(29162); Vaginal gel: 0.75%, 25g/tube(29019); Topica gel: 0.75%. 15g/tube; Inj: 500mg/100mL Bot(30831)

ADR:

COMMON
Abdominal discomfort, loss of appetite, metallic taste, nausea, vomiting, Jarisch Herxheimer reaction, ataxia, dizziness, headache, peripheral neuropathy, seizure, candida infection of genital region, symptomatic cervicitis/vaginitis, vaginal discharge, disulfiram-like reaction
SERIOUS
Leukopenia, thrombocytopenia (rare), ototoxicity (rare)

NOTE: 室溫儲存

· 《Contraindications》alcohol (or products containing propylene glycol) use during and for at least 3 days after metronidazole use (oral, Flagyl(R) IV, vaginal gel); concomitant use with or within the last 2 weeks of disulfiram (oral, Flagyl(R) IV, vaginal gel); hypersensitivity to metronidazole or any other component of the product or to other nitroimidazole agents; hypersensitivity to parabens (vaginal gel); pregnancy, first trimester, in patients being treated for trichomoniasis (immediate-release tablets, capsules) ;
· May cause darkening of urine

藥名相似:

外觀相似:

外觀描述: 100mL透明注射液，藍蓋透明玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2017835

06.06A1 Aminoglycosides, parenteral

30860 **D / Infant risk can**

AMINFEC* INJECTION 125MG/ML (AMIKACIN) "STANDARD" 安炎注射液１２５公絲/公撮（艾米克信）

Amikacin sulfate 250mg/2mL vial

Dosage: 1常備品 30860

Adult
· Bacterial infectious disease due to susceptible organisms:
Traditional dosing: IV infusion, IM, 15mg/kg/day div. q8-12h; Max. 1.5g/day
Once-daily dosing: IV infusion, 15-20mg/kg qd
· Tuberculosis: IV infusion, IM, 15mg/kg/day (up to 1g) 5-7 times/week in conjunction with other antituberculosis agents for 2-4 mons or until culture conversion; may reduce to 2-3 times/week after 2-4 mons

Pediatric
· Bacterial infectious disease due to susceptible organisms: IV infusion, IM,

Neonates: LD 10mg/kg followed by 7.5mg/kg q12h
Infants and children: 15-22.5mg/kg/day div. q8h; Max. 1.5g/day
· Tuberculosis(< 15yrs or ≦40kg): IV infusion, IM, 15-30mg/kg/day (up to 1g) qd or twice weekly in conjunction with other antituberculosis agents

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr>50mL/min: 60%-90% of normal dose q12h
Clcr 10-50mL/min: 30%-70% of normal dose q12-18h
Clcr<10mL/min: 20%-30% of normal dose q24-48h

P: Inj: 250mg/2mL Vial(30860)(37761, 二線TB用藥)

ADR:

SERIOUS
Neuromuscular blockade finding, ototoxicity, nephrotoxicity, respiratory tract paralysis (concomitant use of anesthesia or muscle relaxants)

NOTE: 室溫儲存

· 《Contraindications》Hypersensitivity to amikacin or other aminoglycosides ;
· If a beta-lactam anti-infective (e.g., cephalosporin, penicillin) is administered concomitantly with amikacin, the drugs should be administered separately

藥名相似:

外觀相似:

外觀描述: 2mL透明注射液『藍』蓋透明玻璃小瓶，蓋上有FLIP及OFF字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1037550

06.06A1 Aminoglycosides, parenteral

30866 **D / Infant risk is**

GENTAMYCIN INJECTION 僅大黴素注射液

Gentamicin sulfate inj 80mg/2mL vial

Dosage: 1常備品 30866

Adult
· Bacterial infectious disease due to susceptible organisms:
Usual dosage: IV infusion, IM, 3mg/kg/day div. q8h
Life-threatening infections: IV infusion, IM, 5mg/kg/day div. q6-8h, with reduction to 3mg/kg/day as soon as clinically indicated. (US FDA dosage)
Once-daily dosing: IV infusion, 4-7mg/kg q24h
· Peritoneal dialysis-associated peritonitis:
Intraperitoneal, anuric patients, 0.6mg/kg in one exchange per day; nonanuric patients (residual urine volume greater than 100mL/day), increase dose by 25%

Pediatric
· Bacterial infectious disease due to susceptible organisms: IV infusion, IM,
Neonates(<28 wks gestational age): 2.5mg/kg q24-36h
Neonates(28-32 wks gestational age): 2.5mg/kg q18h
Neonates(33-42 wks gestational age): 2.5mg/kg q12h
Term neonates(<1 wks): 2.5mg/kg q12h
Term neonates(>1 wks), infants and children(<5 yrs): 2.5mg/kg q8h
Children(>5 yrs): 2-2.5mg/kg q8h

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr >50mL/min: 60%-90% of normal dose q8-12h or 100% of normal dose q12-24h
Clcr 10-50mL/min: 30%-70% of normal dose q12h or 100% of normal dose q24-48h
Clcr <10mL/min: 20%-30% of normal dose q24-48h or 100% of normal dose q48-72h

P: Oph oint: 0.3% 5g(29188); Oph soln: 0.3% 5mL(29189); Cream: 0.1% 15g(29302); Inj: 80mg/2mL Vial(30866)

ADR:

SERIOUS
Neuromuscular blockade finding, ototoxicity, nephrotoxicity, respiratory tract paralysis (concomitant use of anesthesia or muscle relaxants)

NOTE: 室溫儲存

· 《Contraindications》Hypersensitivity to gentamicin or other aminoglycosides; cross-sensitivity may occur ;
· If a beta-lactam anti-infective (e.g., cephalosporin, penicillin) is administered concomitantly with gentamicin, the drugs should be administered separately

藥名相似:

外觀相似:

外觀描述: 2mL透明注射液，綠蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1008956

06.06A1 Aminoglycosides, parenteral

37760 **D / Infant risk is**

STREPTOMYCIN INJECTION 1GM "TBC" "信東"鏈黴素注射劑 1 克

(CDC二線TB)Streptomycin sulfate (S.M.) 1g vial

Dosage: 2衛福部提供 -CDC二線TB 37760

Adult
· Tuberculosis: IM, 15mg/kg qd (Max. 1g/day) or 25-30mg/kg/dose 2-3 times weekly (Max. 1.5g/dose) in combination with other antitubercular antibiotics for the first 2 mons of therapy; Max. 120g/course
· Moderate/severe infections: IM, 1-2g/day div. q6-

12h; Max. 2g/day
· Enterococcal endocarditis: IM, 1g q12h for 2 wks, then 500mg q12h for 4 wks in combination with penicillin
· Streptococcal endocarditis: IM, 1g q12h for 1 wk, then 500mg q12h for 1 wk in combination with penicillin
· Plague: IM, 1g q12h for 10 days
· Tularemia: IM, 1-2g/day div. q12h for 7-10 days or until patient is afebrile for 5-7 days

Pediatric
· Tuberculosis: IM, 20-40mg/kg qd (Max. 1g/day) or 25-30mg/kg/dose 2-3 times weekly (Max. 1.5g/dose) in combination with other antitubercular antibiotics for the first 2 mons of therapy; Max. 120g/course
· Moderate/severe infections: IM, 20-40mg/kg/day div. q6-12h
· Plague, Tularemia: IM, 15mg/kg q12h for 10 days; Max. 2g/day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

Clcr >50mL/min: Administer q24h□
Clcr 10-50mL/min: Administer q24-72h□
Clcr <10mL/min: Administer q72-96h

P: Inj: 1g Vial(30869)(37760, 二線TB用藥)

ADR:

COMMON
Drug-induced eosinophilia, facial paresthesia, fever
SERIOUS
Arachnoiditis, encephalopathy, neuromuscular blockade finding (concomitant use of anesthesia or muscle relaxants), peripheral neuritis, disorder of optic nerve, disorder of inner ear, nephrotoxicity, respiratory tract paralysis (concomitant use of anesthesia or muscle relaxants)

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『綠』蓋透明玻璃小瓶

06.06A1 Aminoglycosides, parenteral

37761 **D / Infant risk can**

SIKACIN INJECTION 100MG/ML "SHITEH" 米卡黴素注射液（艾米克信）

(CDC二線TB)Amikacin sulfate 250mg/2mL vial

Dosage: 2衛福部提供-CDC二線TB 37761

Adult
· Bacterial infectious disease due to susceptible organisms:
Traditional dosing: IV infusion, IM, 15mg/kg/day div. q8-12h; Max. 1.5g/day
Once-daily dosing: IV infusion, 15-20mg/kg qd
· Tuberculosis: IV infusion, IM, 15mg/kg/day (up to 1g) 5-7 times/week in conjunction with other antituberculosis agents for 2-4 mons or until culture conversion; may reduce to 2-3 times/week after 2-4 mons

Pediatric
· Bacterial infectious disease due to susceptible organisms: IV infusion, IM,
Neonates: LD 10mg/kg followed by 7.5mg/kg q12h
Infants and children: 15-22.5mg/kg/day div. q8h; Max. 1.5g/day
· Tuberculosis(< 15yrs or ≦40kg): IV infusion, IM, 15-30mg/kg/day (up to 1g) qd or twice weekly in conjunction with other antituberculosis agents

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr >50mL/min: 60%-90% of normal dose q12h
Clcr 10-50mL/min: 30%-70% of normal dose q12-18h
Clcr <10mL/min: 20%-30% of normal dose q24-48h

P: Inj: 250mg/2mL Vial(30860)(37761, 二線TB用藥)

ADR:

SERIOUS
Neuromuscular blockade finding, ototoxicity, nephrotoxicity, respiratory tract paralysis (concomitant use of anesthesia or muscle relaxants)

NOTE: 室溫儲存

· If a beta-lactam anti-infective (e.g., cephalosporin, penicillin) is administered concomitantly with amikacin, the drugs should be administered separately

藥名相似:

外觀相似:

外觀描述: 2.5mL注射液透明玻璃銀色鐵鋁瓶口

06.06A1 Aminoglycosides, parenteral

37762 **D / Infant risk is**

(CDC二線TB)Kanamycin (KM) 1g vial

Dosage: 2衛福部提供-CDC二線TB 37762

Adult
· Tuberculosis: IM, 15mg/kg/day (up to 1g) 5-7 times/week in conjunction with other antituberculosis agents for 2-4 mons or until culture conversion; may reduce to 2-3 times/week after 2-4 mons
· Bacterial infectious disease due to susceptible organisms: IM, 15mg/kg/day in 2-4 divided doses; Max. 1.5g/day

Pediatric
· Tuberculosis(< 15yrs or ≦40kg): IM, 15-30mg/kg/day (up to 1g) qd or twice weekly in conjunction with other antituberculosis agents
· Bacterial infectious disease due to susceptible organisms: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr >50mL/min: 60%-90% of normal dose q8-12h
Clcr 10-50mL/min: 30%-70% of normal dose q12h
Clcr <10mL/min: 20%-30% of normal dose q24-48h

P: Inj: 1g Vial(37762)

ADR:

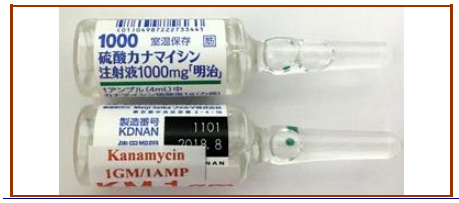
Neuromuscular blockade finding, ototoxicity, nephrotoxicity, local pain or irritation

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 透明玻璃小瓶



06.06A2 Aminoglycosides, oral

20862 **D / Caution**

NEOMYCIN CAPSULES 250MG 紐奧黴素膠囊 2 5 0 公絲

Neomycin sulfate 250mg cap

Dosage: 1常備品 20862

Adult
· Hepatic coma: PO, 4-12g/day div. q4-6h for 5-6 days, Max. 12g/day; do not use longer than 2 weeks
· Pre-operative bowel preparation: PO, 1g every hour for 4h, then 1g q4h for the remaining 24h; or 1g 19, 18 and 9 hrs prior to surgery with erythromycin as an adjunct to mechanical cleansing of the bowel

Pediatric
· Hepatic coma: PO, 2.5-7g/m(2)/day div. q4-6h for 5-6 days; Max. 12g/day; do not use longer than 2 wks
· Pre-operative bowel preparation: PO, 90mg/kg/day div. q4h for 2 days; or 25mg/kg 19, 18 and 9 hrs prior to surgery with erythromycin as an adjunct to mechanical cleansing of the bowel

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr >50mL/min: Administer q6h
Clcr 10-50mL/min: Administer q12-18h
Clcr <10mL/min: Administer q18-24h

P: Cap: 250mg(20862); Oint: 150mg/30g(29309)

ADR:

COMMON
Diarrhea, nausea, vomiting
SERIOUS
Neuromuscular blockade finding, ototoxicity, nephrotoxicity, respiratory tract paralysis (concomitant use of anesthesia or muscle relaxants)

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 棕/粉橘色膠囊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1011518

06.06B1 Cephalosporins, 1st-generation

20901 **B / Infant risk is**

CEPHALEXIN CAPSULES "S.T." 賜福力欣膠囊

Cephalexin 500mg cap

Dosage: 1常備品 20901

Adult
·Usual dose: PO, 250mg-1g q6h; Max. 4g/day; depending on type and severity of infection
·Streptococcal pharyngitis, Skin/skin tissue infections: PO, 250mg q6h or 500mg q12h
·Uncomplicated cystitis: PO, 500mg q12h for 7-14 days
·Respiratory tract infections, Otitis media, Osteomyelitis: PO, 250mg-1g q6h

Pediatric
· Mild/moderate infections: PO, 25-50mg/kg/day div. q6h; Max. 4g/day
· Severe infections: PO, 50-100mg/kg/day div. q6h
· Otitis media: PO, 75-100mg/kg/day div. q6h

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr <50mL/min: 250-500mg q12h

P: Cap: 500mg(20901), 250mg(20902)

ADR:

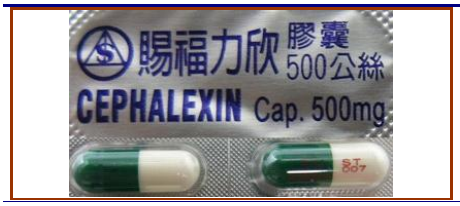
COMMON
Abdominal pain, diarrhea, transient elevation in liver enzymes

NOTE: 室溫儲存

藥名相似: Cap: 500mg(20901), 250mg(20902)

外觀相似: Fucou*(24403),

外觀描述: 白/綠色膠囊，有"ST"及"007"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1015660

06.06B1 Cephalosporins, 1st-generation

20902 B / Infant risk is

CEPHALEXIN CAPSULES 信保欣膠囊

Cephalexin 250mg cap

Dosage: 1常備品 20902

Adult
·Usual dose: PO, 250mg-1g q6h; Max. 4g/day; depending on type and severity of infection
·Streptococcal pharyngitis, Skin/skin tissue infections: PO, 250mg q6h or 500mg q12h
·Uncomplicated cystitis: PO, 500mg q12h for 7-14 days
·Respiratory tract infections, Otitis media, Osteomyelitis: PO, 250mg-1g q6h

Pediatric
· Mild/moderate infections: PO, 25-50mg/kg/day div. q6h; Max. 4g/day
· Severe infections: PO, 50-100mg/kg/day div. q6h
· Otitis media: PO, 75-100mg/kg/day div. q6h

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr <50mL/min: 250-500mg q12h

P: Cap: 500mg(20901), 250mg(20902)

ADR:

COMMON
Abdominal pain, diarrhea, transient elevation in liver enzymes

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白/綠色膠囊，印有ST及006字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1006747

06.06B1 Cephalosporins, 1st-generation

28430 B / Infant risk is

ULEXIN FOR ORAL SUSPENSION (CEPHALEXIN) "優良" 優力黴素口服懸液用顆粒（賜福力欣）

Cephalexin susp 25mg/mL, 60mL/bot

Dosage: 1常備品 28430

Adult
·Usual dose: PO, 250mg-1g q6h; Max. 4g/day; depending on type and severity of infection
·Streptococcal pharyngitis, Skin/skin tissue infections: PO, 250mg q6h or 500mg q12h
·Uncomplicated cystitis: PO, 500mg q12h
·Respiratory tract infections, Otitis media, Osteomyelitis: PO, 250mg-1g q6h

Pediatric
· Mild/moderate infections: PO, 25-50mg/kg/day div. q6h; Max. 4g/day
· Severe infections: PO, 50-100mg/kg/day div. q6h
· Otitis media: PO, 75-100mg/kg/day div. q6h

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr <50mL/min: 250-500mg q12h

P: Cap: 500mg(20901), 250mg(20902); Susp: 25mg/mL, 60mL/B(28430)

ADR:

COMMON
Abdominal pain, diarrhea, transient elevation in liver enzymes

NOTE: 泡後冷藏

·《Contraindications》Hypersensitivity to cephalexin or other members of the cephalosporin class；
·Cephalexin suspension after mixing is stable for 7 days if stored in the refrigerator.
·依瑞士藥廠的安定性報告，本品開瓶後冷藏確認可存放14天。考量藥瓶標籤與仿單仍標註 7天，故藥袋亦維持"泡製後冷藏可保存7天。(2016.07.25)
·本品賦形劑不含阿斯巴甜

藥名相似: Cap: 500mg(20901), 250mg(20902); Susp: 25

外觀相似:

外觀描述: 60mL塑膠瓶，內有粉紅色粉末

06.06B1 Cephalosporins, 1st-generation

30902 B / Infant risk is

CEFAZOLIN* INJECTION 1GM "C.C.P." "中國化學" 西華樂林注射劑 1 公克

Cefazolin sodium inj 1g pow in vial

Dosage: 1常備品 30902

Adult
· Mild infections: IV, IM, 250-500mg q8h
· Moderate to severe infections: IV, IM, 0.5-1g q6-8h
· Severe, life-threatening infections: IV, IM, 1-1.5g q6h; Max. 12g/day
· Prevention of perinatal group B Streptococcal disease: IV, initial 2g started at the time of labor or rupture of membranes, then 1g q8h until delivery
· Pneumococcal pneumonia: IV, IM, 500mg q12h
· Perioperative prophylaxis: IV, IM, 1g 0.5-1h prior to surgery (repeat with 0.5-1g during prolonged surgery), followed by 0.5-1g q6-8h for 24h

postoperatively for contaminated or potentially contaminated surgery
· Uncomplicated urinary tract infections: IV, IM, 1g q12h

Pediatric(>1 mon)
· Susceptible infections: IV, IM, 25-100mg/kg/day div. q6-8h, Max. 6g/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Adults
Clcr 35-54mL/min: Full dose with at least 8-hour intervals
Clcr 11-34mL/min: 50% of usual dose q12h
Clcr ≦10mL/min: 50% of usual dose q18-24h
Pediatric(>1 mon)
Clcr 40-70mL/min: 60% of usual dose q12h
Clcr 20-40mL/min: 25% of usual dose q12h
Clcr 5-20mL/min: 10% of usual dose q24h

P: Inj: 1g Vial(30902)

ADR:

COMMON
Pruritus, diarrhea, drug-induced eosinophilia
SERIOUS
Stevens-Johnson syndrome, pseudomembranous enterocolitis, leukopenia, thrombocytopenia, hepatotoxicity, anaphylaxis, encephalopathy, seizure

NOTE: 室溫儲存25℃以下

· 《Contraindications》Hypersensitivity to cephalosporins；
· Penicillin G is the drug of choice for prevention of perinatal group B Streptococcal disease; cefazolin is recommended in patients allergic to penicillin but at low risk for anaphylaxis.

藥名相似:

外觀相似:

外觀描述: 白色乾粉，『紫』蓋透明玻璃小瓶，白底黑字標籤有淺藍色區塊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1017712

06.06B2 Cephalosporins, 2nd-generation

20906 B / Infant risk is

CEFLOUR FILM COATED TABLETS 250MG 喜華 膜衣錠 250公絲

Cefuroxime axetil 250mg FC tab

Dosage: 1常備品 20906

Adult
· Bronchitis: PO, 250 or 500mg q12h for 5-10 days
· Pharyngitis, tonsillitis, sinusitis: PO, 250mg q12h for 10 days
· Uncomplicated skin/skin structure infections: PO, 250 or 500mg q12h for 10 days
· Uncomplicated urinary tract infections: PO, 125 or 250mg q12h for 7-10 days
· Uncomplicated gonorrhea: PO, 1g as a single dose
· Lyme disease: PO, 500mg q12h for 14-21 days

Pediatric(3 mons-12 yrs)
· Pharyngitis, tonsillitis: PO, 125mg q12h for 10 days
· Acute otitis media, impetigo: PO, 250mg q12h for 10 days
· Acute bacterial maxillary sinusitis: PO, 250mg q12h for 10 days

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Dosage adjustment required (no specific recommendations available); Max. 1g/day in patient on renal dialysis

P: Tab: 250mg(20906); Inj: 750mg Vial(30910)

ADR:

COMMON
Diarrhea, nausea, vomiting, vaginitis
SERIOUS
Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, hepatotoxicity, anaphylaxis, hypersensitivity reaction

NOTE: 室溫儲存

· 《Contraindications》Hypersensitivity to cephalosporin antibiotics；
· Tablets may take without regard to food
· Tablet has a strong bitter taste if broken or crushed
· Tablets and suspension are not substitutable on a mg/mg basis

藥名相似: Tab: 250mg(20906); Inj: 750mg Vial(30910)

外觀相似:

外觀描述: 白色長橢圓形扁定，有YSP39字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045671

06.06B2 Cephalosporins, 2nd-generation

28462 B / Infant risk can

CEFACLOR* FOR ORAL SUSPENSION 25MG/ML "SCB" 賜福樂素口服懸液用顆粒25毫克/毫升

Cefaclor susp 25mg/mL, 60mL/bot

Dosage: 1常備品 28462

Adult
· Acute otitis media, pharyngitis, lower respiratory infection, skin infection, urinary tract infections: PO, 250-500 mg q8h

Pediatric (≧1 mon)
· Acute otitis media: PO, 40 mg/kg/day div.q8~12h. Max. 1 g/day
· Lower respiratory tract infection, pharyngitis, tonsillitis, skin infection, urinary tract infections: PO, 20-40 mg/kg/day div.q8h. Max.1 g/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

(一)仿單
· Moderate to severe impairment: No dosage adjustment needed
· Severe impairment: Use with caution
(二)Micromedex
· Clcr 10-50ml/min: Administer 50-100% of dose
· Clcr <10mL/min: Administer 50% of dose
(三)UpToDate(Alternative recommendations(Aronoff 2007):
Dosing based on usual dose of 20~40 mg/kg/day div. q8~12h
· GFR ≧10 mL/min/1.73m(2): No dosage adjustment needed
· GFR <10 mL/min/1.73m(2): Administer 50% of the dose

P: Susp: 25mg/mL, 60mL/bot(28462)

ADR:

COMMON
Diarrhea
SERIOUS
Stevens-Johnson syndrome, toxic epidermal necrolysis, clostridium difficile colitis, hemolytic anemia, serum sickness due to drug

NOTE: 泡後冷藏

· After mixing, cefaclor suspension should be stored in the refrigerator and discarded after 14 days. Do not freeze.
· 本品賦形劑不含阿斯巴甜

藥名相似:

外觀相似:

外觀描述: 淺黃色顆粒，半透明塑膠瓶裝，白底 紫/黑字標籤，紙盒包裝

06.06B2 Cephalosporins, 2nd-generation

30910 **B / Infant risk is**

CEFUROXIME INJECTION 750MG "中國化學" 賜福樂信注射劑７５０公絲（希福辛）

Cefuroxime sodium inj 750mg pow in vial

Dosage: 1常備品 30910

Adult
· Bone and joint infections, gonococcal infections, pneumonia, skin/skin structure infections, urinary tract infections: IV, IM, 750mg-1.5g q8h; depending on type and severity of infection
· Life-threatening or less susceptible infections: IV, IM, 1.5g q6h
· Meningitis: IV, IM, 750mg-1.5g q6-12h, Max. 3g q8h
· Perioperative prophylaxis: IV, 1.5g 0.5-1h prior to surgery; repeat doses q12h for 3 doses recommended for open-heart surgery

Pediatric(≧3 mons)
· Susceptible infections: IV, IM, 50-100mg/kg/day div. q6-8h; depending on type and severity of infection
· Bone and joint infections: IV, IM, 150mg/kg/day div. q8h
· Meningitis: IV, IM, 200-240mg/kg/day div. q6-8h; Max. 9g/day
· Perioperative prophylaxis: IV, 50mg/kg 0.5-1h prior to surgery

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 10-20mL/min: 750mg q12h
Clcr <10mL/min: 750mg q24h

P: Tab: 250mg(20906); Inj: 750mg Vial(30910)

ADR:

COMMON
Eosinophil count raised.
SERIOUS
Erythema multiforme, Stevens-Johnson syndrome, Toxic epidermal necrolysis,Thrombocytopenia, Anaphylaxis, Hypersensitivity reaction, Interstitial nephritis.

NOTE: 儲存於25℃以下

·《Contraindications》Hypersensitivity to cephalosporin antibiotics ；
·Cefuroxime is slow to sterilize the CSF, it is not the preferred antibiotic for treatment of meningitis in children; a third generation cephalosporin (usually ceftriaxone or cefotaxime) generally is recommended

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『綠』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1030620

06.06B2 Cephalosporins, 2nd-generation

30911 **B / Unknown(有**

METACIN FOR INJECTION (CEFMETAZOLE) 西腹黴素注射劑（西華美達諾）

Cefmetazole sodium inj 0.5g pow in vial

Dosage: 1常備品 30911

Adult
·IV, IV infusion, 2g q6-12h for 5 to 14 days, with severe or life-threatening infections requiring 8g/day

Pediatric: IV, IV infusion
·Usual dose: 25-100mg/kg/day in 2-4 div. doses
·Severe infections: 150mg/kg/day in 2-4 divided doses

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 50 -90mL/min: 1 or 2g q12h
Clcr 30-49mL/min: 1 or 2g q16h
Clcr 10-29mL/min: 1 or 2g q24h
Clcr <10mL/min: 1 or 2g q48h after hemodialysis

P: Inj: 0.5g Vial(30911)

ADR:

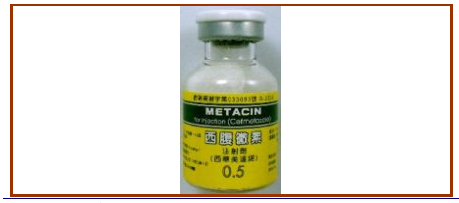
Eosinophilia, positive Coombs test, leukopenia, anemia, aplastic anemia, epistaxis, bleeding tendencies, phlebitis, hypotension, tachycardia, hot flushes, chest pain, dyspnea, nausea, vomiting, diarrhea, anorexia, abdominal pain, melena, pseudomembranous colitis, acute renal failure, elevated hepatic enzymes, rashes, erythema, pruritus, disulfiram-like reactions, anaphylaxis

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『白』蓋 透明玻璃小瓶



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1033093

06.06B2 Cephalosporins, 2nd-generation

30928 **B / Infant risk is**

LOFATIN* INJECTION 1000MG (CEFOXITIN) "GENTLE" "政德" 樂華淨注射劑500毫克、1000毫克、2000毫克（西福斯汀）

Cefoxitin inj 2g pow in vial

Dosage: 1常備品 30928

Adult
· Uncomplicated infections: IM, IV, 1g q6-8h
· Moderate to severe infections: IM, IV, 1g q4h or 2g q6-8h, doses may up to 2g q4h or 3g q6h; Max. 12g/day
· Uncomplicated gonorrhea: IM, 2g as a single dose
· Pelvic inflammatory disease:
(1)Parenteral regimen: IV, 2g q6h plus oral doxycycline 100mg q12h for at least 24 to 48 hours after clinical improvement, followed by oral doxycycline to complete 14 days of therapy
(2)IM/Oral regimen: IM, 2g plus oral probenecid 1g as a single dose, followed by oral doxycycline 100mg q12h with or without metronidazole 500mg q12h for 14 days
· Perioperative prophylaxis: IM, IV, 1-2g 0.5-1h prior to surgery, followed by 1-2g q6-8h for no more than 24hrs after surgery depending on the procedure

Pediatric(≧3 mons)
· Susceptible infections: IM, IV, 80-160mg/kg/day div. q4-6h, depending on type and severity of infection; Max.12g/day
· Perioperative prophylaxis: IM, IV, 30-40mg/kg 0.5-1h prior to surgery, followed by 30-40mg/kg q6h for no more than 24hrs after surgery depending on the procedure

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 30-50mL/min: LD 1-2g, then 1-2g q8-12h
Clcr 10-29mL/min: LD 1-2g, then 1-2g q12-24h
Clcr 5-9mL/min: LD 1-2g, then 0.5-1g q12-24h
Clcr <5mL/min: LD 1-2g, then 0.5-1g q24-48h

P: Inj: 2g vial(30928)

ADR:

COMMON
Injection site reactions, thrombophlebitis
SERIOUS
Erythema multiforme, Stevens-Johnson syndrome, pseudomembranous enterocolitis, anaphylaxis, seizure

NOTE: 室溫儲存

仿單內容貯存資訊變更如下：(來文：浩?藥品有限公司【優管字第1060406001號】)
1.未配製之注射乾粉：儲存條件由「30℃以下」變更為「25℃以下」。
2.配製後的注射液：儲存條件由「室溫下可保存24小時，置於小於5℃則可保存30個星期」變更為「室溫下可保存24小時，置於冷藏(小於5℃)則可保存1個星期」。

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『綠』蓋透明玻璃小瓶，白底黑字紙標籤，有"橘"色區塊

06.06B3 Cephalosporins, 3rd-generation

20910 **B / Caution**

CEXIME* Capsules 100 mg (Cefixime) "信東" 賜信膠囊 100 毫克

Cefixime 100mg cap

Dosage: 1常備品 20910

Adult
· Bronchitis, otitis media, pharyngitis, tonsillitis, urinary tract infections: PO, 400mg qd or div. q12h
· Gonorrhea: PO, 400mg as a single dose

Pediatric (6mons-12yrs)
· Bronchitis, otitis media, pharyngitis, tonsillitis, urinary tract infections: PO, 8mg/kg/day qd or div. q12h

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 21-60mL/min: Administer 75% of usual dose
Clcr <20mL/min: Administer 50% of usual dose

P: Cap: 100mg(20910)

ADR:

COMMON

Pruritus, rash, urticaria, abdominal pain, diarrhea, nausea

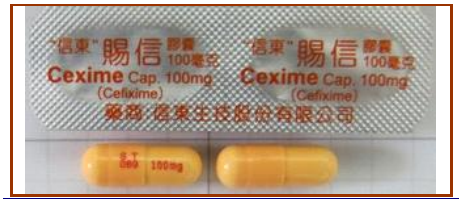
NOTE: 室溫儲存25℃以下

· 《Contraindications》Known allergy to cefixime or other cephalosporins；

藥名相似: Cap: 100mg(20910)

外觀相似:

外觀描述: 淡橙色膠囊、印有"ST 089"及"100mg"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048892

06.06B3 Cephalosporins, 3rd-generation

30874 **UK / Unknown(有**

Flumarin for Injection 1g 氟黴寧靜脈注射劑1公克

Flomoxef sodium 1g vial

Dosage: 1常備品 30874

Adult: IV, IV infusion
· Moderate to severe infections: 1g q6-8h
· Refractory or serious infections: 4g/day in 2-4 doses

Pediatric: IV, IV infusion
· Urinary tract infection, otitis, impetigo, aspiration pneumonia, soft tissue infections: 60-80mg/kg/day div. into 3-4 doses, may be increased to 150mg/kg/day div. into 3-4 doses
· Premature neonate & neonate: 20mg/kg bid-tid before the 3rd day, tid-qid after the 4th day, may be increased to 150mg/kg/day div. into 3-4 doses

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 50-80mL/min: 1g q8h
Clcr 25-50mL/min: 1g q12h
Clcr 5-25mL/min: 1g q24h

P: Inj: 1g Vial(30874)

ADR:

Rash, anemia, asymptomatic elevation in liver enzymes

NOTE: 室溫儲存

Depending on infection severity, adult dose may increase to 4g/day, divided into 2~4 doses.

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『橘』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024321

06.06B3 Cephalosporins, 3rd-generation

30906 **B / Infant risk is**

LOFORAN* FOR INJECTION 2GM "GENTLE"(CEFOTAXIME SODIUM) "政德"樂活朗注射劑1公克，2公克（使治他新鈉）

Cefotaxime inj 2g pow in vial

Dosage: 1常備品 30906

Adult
· Uncomplicated infections: IV, IM, 1g q12h
· Moderate to severe infections: IV, IM, 1-2g q8h
· Septicemia (and infections requiring higher doses): IV, 2g q6-8h
· Life-threatening infections: IV, 2g q4h; Max. 12g/day

Pediatric
· Neonates:
0-1 week: IV, 50mg/kg q12h
1-4 weeks: IV, 50mg/kg q8h
· Infants and children(1 mon-12 yrs):
<50kg: IV, IM, 50-180mg/kg/day div. q4–6h depending on type and severity of infection; Max. 12g/day
>50kg: usual adult dose; Max. 12g/day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr <20mL/min: Reduce dose by 50%

P: Inj: 250mg Vial(30903), 2g Vial(30906)

ADR:

COMMON
Diarrhea, vomiting, rash, phlebitis and pain at injection site
SERIOUS
Cardiac dysrhythmia, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, agranulocytosis, granulocytopenic disorder, hypersensitivity reaction

NOTE: 室溫儲存25℃以下

· 《Contraindications》Hypersensitivity to cefotaxime sodium or to any cephalosporin；

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『白』蓋透明玻璃小瓶 ，白底黑字標籤有紅色"Cefotaxime Sodium 2g"字樣及黃色區塊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1027325

06.06B3 Cephalosporins, 3rd-generation

30922 **B / Infant risk is**

SINTRIX FOR INJECTION (CEFTRIAXONE) "信東"信得瑞注射劑

Ceftriaxone inj 1g pow in vial

Dosage: 1常備品 30922

Adult
· Usual dose: IV, 1-2g q12-24h; Max. 4g/day
· Disseminated gonococcal infection: IV, 1g q24h
· Meningitis: IV, 4g/day div. q12-24h
· Community-acquired pneumonia: IV, 1g q12-24h
· Perioperative prophylaxis: IV, 1g 0.5-2h prior to surgery
· Endocarditis: IV, 2g q24h

Pediatric
· Usual dose: IV, 50-100mg/kg/day div. q12-24h; Max. 2g/day
· Disseminated gonococcal infection: IV, ≦45kg: 25-50mg/kg q24h; Max. 1g/day
· Meningitis: IV,100mg/kg/day div. q12-24h; Max. 4g/day
· Acute otitis media: IV, 50mg/kg/day as a single dose or once-daily for 3 days
· Endocarditis: IV, 100mg/kg q24h

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed
Combined renal and hepatic impairment: Doses should not exceed 2g/day without serum concentration monitoring

P:

ADR:

COMMON
Diarrhea, transient increase liver enzyme
SERIOUS
Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, immune-mediated hemolysis, disorder of gallbladder (reversible), immune hypersensitivity reaction, kernicterus of newborn, kidney/lung finding (death associated with calcium-ceftriaxone precipitates)

NOTE: 室溫儲存

· 《Contraindications》Concurrent administration of calcium-containing IV solutions, including continuous calcium-containing infusions such as parenteral nutrition, in neonates aged 28 days or less due to risk of fatal salt precipitation in lungs and kidneys; Hyperbilirubinemic neonates, due to increased risk of bilirubin encephalopathy (kernicterus), especially in premature neonates; Hypersensitivity to cephalosporins
· Sodium contents: 83mg(3.6mEq)/vial
· Solutions or products that contain calcium must not be administered within 48 hours of ceftriaxone administration by the same or different infusion lines

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『藍』蓋透明玻璃小瓶，白底紅字標籤，有綠色"C"形圖樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1036751

06.06B3 Cephalosporins, 3rd-generation

30923 **B / Infant risk is**

CEFADIME* powder for IV Injection 賜福寧靜脈乾粉注射劑

Ceftazidime inj 2g pow in vial

Dosage: 1常備品 30923

Adult
· Usual dose: IV, IV infusion, IM, 1-2g q8-12h
· Urinary tract infection: IV, IV infusion, IM, 250-500mg q8-12h
· Pneumonia, skin/skin structure infections: IV, IV infusion, IM, 0.5-1g q8h
· Bone/joint infections: IV, IV infusion, 2g q12h
· Meningitis, intra-abdominal infections, severe life-threatening infections: IV, IV infusion, 2g q8h
· Cystic fibrosis (pseudomonal lung infection): IV, IV infusion, 30-50mg/kg q8h; Max. 6g/day

Pediatric
· Usual dose:(0-4 wks) IV, IV infusion, 30mg/kg q12h
· Usual dose:(1 mon-12 yrs) IV, IV infusion, 30-50mg/kg q8h; Max. 6g/day
· Meningitis: IV, IV infusion, 150mg/kg/day div q8h; Max. 6g/day
· American Academy of Pediatrics (AAP) recommendation
<1 wk: IV, IV infusion,
≦2 kg: 50mg/kg q12h; >2 kg: 50mg/kg q8-12h
1-4 wks: IV, IV infusion,
≦1.2 kg: 50mg/kg q12h; >1.2 kg: 50mg/kg q8h
> 1 mon: IV, IV infusion,
Mild to moderate infections: 75-100 mg/kg/day div q8h
Severe infections: 125-150 mg/kg/day div q8h; Max. 6g/day
> 12 yrs: same as adult

Dosing adjustments in hepatic impairment:

No dosage adjustment required

Dosing adjustments in renal impairment:

Clcr 31-50mL/min: Administer 1g q12h
Clcr 16-30mL/min: Administer 1g q24h
Clcr 6-15mL/min: Administer 500mg q24h
Clcr <5 mL/min: Administer 500mg q48h

P: Inj: 1g Vial(30918), 2g Vial(30923)

ADR:

COMMON
Diarrhea
SERIOUS
Stevens-Johnson syndrome, toxic epidermal necrolysis, pseudomembranous enterocolitis, anaphylaxis, asterixis, coma, encephalopathy, myoclonia, seizure

NOTE: 室溫儲存

· 上大藥品有限公司【(106)上字第10603003號】: 廠商來文說明CEFULIN*與CEFDIME*為同製造廠製造，可視二者之安定性為相同結果。檢附CEFDIME*仿單及ceftazidime注射劑調配後溶液安定性試驗計劃與報告結果，將新增安定性資料於仿單。

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『藍』蓋透明玻璃小瓶，白底黑字標籤有淺藍色區塊及藍色/褐色字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1050081

06.06B3 Cephalosporins, 3rd-generation

30926 **B / Infant risk is**

TRICEF FOR I.V. INJECTION "SWISS" (CEFTRIAXONE) " 瑞士" 得力伏靜脈注射劑（西華崙隆）

Ceftriaxone inj 2g pow in vial

Dosage: 1常備品 30926

Adult
· Usual dose: IV, 1-2g q12-24h, Max. 4g/day
· Bloodstream infection: IV, 2g q12-24H
· Bacterial meningitis: IV, 2g q12H
· Intra-abdominal infection , community-acquired pneumonia, skin and soft tissue infection: IV, 1-2g q24h
· Osteomyelitis and/or discitis, prosthetic joint infection, septic arthritis: IV, 2g q24h
· Urinary tract infection, complicated (including pyelonephritis): IV, 1g q24h
· Perioperative prophylaxis: IV, 1-2g 0.5-2 hours prior to surgery

Pediatric
· Usual dose: IV, 50-100mg/kg/day div. q12-24h, Max. 4g/day
· Complicated intra-abdominal infection, skin and skin structure infection: IV, 50-75mg/kg/day div. q12-24h, Max. 2g/day
· Meningitis: IV, 80-100mg/kg/day div. q12-24h, Max. 4g/day
· Community-acquired pneumonia: IV, 50-100mg/kg/day div. q12-24h, Max. 2g/day (4g/day for HIV-exposed/-positive patients)
· Acute otitis media: IV, 50mg/kg/dose q24h for 1 or 3 days, Max. 1g/dose
· Disseminated gonococcal infection: IV, Neonate: 25-50mg/kg qd
<45kg: 50mg/kg/dose q24h, Max. 1g/dose
≧45kg: 1g q24h

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed
Combined renal and hepatic impairment: Doses should not exceed 2g/day without serum concentration monitoring

P: P Inj: 2g pow in vial(30926), 1g pow in vial(30922)

ADR:

COMMON
Diarrhea, eosinophil count raised, thrombocytosis
SERIOUS
Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, Clostridium difficile colitis, hemolytic anemia, hypersensitivity reaction, kernicterus of newborn, renal failure, injury of lung

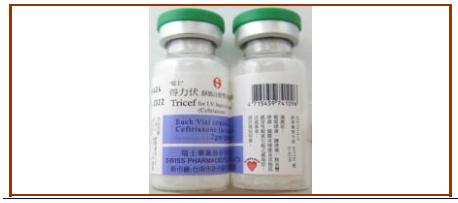
NOTE: 室溫儲存

· Do not reconstitute vials or administer simultaneously with calcium-containing solutions (eg, Ringer or Hartmann solution), products, or continuous calcium-containing solutions (eg, parenteral nutrition) in the same IV line or Y-site due to risk of precipitate formation.
· In adult and pediatric patients older than 28 days of age, ceftriaxone and calcium-containing solutions may be administered sequentially if the infusion lines are thoroughly flushed between infusions with a compatible fluid (e.g., 0.9% N/S, D5W).

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『綠』蓋透明玻璃小瓶，白底黑字標籤，有『紫』色區塊



06.06B3 Cephalosporins, 3rd-generation

30932 **UK / Unsafe**

Brosym for Injection 博益欣注射劑

Cefoperazone sodium 1000mg, Sulbactam sodium 1000mg vial

Dosage: 1常備品 30932

Adult: Dose expressed as cefoperazone/sulbactam.
· Susceptible infections: Slow IV, IV infusion, 0.5-1g/0.5-1g (0.5-1 vial) q12h; Max. 2g/2g (2 vial) q12h

Pediatric: Dose expressed as cefoperazone/sulbactam.
·Susceptible infections: Slow IV, IV infusion, 20-40mg/20-40mg/kg/day in 2-4 divided doses; Max. 80mg/80mg/kg/day

Dosing adjustments in hepatic impairment:

Dosage adjustment may be required

Dosing adjustments in renal impairment:

Clcr 15-30 mL/min: Max. 1g/1g q12h (2g/2g/day)
Clcr≦15mL/min: Max. 500mg/500mg q12h (1g/1g/day)

P: P Inj: 1000/1000mg vial(30932), 500/500mg vial(30915), Sulbactam 500mg vial(31020)

ADR:

Elevated serum transaminases, elevated serum alkaline phosphatase, convulsion, vitamin K

deficiency(hypoprothrombinemia, bleeding tendency), symptoms of vitamin B deficiency(glossitis, stomatitis, loss of appetite, neuritis), hypotension, vasculitis, injection site phlebitis, injection site pain, skin rash, itching, thrombocytosis, eosinophilia, neutropenia, hyperbilirubinemia, diarrhea, nausea, vomiting, fever, urticaria, anemia, jaundice, candidiasis, headache, hematuria, anaphylactic reactions, acute renal impairment, pseudomembranous colitis, interstitial pneumonia, pulmonary infiltration with eosinophilia, Stevens-Johnson syndrome, blood disorders(hemolytic anemia, pancytopenia, neutropenia, thrombocytopenia), fulminant hepatitis

NOTE: 室溫儲存

此藥具有NMTT支鏈(N-methylthiotetrazole side chain)，可能影響凝血功能，必要時可補充vitamin K。

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『黃』蓋透明玻璃小瓶，紫底白字/白底黑字標籤

06.06B3 Cephalosporins, 3rd-generation

30933 **ɔt be ruled out / Infant risk can**

Zavicefta 2 g/0.5 g powder for concentrate for solution for infusion 贊飛得注射劑2 g/0.5 g

急用Ceftazidime pentahydrate 2g, Avibactam sodium 500mg vial

Dosage: 2急用藥 30933

Adult: Dose expressed as ceftazidime/avibactam combination
·Complicated urinary tract infection (including pyelonephritis), hospital acquired pneumonia, ventilator associated pneumonia: IV infusion over 2 hrs, 2.5g (1 vial) q8h for 7-14 days
·Complicated intra-abdominal infection: IV infusion over 2 hrs, 2.5g (1 vial) q8h in combination with metronidazole for 5-14 days

Pediatric:
(1)Safety and efficacy have not been established (國內仿單)
(2)Dose expressed as ceftazidime/avibactam combination (Micromedex)
·Complicated urinary tract infection (including pyelonephritis): IV infusion over 2 hrs,
≧3 mons to <6 mons: 50mg/kg q8h for 7-14 days
≧6 mons: 62.5mg/kg q8h for 7-14 days; Max. 2.5g/dose
·Complicated intra-abdominal infection: IV infusion over 2 hrs,
≧3 mons to <6 mons: 50mg/kg q8h in combination with metronidazole for 5-14 days
≧6 mons: 62.5mg/kg q8h in combination with metronidazole for 5-14 days; Max. 2.5g/dose

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

(1)Adult
CrCl >50 mL/min: No dosage adjustment needed
CrCl 31-50 mL/min: 1.25g q8h
CrCl 16-30 mL/min: 0.94g q12h
CrCl 6-15 mL/min: 0.94g qd
CrCl ≦5 mL/min, HD: 0.94g qod (AD on dialysis day)
(2)Pediatric(Micromedex - Schwartz bedside formula)
eGFR > 50 mL/min/1.73 m2: No dosage adjustment needed
eGFR 31-50 mL/min/1.73 m2: 31.25mg/kg q8h; Max. 1.25g/dose
eGFR 16-30 mL/min/1.73 m2: 23.75mg/kg q12h; Max. 0.94g/dose
eGFR 6-15 mL/min/1.73 m2: 23.75mg/kg qd; Max. 0.94g/dose
eGFR ≦ 5 mL/min/1.73 m2: 23.75mg/kg qod (AD on dialysis day); Max. 0.94g/dose

P: P Inj: 2.5g vial(30933), Ceftazidime 1g vial(30918), Ceftazidime 2g vial(30923)

ADR:

COMMON
Injection site phlebitis, rash, constipation, diarrhea, nausea, vomiting, anxiety
SERIOUS
Clostridium difficile diarrhea, hypersensitivity reaction, asterixis, encephalopathy, neuromuscular excitability, nonconvulsive status epilepticus, seizure, coma

NOTE: 室溫儲存

·The sodium content of each vial is approximately 148 mg (6.44 mmol).

藥名相似:

外觀相似:

外觀描述: 白色乾粉，『藍』蓋,藍色鋁封 透明玻璃小瓶，白底黑字標籤

06.06B4 Cephalosporins, 4th-generation

30924 **b2 / Unsafe**

SAFEROME* POWDER FOR I.V. INJECTION 1G "STANDARD" "生達"西服洛乾粉注射劑1公克

Cefpirome inj 1g pow in vial

Dosage: 1常備品 30924

Adult
· Treatment of severe gram-negative infections resistant to other third-generation cephalosporins: IV, 1-2g q12h; Max. 4g/day

Pediatric

Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

Clcr 20-50mL/min: LD 1 or 2g, then 0.5g or 1g q12h
Clcr <20mL/min: LD 1or 2g, then 0.5g or 1g qd

P: Inj: 1g Vial(30924)

ADR:

Nausea, diarrhea, taste disorders, headache, skin rash, fever

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『深藍』蓋透明玻璃小瓶，白底深藍字標籤，有深藍色區塊與粉紅色"1公克"、"1g"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=51058212

06.06B4 Cephalosporins, 4th-generation

30925 B / Infant risk is

Supecef Powder for Injection 斯沛服乾粉注射劑

Cefepime HCl inj 500mg pow in vial

Dosage: 1常備品 30925

Adult: IM, IV, IV infusion
Febrile neutropenia: 2g q8h for 7 days or until neutropenia resolves
· Urinary tract infections (mild to moderate): 0.5-1g q12h for 7-10 days
· Urinary tract infections (severe), skin/subcutaneous tissue infections: 2g q12h for 10 days
· Pneumonia (Moderate to Severe): 1-2g q8-12h for 10 days
· Hospital-acquired or ventilator-associated pneumonia: 2g q8h

Pediatric(≧2mons): IM, IV, IV infusion
· Febrile neutropenia: 50mg/kg q8h for 7 days or until neutropenia resolves; Max. 2g/dose
· Pneumonia, skin/subcutaneous tissue infections, urinary tract infections: 50mg/kg q12h; Max. 2g/dose

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

· MICROMEDEX, 熱病 2018

Clcr >60mL/min	Clcr 30~60mL/min	Clcr 11~29mL/min	Clcr <10mL/min
500mg q12h	500mg q24h	500mg q24h	250mg q24h
1g q12h	1g q24h	500mg q24h	250mg q24h
2g q12h	2g q24h	1g q24h	500mg q24h
2g q8h	2g q12h	2g q24h	1g q24h

P: Inj: 500mg Vial(30925)

ADR:

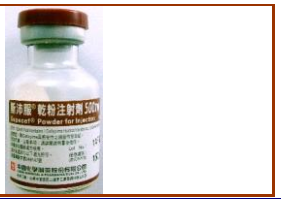
COMMON
Injection site inflammation, rash, colitis, diarrhea, indigestion, headache
SERIOUS
Encephalopathy, myoclonus, seizures (rare, renally impaired without dose adjustment)

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『棕』蓋透明玻璃小瓶



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049147

06.06B5 Cephalosporins, 5th-generation

30929 ɔt be ruled out / Infant risk can

Zinforo 600 mg powder for concentrate for solution for infusion 捷復寧注射劑600毫克

Ceftaroline fosamil inj 600mg pow in vial

Dosage: 1常備品 30929

Adult (IV infusion over 60 mins)
· Community-acquired pneumonia (CAP): 600mg q12h
· Complicated skin and soft tissue infections (cSSTI): 600mg q12h
· cSSTI confirmed or suspected to be caused by S. aureus with an MIC = 2 mg/L or 4 mg/L to ceftaroline: IV infusion over 120 mins, 600mg q8h

Pediatric (IV infusion over 60 mins)
· Community-acquired pneumonia (CAP), complicated skin and soft tissue infections (cSSTI):
· ≧2 mons ~ < 2 yrs: 8mg/kg q8h
· ≧2yrs ~ < 18 yrs, BW < 33 kg: 12mg/kg q8h; Max. 400mg/dose
· > 12 yrs ~ < 18 yrs, BW ≧ 33 kg: same as adult
· cSSTI confirmed or suspected to be caused by S. aureus with an MIC = 2 mg/L or 4 mg/L to ceftaroline: IV infusion over 120 mins,
· > 12 yrs ~ < 18 yrs with bodyweight≧33 kg: same as adult

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Adult
· CrCl > 50 mL/min: No dosage adjustment needed
· CrCl >30 ~ ≦50 mL/min: 400mg q12h or q8h (cSSTI caused by S. aureus with an MIC = 2 mg/L or 4 mg/L)

· CrCl≧15 ~ ≦30 mL/min: 300mg q12h or q8h (cSSTI caused by S. aureus with an MIC = 2 mg/L or 4 mg/L)
· ESRD (CrCl < 15 mL/min) or HD: 200mg q12h or q8h (cSSTI caused by S. aureus with an MIC = 2 mg/L or 4 mg/L)
Pediatric (based on pharmacokinetic modelling)
· ≧2 yrs, BW <33 kg:
CrCl >30 ~ ≦50 mL/min: 8mg/kg q8h (Max: 300mg/dose)
CrCl≧15 ~ ≦30 mL/min: 6mg/kg q8h (Max: 200mg/dose)
· ≧2 yrs, BW ≧33 kg: Same as adult

P: P Inj: 600mg vial(30929)

ADR:

COMMON
Rash, diarrhea, nausea, vomiting, fever
SERIOUS
Clostridium difficile diarrhea, ALT/SGPT level raised, AST/SGOT level raised, hepatitis, anaphylaxis, hypersensitivity reaction, seizure, renal failure

NOTE: 室溫儲存

· The recommended durations of treatment are 5-7 days for community-acquired pneumonia (CAP) and 5-14 days for complicated skin and soft tissue infections (cSSTI).
· It should not be used totreat cSSTI due to S. aureus for which the ceftaroline MIC is > 4 mg/L.

藥名相似:

外觀相似:

外觀描述: 注射乾粉，『藍』蓋玻璃小瓶，白底深藍/黑色標籤

06.06C1 Carbapenems

31070 **B / Caution**

INVANZ 1G INJECTION 益滿治 注射劑 1 公克

Ertapenem 1g vial

Dosage: 1常備品 31070

Adult: IV infusion, IM
·Community acquired pneumonia, complicated urinary tract infection: 1g qd for 10-14 days
·Complicated infection of skin and/or subcutaneous tissue: 1g qd for 7-14 days
·Complicated infection of abdomen: 1g qd for 5-14 days
·Acute pelvic infections: 1g qd for 3-10 days

Pediatric: IV infusion, IM
·Community acquired pneumonia, complicated urinary tract infection: 3 mons-12 yrs: 15mg/kg/dose q12h, Max. 1g/day; ≧13yrs: 1g qd for 10-14 days
·Complicated infection of skin and/or subcutaneous tissue: 3 mons-12 yrs: 15mg/kg/dose q12h, Max. 1g/day; ≧13yrs: 1g qd for 7-14 days
·Complicated infection of abdomen: 3 mons-12 yrs: 15mg/kg/dose q12h, Max. 1g/day; ≧13yrs: 1g qd for 5-14 days
·Acute pelvic infection: 3 mons-12 yrs: 15mg/kg/dose q12h, Max. 1g/day; ≧13yrs: 1g qd for 3-10 days

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr<30mL/min: 500mg/day
HD: When the daily dose is given within 6 hrs prior to HD, a supplementary dose of 150mg is required following HD.

P: Inj: 1g Vial(31070)

ADR:

COMMON
Injection site reaction, abdominal pain, constipation, diarrhea, indigestion, nausea, vomiting, headache, vaginitis
SERIOUS
Seizure

NOTE: 室溫儲存

1. IV infusion over 30 mins, IM(reconstitute with 3.2mL of 1% lidocaine HCl (without epinephrine))
2. Do not mix or co-infuse with other medications; do not use diluents containing dextrose

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『白』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023749

06.06C1 Carbapenems

31072 **C / Unknown(有**

Bestnem Powder for I.V. Injection 倍特寧靜脈乾粉注射劑

Imipenem 500mg[C], Cilastatin sodium 500mg[C] inj pow in vial

Dosage: 1常備品 31072

Adult: (Based on Imipenem) IV Infusion,
· Mild infections: 250mg-500mg q6h
· Moderate infections: 500mg q6-8h or 1g q8h
· Severe, life-threatening infections: 500mg q6h or 1g q6-8h; Max. 50mg/kg/day or 4g/day
· Cystic fibrosis: up to 90mg/kg/day div. q6h; Max. 4g/day
· Urinary tract infections: 250-500mg q6h; Max. 50mg/kg/day

Pediatric: (Based on Imipenem) IV Infusion,
· Susceptible non-CNS infections
< 1 wk of age: 25mg/kg q12h
1-4 wks of age: 25mg/kg q8h
4 wks-3 mons of age: 25mg/kg q6h
> 3 mons of age: 15-25mg/kg q6h; Max. 2g/day for fully susceptible organisms; Max. 4g/day for moderately susceptible organisms including P.

aeruginosa

Dosing adjustments in hepatic impairment:

Hepatic dysfunction may further impair cilastatin clearance; consider decreasing the dosing frequency.

Dosing adjustments in renal impairment:

・仿單

Total daily dose	CrCl 41~70mL/min	CrCl 21~40mL/min	CrCl 6~20mL/min
1.0 g/day	250mg q8h	250mg q12h	250mg q12h
1.5 g/day	250mg q6h	250mg q8h	250mg q12h
2.0 g/day	500mg q8h	250mg q6h	250mg q12h
3.0 g/day	500mg q6h	500mg q8h	500mg q12h(註1)
4.0 g/day	750mg q8h	500mg q6h	500mg q12h(註1)

・CrCl< 5mL/min: Not recommended unless hemodialysis is instituted within 48 hrs
*A further proportionate reduction in dose administered must be made for patients with a body weight < 70 kg.
註1: When 500mg dose is used in patients with CrCl 6-20 mL/min there may be an increased risk of seizures.

・熱病 2018

Dose	CrCl>50~90mL/min	CrCl 10~50mL/min	CrCl<10mL/min
500mg q6h	250~500mg q6-8h	250mg q8-12h	125-250mg q12h

HD: 125-250mg q12h (given one of the dialysis day doses AD)

P: Inj: 500mg Vial(31072)

ADR:

COMMON
Phlebitis, Rash, Diarrhea, Nausea, Vomiting, Thrombophlebitis.
SERIOUS
Stevens-Johnson syndrome, Toxic epidermal necrolysis, Clostridium difficile diarrhea, Hypersensitivity reaction, Seizure.

NOTE: 室溫儲存

・《Contraindications》Hypersensitivity to imipenem or cilastatin, or any component of the product；
・Imipenem is NOT recommended for use in pediatric patients with CNS infections; increased risk of seizures

藥名相似:

外觀相似:

外觀描述: 白色乾粉,透明玻璃小瓶,『淺藍』蓋銀鋁環,白底黑字標籤,有部分綠色字與線條

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048911

06.06C1 Carbapenems

31074 **B / Caution**

Finibax(R) for Injection 0.25g 伏霸(R)注射劑 0.25公克

Doripenem inj 250mg pow in vial

Dosage: 1常備品 31074

Adult
·Complicated urinary tract infections, pyelonephritis: IV infusion over 1 hour, 500mg q8h for 10-14 days
·Complicated intra-abdominal infections: IV infusion over 1 hour, 500mg q8h for 5-14 days

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 30-50mL/min: 250mg q8h
Clcr 10-30mL/min: 250mg q12h
Intermittent HD: 250mg q24h; if treating infections caused by Pseudomonas aeruginosa, administer 500mg q12h on day 1, followed by 500mg q24h (Uptodate 2018)

P: Inj: 250mg vial(31074)

ADR:

COMMON
Phlebitis, rash, diarrhea, nausea, anemia, headache
SERIOUS
Skin reaction - finding, Stevens-Johnson syndrome, toxic epidermal necrolysis, clostridium difficile colitis, anaphylaxis, hypersensitivity reaction, seizure, renal failure, interstitial pneumonia

NOTE: 室溫儲存

仿單內容變更，摘述如下：(自批號0024起)
1.警語及注意事項增列(A)本藥用於治療呼吸器相關細菌性肺炎會增加死亡率，本藥並未核准用於治療該病症。(B)有報告指出Carbapenem類曾引起癲癇，包含doripenem。臨床試驗中，以本藥治療原有CNS疾病的病人時，腎功能受損的病人與給藥劑量超過每八小時500mg的病人顯示有較高的風險會引發癲癇。
2.更新臨床試驗不良反應的相關資訊。
3.病患諮商訊息增列若病患有中樞神經系統疾病如中風或癲癇病史應告知醫師。

藥名相似:

外觀相似:

外觀描述: 白色乾粉，綠蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025066

06.06C1 Carbapenems

31075 B / Caution

MEPEM INTRAVENOUS INJECTION 0.25G/VIAL 0.5G/VIAL 美平乾粉注射劑０．２５、０．５公克

Meropenem trihydrate inj 250mg vial

Dosage: 1常備品 31075

Adult
· Intra-abdominal infections, pneumonia: IV infusion, 1g q8h
· Bacterial meningitis: IV infusion, 2g q8h
· Skin and skin structure infections: IV infusion, 500mg-1g q8h

Pediatric (>3 mons)
<50kg: IV infusion, 10-40mg/kg q8h
>50kg: Same as adult

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 26-50mL/min: Usual dose q12h
Clcr 10-25mL/min: One-half usual dose q12h
Clcr <10mL/min: One-half usual dose q24h

P: Inj: 500mg vial(31077)(31067), 250mg vial(31075)

ADR:

COMMON
Injection site inflammation, rash, constipation, diarrhea, nausea, vomiting, anemia, headache, pain
SERIOUS
Cardiac arrest, heart failure, myocardial infarction, shock, syncope, bowel obstruction, Clostridium difficile diarrhea, gastrointestinal hemorrhage, nontraumatic hemoperitoneum, bleeding, cholestatic jaundice syndrome, Jaundice, liver failure, anaphylaxis, hypersensitivity reaction, seizure, renal failure, hypoxia, pleural effusion, pulmonary edema, pulmonary embolism, angioedema, sepsis

NOTE: 室溫儲存

· 《Contraindications》Anaphylactic reaction to beta-lactam antibiotics; Hypersensitivity to meropenem or any component of the product or other drugs in the same class (ie, carbapenems) ;

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『藍』蓋白色玻璃小瓶，蓋上有美平及0.25g字樣

06.06C1 Carbapenems

31077 B / Caution

MEROPENEM KABI* 500MG POWDER FOR SOLUTION FOR INJECTION OR INFUSION "卡比"美諾平乾粉注射劑 500毫克,1公克

Meropenem trihydrate inj 500mg pow in vial

Dosage: 1常備品 31077

Adult
· Intra-abdominal infections, pneumonia: IV infusion, 1g q8h
· Bacterial meningitis: IV infusion, 2g q8h
· Skin and skin structure infections: IV infusion, 500mg q8h

Pediatric (>3 mons)
· <50kg: IV infusion, 10-40mg/kg q8h
· >50kg: Same as adult

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 26-50mL/min: Usual dose q12h
Clcr 10-25mL/min: One-half usual dose q12h
Clcr <10mL/min: One-half usual dose q24h

P: Inj: 500mg Vial(31077)(31067)

ADR:

COMMON
Constipation, diarrhea, nausea, vomiting, anemia, headache, pain, injection site inflammation, rash
SERIOUS
Cardiac arrest, heart failure, myocardial infarction, shock, syncope, bowel obstruction, clostridium difficile diarrhea, gastrointestinal hemorrhage, nontraumatic hemoperitoneum, bleeding, cholestatic jaundice syndrome, jaundice, liver failure, anaphylaxis, hypersensitivity reaction, seizure

NOTE: 室溫儲存30℃以下

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『淺紫』蓋玻璃小瓶，白底黑字標籤有深/淺紫色區塊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=52026737

06.06E1 Erythromycins

20961 B / Infant risk is

ERYTHROMYCIN STEARATE FILM COATED TABLETS 250MG "SHITEH" "西德有機"紅黴素硬脂酸醯膜衣錠 ２５０毫克

Erythromycin 250mg FC tab

Dosage: 1常備品 20961

Adult
· Susceptible infections: PO, 250mg q6h or 500mg q 12h; Max. 4g/day
· Legionnaire's disease: PO, 1-4g in div. doses
· Rheumatic fever prophylaxis: PO, 250mg q12h

Pediatric
· Susceptible infections: PO, 30-50mg/kg/day in div. doses, the dosage may be doubled for more severe infections; Max. 4g/day
· Amebiasis, intestinal: PO, 30-50mg/kg/day in div.

doses for 10-14 days

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Clcr>10mL/min: No dosage adjustment needed.
Clcr<10mL/min: Should receive 50 to 75% of the normal dose at the usual dosing interval. MD: 2g/day

P: Tab: 250mg(20961); Susp: 25mg/mL, 60mL/bot(28452); Inj: 500mg Vial(30963)

ADR:

COMMON
Urticaria, abdominal pain, diarrhea, loss of appetite, nausea, vomiting
SERIOUS
Prolonged QT interval, ventricular arrhythmia (rare), Stevens-Johnson syndrome, toxic epidermal necrolysis (rare), pseudomembranous enterocolitis, decreased liver function, anaphylaxis, hearing loss (high dose patients with renal insufficiency)

NOTE: 室溫儲存

· 《Contraindications》Concomitant use with astemizole, cisapride, ergotamine, dihydroergotamine, pimozide, or terfenadine; Concomitant use with HMG CoA reductase inhibitors (statins) that are extensively metabolized by CYP3A4 due to increased risk of myopathy, including rhabdomyolysis; Hypersensitivity to erythromycin products ;
· Swallow whole tablet; do not crush or chew

藥名相似:

外觀相似:

外觀描述: 暗紅圓扁錠，有SHITEH及A39字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1025739

06.06E1 Erythromycins

30963 B / Infant risk is

ERYTHROCIN LACTOBIONATE-I.V. 威黴素５００公絲靜脈注射劑

Erythromycin lactobionate 500mg vial

Dosage: 1常備品 30963

Adult
· Susceptible infections: IV infusion, 15-20mg/kg/day div. q6h; Max. 4g/day
· Pelvic inflammatory disease (N. gonorrheae): IV infusion, 500mg q6h for 3 days
· Perinatal GBS disease, intrapartum prophylaxis: IV infusion, 500mg q6h until delivery

Pediatric
· Susceptible infections: IV infusion, 15-20mg/kg/day div. q6h; Max. 4g/day

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Clcr>10mL/min: No dosage adjustment needed.
Clcr<10mL/min: Should receive 50 to 75% of the normal dose at the usual dosing interval. MD: 2g/day

P: Tab: 250mg(20961); Susp: 25mg/mL, 60mL/bot(28452); Inj: 500mg Vial(30963)

ADR:

COMMON
Venous irritation symptom (occasional), urticaria
SERIOUS
Prolonged QT interval (rare), ventricular tachycardia (rare), erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (rare), anaphylaxis, hearing loss (patients with renal insufficiency, high doses)

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『橘』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2020266

06.06E3 Other Macrolides

20964 ɔt be ruled out / Infant risk can

ZITHROMAX 250MG TABLETS 日舒錠250毫克

Azithromycin 250mg tab

Dosage: 1常備品 20964

Adult
· Respiratory tract, skin infections: PO, 500mg qd on day 1; followed by 250mg qd on day 2-5
· Chlamydial infections: PO, 1g as a single dose
· Gonorrhea: PO, 2g as a single dose

Pediatric
· Pharyngitis/tonsillitis (>2 yrs): PO, 12mg/kg qd for 5 days (not to exceed 500mg/day)
· Community-acquired pneumonia, otitis media (≧6 mons): PO, 10mg/kg on day 1 (not to exceed 500mg), followed by 5mg/kg qd (not to exceed 250mg/day) on day 2–5

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr<10mL/min: Use with caution

P: Tab: 250mg(20964); Susp: 40mg/mL, 15mL/B(28463)

ADR:

COMMON
Abdominal pain, diarrhea, flatulence, nausea, vomiting, increased liver enzymes, headache, abnormal vision
SERIOUS
Prolonged QT interval, Torsades de pointes, acute generalized exanthematous pustulosis, Stevens-

Johnson syndrome, toxic epidermal necrolysis, congenital hypertrophic pyloric stenosis, hepatic necrosis, hepatitis (<1%), liver failure, drug reaction with eosinophilia and systemic symptoms, hypersensitivity reaction, Eaton-Lambert syndrome, exacerbation of myasthenia gravis, myasthenic crisis, corneal erosion (<1%)

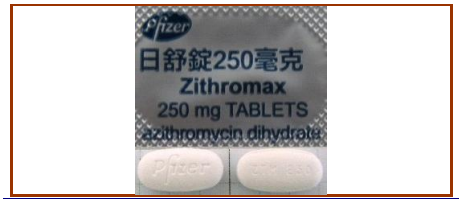
NOTE: 室溫儲存

· Tablets: may give with or without food (tolerability improves when taken with food); avoid aluminum-and magnesium-containing antacids
· 仿單內容變更，摘述如下：(版本Australia LPD 20130613-2)
1.注意事項：加註(A)在衡量開立本藥的風險及好處時，針對高風險族群，應考慮QT延長之風險(可能致命)。(B)QT間距有延長傾向者增列老年病患。
2.更新基因毒性、致癌性、對實驗室檢驗的影響的相關資訊。
· 如果發生過敏反應，應停藥並給予適當的治療。醫師應審慎注意：過敏症狀在症狀性治療停止後仍有可能復發。
· 仿單注意事項於兒童使用部份加註：過去曾在使用本藥後(最晚治療至出生後第42天)的新生兒中，有嬰兒肥厚性幽門狹窄的報告。嬰兒若於餵食期間出現嘔吐或易怒等狀況，應聯絡醫師。(版本Australia LPD 20160114-1)
· 仿單(版本：Australia 20190620-2)在治療肺炎方面
· 不應使用於因為中度至嚴重病症或者因為以下危險因子而不適合門診口服治療的肺炎病人，其中的危險因子包括：
(a)囊狀纖維化 (Cystic fibrosis)的病人
(b)院內感染的病人
(c)已知或懷疑為菌血症的病人
(d)需要住院的病人
(e)老年或病況不良的病人
(f)有重大既存健康問題(underlying health problems)而會損及對疾病回應能力者(包括免疫不全或脾機能不全)
。

藥名相似:

外觀相似:

外觀描述: 白色長橢圓錠，有pfizer及ZTM 250字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023257

06.06E3 Other Macrolides

21012 ɔt be ruled out / Infant risk can

KLARICID* FILM-COATED TABLETS 500MG 開羅理黴素膜衣錠５００毫克

Clarithromycin 500mg tab

Dosage: 1常備品 21012

Adult
· Respiratory tract infections: PO, 250-500mg q12h for 7-14 days
· Skin and skin structure infections: PO, 250mg q12h for 7-14 days
· Mycobacterium Avium Complex (MAC) infections: PO, 500mg q12h
· Helicobacter pylori infection (triple combination regimen): PO, 500mg q12h for 7-14 days

Pediatric(≥6 mons)
· Respiratory tract infections: PO, 7.5mg/kg q12h for 10 days; Max. 1g/day
· Skin and skin structure infections: PO, 7.5mg/kg q12h for 10 days; Max. 1g/day
· Mycobacterium Avium Complex (MAC) infections: PO, 7.5mg/kg q12h; Max. 1g/day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr< 30mL/min: Dose should be halved or the dosing interval doubled

P: Tab: 500mg(21012); Susp: 1750mg/70mL bot(28451); Inj: 500mg vial(30950)

ADR:

COMMON
Abdominal pain, diarrhea, disorder of taste, indigestion, nausea, vomiting, headache
SERIOUS
Out of hospital cardiovascular death, prolonged QT interval, Henoch-Schonlein purpura, Stevens-Johnson syndrome, toxic epidermal necrolysis, Clostridium difficile diarrhea, hepatitis, liver failure, anaphylaxis, drug reaction with eosinophilia and systemic symptoms, cerebrovascular disease, all-cause death

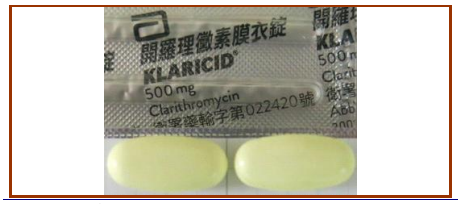
NOTE: 室溫儲存15-30℃

· 《仿單禁忌》藥物交互作用，本藥嚴格禁止併用 domperidone；

藥名相似:

外觀相似:

外觀描述: 淡黃色長橢圓錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022420

06.06E3 Other Macrolides

27320 B / Caution

DIFICID* Film-coated Tablet 200mg 鼎腹欣膜衣錠 200毫克

急用Fidaxomicin 200mg FC tab

Dosage: 2急用藥 27320

Adult
· Clostridium difficile-associated diarrhea (CDAD): PO, 200mg bid for 10 days

Pediatric
· Safety and efficacy have not been established in patients less than 18 yrs old

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 200mg(27320)

ADR:

COMMON
Abdominal pain, nausea, vomiting, anemia, neutropenia
SERIOUS
Bowel obstruction, gastrointestinal hemorrhage

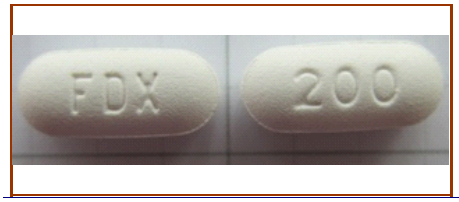
NOTE: 儲存於15~30℃

· May be administered with or without food
· Do not use for systemic infections because fidaxomicin systemic absorption is negligible.

藥名相似:

外觀相似:

外觀描述: 白色至灰白色長橢圓錠，一面有FDX、另一面有200字樣



06.06E3 Other Macrolides

28451 **ɔt be ruled out / Infant risk can**

KLARICID PAEDIATRIC SUSPENSION 125MG/5ML 開羅理黴素懸液劑125毫克/5毫升

Clarithromycin suspension 25mg/mL, 70mL/bot

Dosage: 1常備品 28451

Pediatric
·Mycobacterium avium complex: PO, 7.5mg/kg q12h; Max. 500mg q12h
·Otitis media, pharyngitis/tonsillitis, community-acquired pneumonia, sinusitis, skin and skin structure infections(>6 mons): PO, 7.5mg/kg q12h for 10 days; Max. 500mg q12h

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

CrCl< 30mL/min: Dose should be reduced by 50%

P: Tab: 500mg(21012); Susp: 1750mg/70mL bot(28451); Inj: 500mg vial(30950)

ADR:

COMMON
Abdominal pain, diarrhea, disorder of taste, indigestion, nausea, vomiting, headache
SERIOUS
Out of hospital cardiovascular death, prolonged QT interval, Henoch-Schonlein purpura, Stevens-Johnson syndrome, toxic epidermal necrolysis, Clostridium difficile diarrhea, hepatitis, liver failure, anaphylaxis, drug reaction with eosinophilia and systemic symptoms, cerebrovascular disease, all-cause death

NOTE: 室溫儲存25℃以下

·《Contraindications》Hypersensitivity to clarithromycin, erythromycin, or any of the macrolide antibacterial drugs; Concomitant use with cisapride and pimozide; History of cholestatic jaundice or hepatic dysfunction with prior use of clarithromycin; Concomitant use with colchicine in patients with renal or hepatic impairment; Concomitant use with lomitapide, lovastatin or simvastatin; Concomitant use with ergotamine or dihydroergotamine；
·整瓶加37cc冷開水搖勻,泡製後室溫可保存14天
·本品賦形劑不含阿斯巴甜
·仿單禁忌：藥物交互作用，本藥嚴格禁止併用domperidone。

藥名相似:

外觀相似:

外觀描述: 外包裝紙盒,內為塑膠瓶裝白色粉末

06.06E3 Other Macrolides

28463 **ɔt be ruled out / Infant risk can**

ZITHROMAX POWDER FOR ORAL SUSPENSION 日舒懸液用粉47.78毫克/公克

Azithromycin susp 40mg/mL, 15mL/bot

Dosage: 1常備品 28463

--

Pediatric
· Pharyngitis/tonsillitis (>2 yrs): PO, 12mg/kg qd for 5 days (Max. 500mg/day)
· Community-acquired pneumonia, otitis media (≥6 mon): PO, 10mg/kg on day 1 (Max. 500mg), followed by 5mg/kg qd (Max. 250mg/day) on day 2–5

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr<10mL/min: Use with caution

P: Tab: 250mg(20964); Susp: 40mg/mL, 15mL/B(28463)

ADR:

COMMON
Abdominal pain, diarrhea, flatulence, nausea, vomiting, increased liver enzymes, headache, abnormal vision
SERIOUS
Prolonged QT interval, Torsades de pointes, acute generalized exanthematous pustulosis, Stevens-Johnson syndrome, toxic epidermal necrolysis, congenital hypertrophic pyloric stenosis, hepatic necrosis, hepatitis (<1%), liver failure, drug reaction with eosinophilia and systemic symptoms, hypersensitivity reaction, Eaton-Lambert syndrome, exacerbation of myasthenia gravis, myasthenic crisis, corneal erosion (<1%)

NOTE: 室溫儲存

· 《Contraindications》Cholestatic jaundice with prior azithromycin therapy; Hepatic dysfunction

with prior azithromycin therapy; Hypersensitivity to azithromycin or to any product component, erythromycin, or any macrolide or ketolide antibiotic ;
· Oral suspension: may give with or without food ; avoid aluminum-and magnesium-containing antacids
· 整瓶加9mL開水搖勻，泡製後室溫可保存天數原為10天，自批號626802起改為5天。
· 本品賦形劑不含阿斯巴甜
· 自批號630000起仿單內容變更，摘述如下：(文號：乙1060005050)
1.使用時的特殊警語及注意事項：加註嗜酸性球增多症合併全身症狀的藥物反應(DRESS)。
2.不良反應增列嗜酸性球增多症合併全身症狀的藥物反應(DRESS)。
3.更新懷孕、作用模式、抗藥性機轉、判定體外細菌對azithromycin敏感度的方法學、抗菌範圍及通常對azithromycin產生敏感性的微生物之相關資訊。

藥名相似:

外觀相似:

外觀描述: 外包裝紙盒,內為塑膠瓶裝白色粉末

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021830

06.06E3 Other Macrolides

30950 ɔt be ruled out / Infant risk can

Klaricid IV 500mg 開羅理徽素靜脈注射劑500毫克

Clarithromycin inj 500mg vial

Dosage: 1常備品 30950

Adult
· Respiratory tract infections, skin and soft tissue infections, Mycobacterium Avium Complex (MAC) infections: IV infusion > 60 mins, 1 g/day divided into two doses

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use is not recommended

P: P Tab: 500mg(21012); Susp: 1750mg/70mL bot(28451); Inj: 500mg vial(30950)

ADR:

COMMON
Abdominal pain, diarrhea, disorder of taste, indigestion, nausea, vomiting, headache, injection site reaction(phlebitis, pain or inflammation)
SERIOUS
Out of hospital cardiovascular death, prolonged QT interval, Henoch-Schonlein purpura, Stevens-Johnson syndrome, toxic epidermal necrolysis, Clostridium difficile diarrhea, hepatitis, liver failure, anaphylaxis, drug reaction with eosinophilia and systemic symptoms, cerebrovascular disease, all-cause death

NOTE: 室溫儲存

· 《仿單禁忌》藥物交互作用，本藥嚴格禁止併用 domperidone ;

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『藍』蓋透明玻璃小瓶，白底黑字及『藍』色Klaricid I.V.字樣與色塊

06.06F1 Natural penicillins

37791 B / Infant risk can

Bicillin L-A Injectable Suspension 必希寧注射劑

Penicillin G Benzathine inj 2.4MU/4mL syringe

Dosage: 1常備品 37791

Adult
· Prophylaxis for rheumatic fever: IM, 1.2 million units once a mon or 600,000 units q2wk
· Streptococcal infections: IM,1.2 million units as a single dose
· Early syphilis: IM, 2.4 million units as a single dose
· Late latent syphilis: IM, 2.4 million units once a wk for 3 successive wks

Pediatric
· Streptococcal infections: IM, 25,000-50,000units/kg as a single dose; Max. 1.2 million units
· Prophylaxis for rheumatic fever: IM, 25,000-50,000 units/kg every 3 to 4 wks
· Early syphilis: IM, 50,000units/kg as a single dose; Max. 2.4 million units
· Late latent syphilis: IM, 50,000units/kg once a wk for 3 successive wks

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr>50 mL/min :No dosage adjustment needed
Clcr10-50mL/min:reduce the dose to 75% of the normal dose
Clcr<10mL/min:reduce the dose to 20%- 50% of the normal dose

P: Inj: 2.4MU/4mL syringe(37791)

ADR:

COMMON
Rash, urticaria, nausea, vomiting, eosinophil count raised, Jarisch Herxheimer reaction, fatigue, fever
SERIOUS
Clostridium difficile colitis, anaphylaxis, agitation, fear of death, hallucinations, seizure, renal failure, edema of larynx

NOTE: 冰箱冷藏

· Penicillin G benzathine is to be administered by deep, intramuscular injection only

・藥物交互作用-Tetracycline為一種抑菌的抗生素，可能會抵制penicillin的殺菌效果，故應避免併用此類藥物。

・使用於老年人-臨床研究65歲(含)以上受試者不足，老年病人應小心選擇劑量，應以給藥範圍的最低值開始治療；此做法反映出老年人肝臟、腎臟或心臟功能下降，以及共存疾病或其他藥物療法發生率較高的現象，且監測腎功能可能會有幫助。

藥名相似:

外觀相似:

外觀描述: 4mL乳白色注射液『灰』蓋注射針筒，附一支注射用針頭

06.06F2 Penicillinase-resistant penicillins

21004 b2 / Caution

DICLOCIN CAPSULES (DICLOXACILLIN) 德可信膠囊（力克沙西林）

Dicloxacillin sodium 250mg cap

Dosage: 1常備品 21004

Adult
・Susceptible infections: PO, 125-500mg q6h ;Max. 2g/day

Pediatric
・Neonates: PO, 4-8mg/kg q6h
・<40 kg: PO, 12.5-50mg/kg/day div. q6h
・>40 kg: PO, 125-500mg q6h

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: 250mg(21004)

ADR:

COMMON
Diarrhea, nausea, vomiting
SERIOUS
Immune hypersensitivity reaction

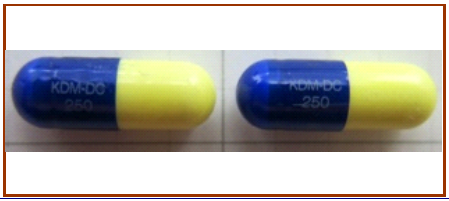
NOTE: 室溫儲存15-30℃

・《Contraindications》History of hypersensitivity, such as anaphylaxis, to penicillins；

藥名相似:

外觀相似:

外觀描述: 藍/黃膠囊,有KDM-DC及250字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1021213

06.06F2 Penicillinase-resistant penicillins

31009 B / Caution

Ocillina Powder for Injection 500mg 歐西林鈉乾粉注射劑

Oxacillin sodium 500mg vial

Dosage: 1常備品 31009

Adult
・Susceptible infections: IV, IM, 250mg-2g q4-6h; Max. 12g/day
・Endocarditis: IV, 2g q4h for 4-6 wks

Pediatric
・Susceptible infections: IV, IM, <40 kg, 50-100mg/kg/day div. q4-6h; > 40 kg, use adult dosing; Max. 12g/day
・Susceptible infections: IV, IM, neonates≦7 days, 50-75mg/kg/day div. q8-12h; neonates>7 days, 75-100mg/kg/day div. q6-8h

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 500mg Vial(31009)

ADR:

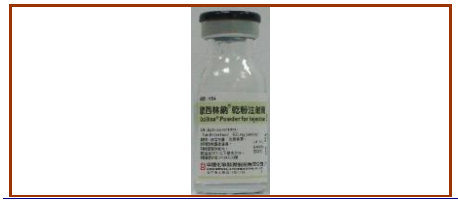
NOTE: 室溫儲存

・《Contraindications》hypersensitivity to oxacillin products/penicillins；

藥名相似:

外觀相似:

外觀描述: 白色乾粉、「黑」蓋透明玻璃小瓶，白底黑字有淺綠色區標簽



06.06F3 Aminopenicillins

21001 B / Infant risk is

AMPICILLIN CAPSULES 500MG "VPP" 安比西林膠囊５００公絲

ampicillin 500mg cap

Dosage: 1常備品 21001

Adult
・Usual dose: PO, ac, 250-500mg q6h
・GI/GU infections: PO, ac, 500mg q6h
・Gonorrhea: PO, ac, 3.5g with 1g of probenecid as a single dose
・Respiratory tract infections: PO, ac, 250mg q6h

Pediatric
・Usual dose: PO, ac, 50-100mg/kg/day div. q6h; Max. 2-4g/day
・GI/GU infections: PO, ac, 100mg/kg/day div. q6h
・Respiratory tract infections: PO, ac, 50mg/kg/day div. q6h

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 10-50mL/min: Administer q6-12h
Clcr <10mL/min: Administer q12-16h

P: Cap: 500mg(21001); Inj: 500mg Vial(31004)

ADR:

COMMON
Rash, urticaria, diarrhea, nausea, vomiting
SERIOUS
Immune hypersensitivity reaction

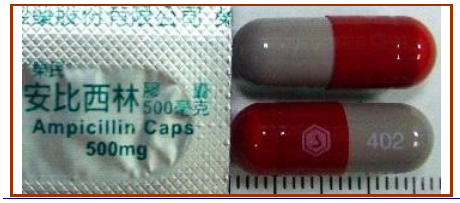
NOTE: 室溫儲存

· 《Contraindications》Hypersensitivity to any penicillin; Infections due to penicillinase-producing organisms ;
· Because ampicillin is distributed into milk, the drug should be used with caution in nursing women.

藥名相似: Cap: 500mg(21001); Inj: 500mg Vial(31004)

外觀相似:

外觀描述: 紅/灰色膠囊,有402及藥廠商標字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1009609

06.06F3 Aminopenicillins

21002 B / Infant risk is

SUPERCILLIN CAPSULES 250MG "榮民" 施徽素膠囊 250毫克

Amoxicillin trihydrate 250mg cap

Dosage: 1常備品 21002

Adult
· Susceptible infections: PO, 500mg q12h or 250mg q8h for mild-to-moderate infections; 875mg q12h or 500mg q8h for severe infections
· Endocarditis prophylaxis in patients undergoing dental procedures: PO, 2g 1hr prior to procedure
· Gonorrhea: PO, 3g as a single dose
· Helicobacter pylori infection: PO, 1g q12h in combination with clarithromycin 500mg q12h and lansoprazole 30mg bid for 14 days; or amoxicillin 1g q8h in combination with lansoprazole 30mg tid for 14 days
· Lower respiratory tract infections: PO, 875mg q12h or 500mg q8h

Pediatric
· Susceptible infections: PO,
≦ 3 mons: 30mg/kg/day div. q12h;
> 3 mons: 20mg/kg/day div. q8h or 25mg/kg/day div. q12h for mild-to-moderate infections;
40mg/kg/day div. q8h or 45mg/kg/day div. q12h for severe infections
· Endocarditis prophylaxis in patients undergoing dental procedures: PO, 50mg/kg 1hr prior to procedure; Max. 2g/dose
· Otitis media: (drug-resistant S pneumoniae) 80-90mg/kg/day div. q8-12h

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 10-30mL/min: 250-500mg q12h
Clcr <10mL/min: 250-500mg q24h

P: Cap: 250mg(21002); Susp: 25mg/mL, 60mL/B(28460)

ADR:

COMMON
Rash, diarrhea, nausea, vomiting, headache
SERIOUS
Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, Clostridium difficile diarrhea, anaphylaxis, hypersensitivity reaction

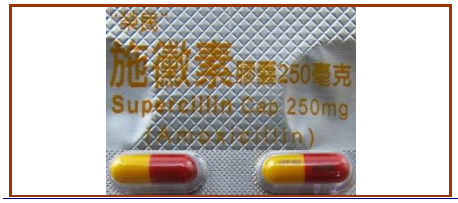
NOTE: 室溫儲存

·《Contraindications》Serious hypersensitivity reactions, such as anaphylaxis and Stevens-Johnson syndrome, to amoxicillin or other beta-lactam antibiotics (eg, penicillins, cephalosporins)

藥名相似: Cap: 250mg(21002); Susp: 25mg/mL, 60mL/B

外觀相似:

外觀描述: 黃/橘色膠囊，有VPP及101字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1010819

06.06F3 Aminopenicillins

21010 ɔt be ruled out / Infant risk is

Curam 1000mg Film-coated tablets 諾快寧膜衣錠 1000毫克

Amoxicillin trihydrate 875mg & Clavulanic acid 125mg FC tab

Dosage: 1常備品 21010

Adult
·Susceptible infections: PO, based on amoxicillin, 875mg q12h

Pediatric (>12yr)
·Susceptible infections: Same as adult

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Clcr< 30mL/min: Not recommended
(Clavulanate cleared by liver. Hence as dose of combination decreased, a deficiency of clavulanate may occur.)

P: Tab: 1g(21010); Syr: 35mL/bot(28465); Inj: 1.2g vial(31023)

ADR:

COMMON
Diaper rash, rash, diarrhea, loose stool, nausea, vomiting, mycosis, vaginitis, candidiasis
SERIOUS
Stevens-Johnson syndrome, toxic epidermal necrolysis, cholestasis, hepatitis, hepatotoxicity, anaphylaxis, hypersensitivity reaction

NOTE: 室溫儲存

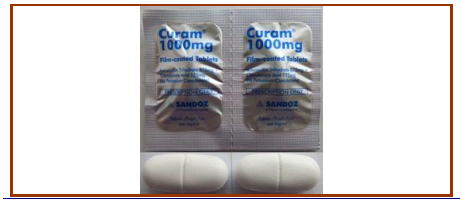
·《Contraindications》Concomitant use of extended-release tablets with hemodialysis; History

of cholestatic jaundice/hepatic dysfunction associated with amoxicillin/clavulanate potassium; Hypersensitivity to amoxicillin, clavulanate, or other beta-lactam antibacterials (eg, penicillins and cephalosporins); Severe renal impairment (ie, CrCl less than 30 mL/min) when administering extended-release tablets
·Swallow whole; do not crush or chew

藥名相似:

外觀相似:

外觀描述: 白色長橢圓形錠，中間有一刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024808

06.06F3 Aminopenicillins

28460 **B / Infant risk is**

AMOLIN POWDER FOR ORAL SUSPENSION (AMOXICILLIN) "永豐"萬博徽素懸液用粉（安莫西林）

Amoxicillin susp 25mg/mL, 60mL/bot

Dosage: 1常備品 28460

Adult
· Susceptible infections: PO, 500mg q12h or 250mg q8h for mild-to-moderate infections; 875mg q12h or 500mg q8h for severe infections
· Endocarditis prophylaxis in patients undergoing dental procedures: PO, 2g 1hr prior to procedure
· Gonorrhea: PO, 3g as a single dose
· Helicobacter pylori infection: PO, 1g q12h in combination with clarithromycin 500mg q12h and lansoprazole 30mg bid for 14 days; or amoxicillin 1g q8h in combination with lansoprazole 30mg tid for 14 days
· Lower respiratory tract infections: PO, 875mg q12h or 500mg q8h

Pediatric
· Susceptible infections: PO,
≦3 mons: 30mg/kg/day div. q12h;
> 3 mons: 20mg/kg/day div. q8h or 25mg/kg/day div. q12h for mild-to-moderate infections;
40mg/kg/day div. q8h or 45mg/kg/day div. q12h for severe infections
· Endocarditis prophylaxis in patients undergoing dental procedures: PO, 50mg/kg 1hr prior to procedure; Max. 2g/dose
· Otitis media: (drug-resistant S pneumoniae) 80-90mg/kg/day div. q8-12h

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 10-30mL/min: 250-500mg q12h
Clcr <10mL/min: 250-500mg q24h

P: Cap: 250mg(21002); Susp: 25mg/mL, 60mL/B(28460)

ADR:

COMMON
Diarrhea, nausea, vomiting, rash
SERIOUS
Immune hypersensitivity reaction

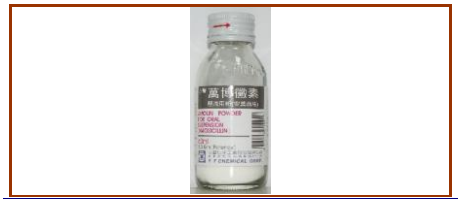
NOTE: 泡後冷藏

· 《Contraindications》Serious hypersensitivity reactions, such as anaphylaxis and Stevens-Johnson syndrome, to amoxicillin or other beta-lactam antibiotics (eg, penicillins, cephalosporins) ;
· Unused portions of the suspension should be discarded 7 days after reconstitution
· 本品賦形劑不含阿斯巴甜

藥名相似:

外觀相似:

外觀描述: 60mL白色上蓋玻璃瓶，內含懸液用粉



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1036160

06.06F3 Aminopenicillins

28465 **B / Infant risk is**

AUGMENTIN SYRUP 457MG/5ML 安滅菌糖漿用粉劑457毫克/5毫升

Amoxycillin 80mg/mL [B], Clavulanic acid 11.4mg/mL, 35mL/bot Syr

Dosage: 1常備品 28465

..

Pediatric: based on amoxycillin, PO,
· Mild to moderate infection: 25mg/kg/day div. q12h
· Severe infection: 45mg/kg/day div. q12h
· Otitis media: (drug-resistant S pneumoniae) 90mg/kg/day div. q12h

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Clcr>30mL/min: No dosage adjustment needed
Clcr<30mL/min: Not recommended

P: Tab: 1g(21010); Syr: 35mL/bot(7:1, 28465); Inj: 600mg Vial(31002), 1.2g vial(31023)

ADR:

COMMON
Diaper rash, rash, diarrhea, loose stool, nausea, vomiting, mycosis, vaginitis, candidiasis
SERIOUS
Stevens-Johnson syndrome, toxic epidermal necrolysis, cholestasis, hepatitis, hepatotoxicity, anaphylaxis, hypersensitivity reaction

NOTE: 泡後冷藏

·《Contraindications》History of cholestatic jaundice/hepatic dysfunction associated with amoxicillin/clavulanate potassium; Hypersensitivity to amoxicillin, clavulanate, or other beta-lactam antibacterials (eg, penicillins and cephalosporins) ;
·含阿斯巴甜，苯酮尿症者不宜使用。(每5mL劑量中含有12.5mg)

藥名相似:

外觀相似:

外觀描述: 透明玻璃瓶，內為乾粉製劑

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022447

06.06F3 Aminopenicillins

31004 **B / Infant risk is**

AMPOLIN INJECTION 500MG 安博徽素注射劑５００公絲

ampicillin sodium 500mg vial

Dosage: 1常備品 31004

Adult: IM, IV, IV infusion
· Usual dose: 0.5-3g q4-6h
· Endocarditis prophylaxis, GI/GU procedures: 1-2g plus gentamicin 1.5mg/kg 30 minutes prior to procedure
· GI/GU infections: 500mg q6h
· Gonorrhea(men): IM, 500mg q12h for 1 day
· Meningitis: 8-14g/day div. q4-6h
· Respiratory tract infections: 250-500mg q6h

Pediatric: IM, IV, IV infusion
· Usual dose: 100-200mg/kg/day div. q4-6h; Max. 12g/day
· Endocarditis prophylaxis: 50mg/kg 30 minutes prior to procedure; add gentamicin 1.5mg/kg in high-risk patients, with follow-up dose of ampicillin 25-50mg/kg 6-8 hr later
· Meningitis: 200-400mg/kg/day div q4-6r; Max. 12g/day
· Neonates(≦1 wk): ≦ 2kg, 50mg/kg/day div. q12h (meningitis, 100mg/kg/day div. q12h); > 2kg, 75mg/kg/day div. q8h (meningitis, 150mg/kg/day div. q8h)
· Neonates (>1 wk): < 1.2kg, 50mg/kg/day div. q12h (meningitis, 100mg/kg/day div. q12h); 1.2-2kg, 75mg/kg/day div. q8h (meningitis, 150mg/kg/day div. q8h); > 2kg, 100mg/kg/day div. q6h (meningitis, 200mg/kg/day div. q6h)

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 10-50mL/min: Administer q6-12h
Clcr< 10mL/min: Administer q12-16h

P: Cap: 500mg(21001); Inj: 500mg Vial(31004)

ADR:

COMMON
Rash, urticaria, diarrhea, nausea, vomiting
SERIOUS
Hypersensitivity reactions

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色乾粉、透明玻璃小瓶銀色鐵鋁瓶口

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1001853

06.06F3 Aminopenicillins

31021 **B / Caution**

AMSULBER* Powder for Injection "CYH" 安疏倍乾粉注射劑

ampicillin 1000mg[B], Sulbactam 500mg[UK] vial

Dosage: 1常備品 31021

Adult: Dose expressed as ampicillin/sulbactam combination.
· Susceptible infections: IM, IV, IV infusion, 1.5-3g q6h depending on severity of infection; Max. 12g/day
· Prophylaxis of surgical infections: IM, IV, IV infusion, 1.5-3g before induction of anesthesia; dose may be repeated q 6 hours for up to 24 hours after surgery

Pediatric: Dose expressed as ampicillin/sulbactam combination.
· Susceptible infections: IV, IV infusion,
≧1 yrs: 300mg/kg/day div. q6h
Infants & neonates: 150mg/kg/day div. q6-8h
The American Academy of Pediatrics recommends a dose of 100-300mg ampicillin/kg/day div. q6h depending on severity of infection in infants >1 mon

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr≧30mL/min: Administer q6-8h
Clcr 15-29 mL/min: Administer q12h
Clcr 5-14mL/min: Administer q24h

P: Inj: 1.5g Vial(31021)

ADR:

COMMON
Injection site reaction, rash, diarrhea
SERIOUS
Chest pain, edema, retrosternal pain, pseudomembranous enterocolitis, thrombophlebitis, dysuria

NOTE: 室溫儲存

仿單不良反應增列嗜中性白血球減少(不常見)、顆粒性白血球缺乏(發生率不明)、血小板減少性紫癜症(發生率不明)、舌炎(罕見)、口腔炎(發生率不明)、舌頭變色(發生率不明)、急性全身性發疹樣膿皮症(發生率不明)、剝落性皮膚炎(發生率不明)。(版本：CDS 20131203-1)

藥名相似:

外觀相似:

外觀描述: 白色乾粉，『橘』蓋 透明玻璃小瓶,白底 黑色字標籤,有淺藍色區塊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1057762

06.06F3 Aminopenicillins

31023 B / Infant risk is

CURAM* powder for injection 500/100 mg, 1000/200 mg 諾快寧靜脈乾粉注射劑500/100 毫克、1000/200 毫克

Amoxicillin sodium 1g[B], Clavulanate potassium[B] 0.2g inj pow in vial

Dosage: 1常備品 31023

Adult (Doses based on AUGMENTIN*)
· Community acquired pneumonia, respiratory tract infections, genito-urinary tract infections, skin and soft tissue infections: IV, IV infusion, 1.2g q6-8h

Pediatric (Doses based on AUGMENTIN*)
· Community acquired pneumonia, respiratory tract infections, genito-urinary tract infections, skin and soft tissue infections: IV, IV infusion,
< 3mons: 30mg/kg q12h in premature infants and during perinatal period, may be increased to q8h thereafter
3mons-12yrs: 30mg/kg q6-8h
≧12yrs: Same as adult

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Clcr 10-30mL/min: LD 1.2g, followed by 600mg q12h
Clcr<10mL/min: LD 1.2g, followed by 600mg q24h

P: Tab: 1g(21010); Syr: 35mL/bot(28465); Inj: 600mg Vial(31002), 1.2g Vial(31023)

ADR:

COMMON
Diaper rash, rash, diarrhea, loose stool, nausea, vomiting, mycosis, vaginitis, candidiasis
SERIOUS
Stevens-Johnson syndrome, toxic epidermal necrolysis, cholestasis, hepatitis, hepatotoxicity, anaphylaxis, hypersensitivity reaction

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『白』蓋透明玻璃小瓶，白底黑字及『紫』色1000字樣與色塊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024847

06.06F4 Extended-spectrum Penicillins

31016 B / Caution

Pisutam Lyo for Injection 必斯袒凍晶注射劑

Piperacillin sodium 2.0g & Tazobactam sodium 0.25g vial

Dosage: 1常備品 31016

Adult: Dose expressed as piperacillin/tazobactam combination
· Moderate to severe infections: IV infusion over 30 mins, 3.375g q6h for 7-10 days
· Nosocomial pneumonia: IV infusion over 30 mins, 4.5g q6h with an aminoglycoside for 7-14 days

Pediatric
· Appendicitis and/or peritonitis: IV infusion over 30 mins,
2-9 mons: 80mg/kg of piperacillin and 10mg/kg of tazobactam q8h
≧9 mons and ≦40kg: 100mg/kg of piperacillin and 12.5mg/kg of tazobactam q8h
>40kg: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 20-40mL/min: 2.25g-3.375g q6h
Clcr <20mL/min: 2.25g q6-8h

P: Inj: 2.25g Vial(31016)

ADR:

COMMON
Diarrhea, nausea, vomiting, headache, injection site reaction, rash, pruritus, immune hypersensitivity reaction
SERIOUS
Anaphylaxis (rare)

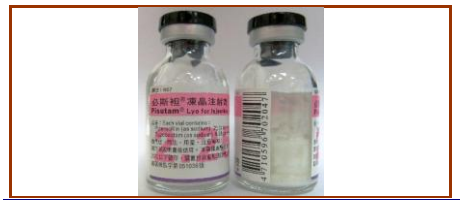
NOTE: 室溫儲存

·《Contraindications》hypersensitivity to beta-lactams, including penicillins and/or cephalosporins ;

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『黑』蓋透明玻璃小瓶



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1051036

06.06F5 Sulbactam

31020 UK / Unknown(有

Sulbactam Powder for Injection 500 mg "C.C.P.C." 舒貝乾粉注射劑 500 毫克

Sulbactam sodium 547mg (500mg base) vial

Dosage: 1常備品 31020

Adult
·Moderate to severe bacterial infections: IM, IV, IV infusion, 0.5-1g q6-12h with other antibiotics; Max. 4g/day

Pediatric
·Moderate to severe bacterial infections: IM, IV, IV

infusion, 50mg/kg/day div. into 2-4 doses with other antibiotics; Max. 80mg/kg/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 15-30mL/min: Max. 2000mg/day
Clcr <15mL/min: Max. 1000mg/day
可於血液透析過程中自血中排除, 因此使用Sulbactam必須與透析並行, 即每隔48小時繼續透析

P: Inj: 500mg Vial(31020)

ADR:

Gastrointestinal disturbances, dizziness, headache, allergic reactions

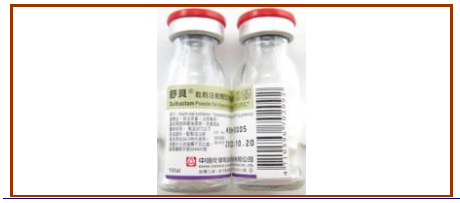
NOTE: 室溫儲存

·《仿單禁忌》依文獻記載已知對β-lactam 類抗生素過敏時，禁止使用Sulbactam sodium。在使用sulbactam時，若不同時使用β-lactam 類抗生素則無意義，因Sulbactamsodium 本身不具任何滅菌作用。

藥名相似:

外觀相似:

外觀描述: 白色乾粉『紅』蓋透明玻璃小瓶，白底黑字紫色線條標籤



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1054647

06.06G1 Tetracyclines

21028 **D / Unsafe**

DOXYCYCLINE CAPSULES 100MG "P.L." "培力"獨克士黴素膠囊１００毫克（去氧羥四環素）

Doxycycline HCl 100mg cap

Dosage: 1常備品 21028

Adult
· Susceptible infections: PO, initial 100mg q12h on the first day, then 100mg/day in 1-2 divided doses
· Severe infections: PO, 100mg q12h
· Anthrax: PO, 100mg q12h for 60 days
· Malaria prophylaxis: PO, 100mg qd beginning 1-2 days prior to travel and continuing for 4 weeks after leaving the area

Pediatric (>8 yrs and ≦45kg)
· Susceptible infections: PO, initial 4.4mg/kg/day div. into 1-2 doses on the first day, then 2.2mg/kg/day in 1-2 divided doses
· Severe infections: PO, 4.4mg/kg/day div. q12h
· Anthrax: PO, 2.2mg/kg q12h for 60 days
· Malaria prophylaxis: PO, 2mg/kg qd beginning 1-2 days prior to travel and continuing for 4 weeks after leaving the area; Max. 100mg/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: 100mg(21028)

ADR:

COMMON
Photosensitivity, drug-induced gastrointestinal disturbance, increased BUN
SERIOUS
Bulging fontanelle(rare)

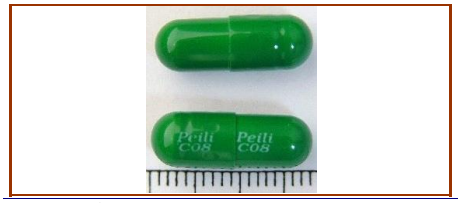
NOTE: 室溫儲存

1.Alternatively, food or milk may be utilized in this setting without compromising the absorption of the drug; however, antacids should be avoided.
2.Generally not recommended for use in children <8 yr because of risk for tooth enamel hypoplasia and discoloration.

藥名相似:

外觀相似:

外觀描述: 綠色膠囊,有Peili及C08字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1034900

06.06G1 Tetracyclines

21031 **D / Caution**

MINOLINE* CAPSLES 100MG (MINOCYCLINE) "S.T" "信東" 美樂寧膠囊１００公絲（美諾四環素）

Minocycline HCl 100mg cap

Dosage: 1常備品 21031

Adult
· Usual dose: PO, initial, 200mg, MD 100mg q12h. Alternatively, initial 100-200mg, MD 50mg q6h
· Acne vulgaris: PO, 100-200mg in 2 div. doses
· Chlamydia: PO, 100mg q12h for at least 7 days
· Uncomplicated gonococcal urethritis (males): PO, 100mg q12h for 5 days
· Syphilis: (patients with penicillin allergy) PO, initial 200mg, MD 100mg q12h for 10-15 days

Pediatric(> 8 yrs)
· Usual dose: PO, initial 4mg/kg, MD 2mg/kg q12h
· Acne vulgaris: PO, 100-200mg in 2 div. doses

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Dosage adjustment required

P: Cap: 100mg(21031); Dental Oint: 10mg/0.5g(29163); Inj:100mg Vial(31031)

ADR:

COMMON
Dizziness, vertigo
SERIOUS
Anaphylaxis, immune hypersensitivity reaction, systemic lupus erythematosus, Bulging fontanelle, Pseudotumor cerebri (rare)

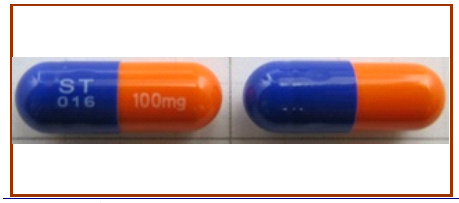
NOTE: 室溫儲存

· Not recommended in children 8 years of age and younger due to potential for tooth discoloration

藥名相似:

外觀相似:

外觀描述: 藍/橙色膠囊，有"ST 016"及"100mg"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1036815

06.06G1 Tetracyclines

21032 **D / Unsafe**

TETRACYCLINE HCL CAPSULES 250MG "VPP" "榮民"鹽酸四環素膠囊２５０毫克

Tetracycline HCl 250mg cap

Dosage: 1常備品 21032

Adult
· Usual dose: PO, 1-2g/day div. into 2-4 doses
· Acne vulgaris: PO, 250mg qod to 500mg qd
· Brucellosis: PO, 500mg qid for 3 wks in combination with streptomycin
· Chlamydia: PO, 500mg qid for 7 days
· Syphilis:(penicillin allergy) PO, 500mg qid for 2 wks

Pediatric(> 8 yrs)
· Usual dose: PO, 25-50mg/kg/day div. into 2-4 doses

Dosing adjustments in hepatic impairment:

Avoid use or maximum dose is 1g/day

Dosing adjustments in renal impairment:

Clcr> 50mL/min: Administer q8-12h
Clcr 10-50mL/min: Administer q12-24h
Clcr< 10mL/min: Administer q24h

P:

ADR:

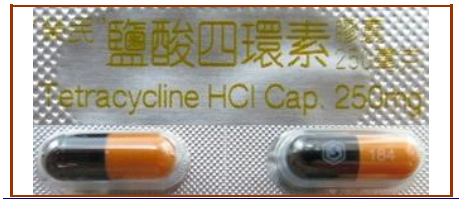
COMMON
Diarrhea, N/V, photosensitivity, rash
SERIOUS
Bulging fontanelle (rare)

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 橘/黑色膠囊，有184及藥廠商標



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1015791

06.06G2 Glycylcycline

31079 **D / Infant risk can**

Tigelin Lyophilized Powder for Injection 50mg 虎霸凍晶注射劑50毫克

Tigecycline 50mg pow in vial

Dosage: 1常備品 31079

Adult (IV infusion over 30~60 mins)
·Complicated skin and skin structure infections, intra-abdominal infections: IV infusion, initial 100mg followed by 50mg q12h for 5-14 days depending on the severity and site of infection and the patient's clinical and bacteriological progress
·Community acquired pneumonia: IV infusion, initial 100mg followed by 50mg q12h for 7-14 days depending on the severity and site of infection, and clinical and bacteriological progress

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

·Mild to moderate hepatic impairment (Child Pugh A and B): No dosage adjustment needed
·Severe hepatic impairment (Child Pugh C): Initial 100mg followed by 25mg q12h

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: P Inj: 50mg(31079)(37878, 須經感染科同意)

ADR:

COMMON
Abdominal pain, diarrhea, nausea, vomiting, headache
SERIOUS
Septic shock, Clostridium difficile diarrhea, acute pancreatitis, ALT/SGPT level raised, AST/SGOT level raised, disease of liver, hyperbilirubinemia, liver failure, anaphylaxis, pseudotumor cerebri, all-cause death, sepsis

NOTE: 室溫儲存

·Tigecycline is structurally similar to tetracycline class antibiotics and may have similar adverse effects(eg. Photosensitivity, pseudotumor cerebri, pancreatitis, anti-anabolic effects)
·An increase in all-cause mortality has been reported with tigecycline versus comparator antibiotics, especially in ventilator-associated pneumonia (unapproved use), with deaths usually resulting from worsening infection, complications of infection, or underlying comorbidities; reserve use for situations when alternatives are not suitable.
·Increases in total bilirubin concentration, prothrombin time and transaminases have been seen in patients treated with tigecycline. Patients who develop abnormal liver function tests during tigecycline therapy should be monitored for evidence of worsening hepatic function and evaluated for risk/benefit of continuing tigecycline therapy. Hepatic dysfunction may occur after the drug has been discontinued.

藥名相似:

外觀相似:

外觀描述: 橘色乾粉、『橘』蓋透明玻璃小瓶，白底黑字標籤，有土色區塊與紫色線條

06.06G2 Glycylcycline

37878 D / Infant risk can

Tygacil (Tigecycline) 50mg Lyophilized Powder 老虎黴素凍晶注射劑50毫克

Tigecycline inj 50mg pow in vial

Dosage: 1常備品 37878

Adult (IV infusion over 30~60 mins)
·Complicated skin and skin structure infections, intra-abdominal infections: IV infusion, initial 100mg followed by 50mg q12h for 5-14 days depending on the severity and site of infection and the patient's clinical and bacteriological progress
·Community acquired pneumonia: IV infusion, initial 100mg followed by 50mg q12h for 7-14 days depending on the severity and site of infection, and clinical and bacteriological progress

Pediatric
·Safety and efficacy have not been established in patients less than 18 years old

Dosing adjustments in hepatic impairment:

·Mild to moderate hepatic impairment (Child Pugh A and B): No dosage adjustment needed
·Severe hepatic impairment (Child Pugh C): Initial 100mg followed by 25mg q12h

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 50mg Vial(37878, 須經感染科同意)(31079)

ADR:

COMMON
Abdominal pain, diarrhea, nausea, vomiting, headache
SERIOUS
Septic shock, Clostridium difficile diarrhea, acute pancreatitis, ALT/SGPT level raised, AST/SGOT level raised, disease of liver, hyperbilirubinemia, liver failure, anaphylaxis, pseudotumor cerebri, all-cause death, sepsis

NOTE: 儲存15-30℃

·Tigecycline is structurally similar to tetracycline class antibiotics and may have similar adverse effects(eg. Photosensitivity, pseudotumor cerebri, pancreatitis, anti-anabolic effects)
·An increase in all-cause mortality has been reported with tigecycline versus comparator antibiotics, especially in ventilator-associated pneumonia (unapproved use), with deaths usually resulting from worsening infection, complications of infection, or underlying comorbidities; reserve use for situations when alternatives are not suitable.
·治療病人可能增加膽紅素濃度、凝血酉每原時間和血清轉胺酉每。若治療期間肝功能檢測異常，則必須要監測以防肝功能惡化，同時治療期間要評估其風險利益。肝功能異常也可能發生於停藥後。

藥名相似:

外觀相似:

外觀描述: 橘色凍晶，『橘』蓋玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024443

06.06H1 Glycopeptides

31059 UK / Unknown(有

TEICOD* FOR INJECTION 200MG 得那林凍晶注射劑 200毫克

Teicoplanine inj 200mg pow in vial

Dosage: 1常備品 31059

Adult
MICROMEDEX:
· Complicated skin and subcutaneous tissue infections, pneumonia, complicated urinary tract infections: IM, IV, LD 6mg/kg q12h for 3 doses, MD 6mg/kg qd
· Bone and joint infections, infective endocarditis:IV, LD 12mg/kg q12h for 3-5 doses, MD 12mg/kg qd
熱病 2018:
· LD: 12mg/kg q12h for 3 doses; MD: 12mg/kg qd

Pediatric
· Methicillin-resistant staphylococcus aureus (MRSA): IV, IM
>12 yrs: LD 6mg/kg q12h for 3 doses, followed by 6mg/kg daily
2 mons-12 yrs: LD 10mg/kg q12h for 3 doses, followed by 6-10mg/kg daily
<2 mons: LD 16mg/kg on day 1, followed by 8mg/kg daily

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

MICROMEDEX:
· Clcr 30-80mL/min: After 4 days of treatment decrease the maintenance dose by 1/2 either by increasing the dosing interval to qod or administering 1/2 of the regular dose once daily
· Clcr <30mL/min or HD: After 4 days of treatment decrease maintenance dose to 1/3 of the regular dose either by increasing the dosing interval to q3d or administering 1/3 of the regular dose once daily
熱病 2018:
· Clcr 10-50mL/min: LD: 12mg/kg q12h for 3 doses; MD: 12mg/kg qod
· Clcr <10mL/min: LD: 12mg/kg q12h for 3 doses; MD: 12mg/kg q3d

P: Inj: 200mg Vial (31059-中化)(31063-SANOFI)

ADR:

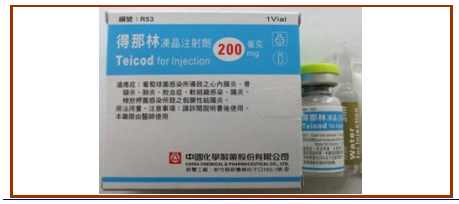
N/V, rash, neutropenia, eosinophilia, ototoxicity, pain on injection, platelet aggregation, thrombophlebitis

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『黃』蓋透明玻璃小瓶，附3ml稀釋液透明安瓿



06.06H1 Glycopeptides

31063 **UK / Unknown(有**

TARGOCID 200MG FOR INJECTION (I.M.I.V.) 得時高凍晶注射劑２００毫克

Teicoplanin inj 200mg pow in vial

Dosage: 1常備品 31063

MICROMEDEX:
· Complicated skin and subcutaneous tissue infections, pneumonia, complicated urinary tract infections: IM, IV, LD 6mg/kg q12h for 3 doses, MD 6mg/kg qd
· Bone and joint infections, infective endocarditis:IV, LD 12mg/kg q12h for 3-5 doses, MD 12mg/kg qd
熱病 2018:
· LD: 12mg/kg q12h for 3 doses; MD: 12mg/kg qd
Pediatric
· Methicillin-resistant staphylococcus aureus (MRSA): IV, IM
>12 yrs: LD 6mg/kg q12h for 3 doses, followed by 6mg/kg daily
2 mons-12 yrs: LD 10mg/kg q12h for 3 doses, followed by 6-10mg/kg daily
<2 mons: LD 16mg/kg on day 1, followed by 8mg/kg daily

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

MICROMEDEX:
· Clcr 30-80mL/min: After 4 days of treatment decrease the maintenance dose by 1/2 either by increasing the dosing interval to qod or administering 1/2 of the regular dose once daily
· Clcr <30mL/min or HD: After 4 days of treatment decrease maintenance dose to 1/3 of the regular dose either by increasing the dosing interval to q3d or administering 1/3 of the regular dose once daily
熱病 2018:
· Clcr 10-50mL/min: LD: 12mg/kg q12h for 3 doses; MD: 12mg/kg qod
· Clcr <10mL/min: LD: 12mg/kg q12h for 3 doses; MD: 12mg/kg q3d

P: Inj: 200mg Vial(31063-SANOFI)(31059-中化)

ADR:

N/V, rash, neutropenia, eosinophilia, ototoxicity, pain on injection, platelet aggregation, thrombophlebitis

NOTE: 儲存25℃以下

· 《Contraindications》Hypersensitivity to teicoplanin or any component of the product；

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『黃』蓋透明玻璃小瓶，附3ml稀釋液透明安瓿

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021848

06.06H1 Glycopeptides

31065 **C / No report(毫**

U-VANCO* INJECTION 500MG 1GM(VANCOMYCIN) "U-LIANG" 優凡可注射劑５００毫克（汎克黴素）

Vancomycin HCl inj 500mg pow in vial

Dosage: 1常備品 31065

IV infusion, 500mg over 1hr
MICROMEDEX:
· Methicillin-resistant Staphylococcus aureus, ampicillin-resistant Enterococcus faecalis/faecium: 15mg/kg q12h
· Endocarditis: 2g/day div q6-12h
熱病 2018
· 15-30mg/kg q12h

IV infusion at a rate not exceeding 10mg/min
· General Dosage: (infants and children) 40mg/kg/day div q6h; (neonates first week of life) initial dose 15 mg/kg followed by 10 mg/kg/dose q12h; (neonates 2 to 4 weeks of life) 10 mg/kg/dose q8h
· Endocarditis: (children) 10 to 15 mg/kg q6h, MAX 2 g/day; (Neonates 2 to 4 weeks) Initial, 15 mg/kg IV, followed by 10 mg/kg q8h; (neonates up to 1 week) initial, 15 mg/kg IV, followed by 10 mg/kg q12h
· Meningitis: (0-7 days) 20-30mg/kg/day div q8-12h; (8-28 days) 30-45mg/kg/day div q6-8h; (infants and children) 60mg/kg/day div q6h

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

MICROMEDEX:
· Adult and pediatric: 15 mg/kg initially and then optimize dose and interval based on serum drug concentrations
· Anuric patients (adults): 1g every 7-10 days
熱病 2018
· CrCl >50-90mL/min: 15-30mg/kg q12h
· CrCl 10-50mL/min: 15mg/kg q24-96h
· CrCl <10mL/min: 7.5mg/kg q2-3days

P: nj: 500mg vial(31065), 500mg vial(37735-捐贈), 1g vial(31076)

ADR:

COMMON
Drug-induced erythroderma, nausea, vomiting
SERIOUS
Neutropenia (rare), anaphylaxis (rare), ototoxicity (rare), nephrotoxicity (rare)

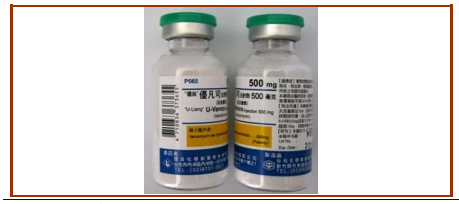
NOTE: 室溫儲存

· 《Contraindications》Allergy to corn or corn products; premixed solution for IV use contains dextrose; Hypersensitivity to vancomycin ;

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『綠』蓋透明玻璃小瓶



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1041443

06.06H1 Glycopeptides

31076 C / No report(毫

VANCO POWDER FOR INJECTION (VANCOMYCIN) "GENTLE" "政德"安克乾粉注射劑（汎克黴素）

Vancomycin HCl inj 1g pow in vial

Dosage: 1常備品 31076

Adult: IV infusion, 500mg over 1hr
MICROMEDEX:
· Methicillin-resistant Staphylococcus aureus, ampicillin-resistant Enterococcus faecalis/faecium: 15mg/kg q12h
· Endocarditis: 2g/day div q6-12h
熱病 2018
· 15-30mg/kg q12h

Pediatric: IV infusion at a rate not exceeding 10mg/min
· General Dosage: (infants and children) 40mg/kg/day div q6h; (neonates first week of life) initial dose 15 mg/kg followed by 10 mg/kg/dose q12h; (neonates 2 to 4 weeks of life) 10 mg/kg/dose q8h
· Endocarditis: (children) 10 to 15 mg/kg q6h, MAX 2 g/day; (Neonates 2 to 4 weeks) Initial, 15 mg/kg IV, followed by 10 mg/kg q8h; (neonates up to 1 week) initial, 15 mg/kg IV, followed by 10 mg/kg q12h
· Meningitis: (0-7 days) 20-30mg/kg/day div q8-12h; (8-28 days) 30-45mg/kg/day div q6-8h; (infants and children) 60mg/kg/day div q6h

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

MICROMEDEX:
· Adult and pediatric: 15 mg/kg initially and then optimize dose and interval based on serum drug concentrations
· Anuric patients (adults): 1g every 7-10 days
熱病 2018
· CrCl >50-90mL/min: 15-30mg/kg q12h
· CrCl 10-50mL/min: 15mg/kg q24-96h
· CrCl <10mL/min: 7.5mg/kg q2-3days

P: Inj: 500mg vial(31065), 500mg(37735-捐贈兒癌), 1g vial(31076)

ADR:

SERIOUS
Cardiac arrest, hypotension, clostridium difficile diarrhea, agranulocytosis, neutropenia, thrombocytopenia, anaphylaxis, drug hypersensitivity syndrome, ototoxicity, nephrotoxicity

NOTE: 室溫儲存

· To minimize adverse effects, it should be administered at a rate not exceeding 10mg/min

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『藍』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1037290

06.06H2 Lincomycins

21060 B / Infant risk can

LINDACIN CAPSULES 150MG (CLINDAMYCIN) "S.T." 利達信黴素膠囊１５０公絲〝信東〞

Clindamycin HCl 150mg cap

Dosage: 1常備品 21060

Adult
· Susceptible infections: PO, 150-450mg q6h

Pediatric
· Susceptible infections: PO, 8-20mg/kg/day div. q6-8h

Dosing adjustments in hepatic impairment:

Severe liver disease: Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: 150mg(21060); Topical soln: 1% 30mL(29457); Inj: 300mg/2mL Amp(31060)

ADR:

COMMON
Rash, diarrhea, nausea
SERIOUS
Pseudomembranous enterocolitis (rare), increased liver function test, jaundice

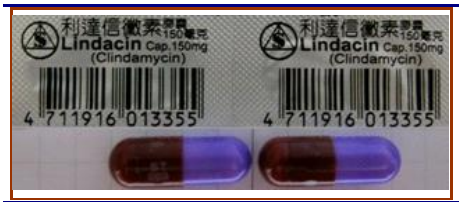
NOTE: 室溫儲存

· 《Contraindications》History of hypersensitivity to clindamycin or lincomycin ;

藥名相似:

外觀相似:

外觀描述: 紅/紫色膠囊，有"ST"及"023"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043991

06.06H2 Lincomycins

31060 **B / Infant risk can**

B. B. INJECTION 150MG/ML (CLINDAMYCIN) 比比徽素注射液１５０公絲/公撮（克林達徽素）

Clindamycin inj 300mg/2mL amp

Dosage: 1常備品 31060

Adult

· Susceptible infections: IV infusion, IM, 600-2700mg/day div. q6-12h; Max. 4.8g/day

· Perinatal GBS disease, intrapartum prophylaxis: IV infusion, 900mg q8h, starting at time of labor or rupture of membranes, until delivery

Pediatric

· Susceptible infections: (neonates <1m) IV infusion, IM, 15-20mg/kg/day div. q6-8h

· Susceptible infections: (1m-16yrs) IV infusion, IM, 20-40mg/kg/day div. q6-8h; Max. 4.8g/day.

Dosing adjustments in hepatic impairment:

Severe liver disease, give q8h.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Cap: 150mg(21060); Topical soln: 1% 30mL(29457); Inj: 300mg/2mL amp(31060)

ADR:

COMMON
Rash, diarrhea, nausea
SERIOUS
Pseudomembranous enterocolitis (rare), increased liver function test, jaundice

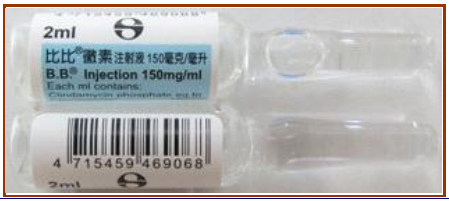
NOTE: 室溫儲存

· 《Contraindications》History of antibiotic-associated colitis, including pseudomembranous colitis, when applied topically or vaginally; History of regional enteritis when applied topically or vaginally; History of ulcerative colitis when applied topically or vaginally; Hypersensitivity to clindamycin or other lincosamides, such as lincomycin ;

藥名相似:

外觀相似:

外觀描述: 2mL透明注射液，『透明』玻璃安瓿，頸部有『藍』點，白底黑色字標籤有淺藍色區塊



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1036469

06.06H3 Oxazolidinones

21063 **C / Caution**

ZYVOX TABLETS 600MG 采福適膜衣錠

Linezolid 600mg tab

Dosage: 1常備品 21063

Adult

· Pneumonia, complicated skin and skin structure infections: PO, 600mg q12h for 10-14 days

· Uncomplicated skin and skin structure infections: PO, 400mg q12h for 10-14 days

· Vancomycin-resistant Enterococcus faecium infections(VRE): PO, 600mg q12h for 14-28 days

· Multi-drug resistant tuberculosis: PO, 600mg qd (須經結核病諮詢委員會討論核可申請使用，此適應症非健保給付，需向疾管署申請費用)

Pediatric

· Pre-term neonates (<34 wks): PO, 10mg/kg q12h; If suboptimal responses or by 7 days of life, increase dose to 10mg/kg q8h

· Pneumonia, complicated skin and skin structure infections: PO, 0-11yrs: 10mg/kg q8h; ≧12yrs: 600mg q12h for 10-14 days

· Uncomplicated skin and skin structure infections: PO, <5yrs: 10mg/kg q8h; 5-11yrs: 10mg/kg q12h; ≧12yrs: 600mg q12h for 10-14 days

· Vancomycin-resistant Enterococcus faecium infections(VRE): PO, 0-11yrs: 10mg/kg q8h; ≧12yrs: 600mg q12h for 14-28 days

Dosing adjustments in hepatic impairment:

Mild to moderate hepatic impairment (Child-Pugh class A or B): No dosage adjustment needed
Severe hepatic impairment: NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 600mg(21063); Inj: 2mg/mL, 300mL Bag(31062)

ADR:

COMMON
Diarrhea, nausea, vomiting, headache
SERIOUS
Lactic acidosis, clostridium difficile diarrhea, myelosuppression, injury of liver, peripheral neuropathy, seizure, disorder of optic nerve, serotonin syndrome
上市後經驗(仿單)
含鐵血球芽細胞貧血(sideroblastic anemia)、過敏反應、血管性水腫及大泡性皮膚異常包含嚴重型皮膚藥物過敏反應(例如毒性表皮溶解症及Steven-Johnson症候群之皮膚異常)、牙齒表面變色及舌頭變色、低血糖。

NOTE: 儲存25℃以下

· Avoid consuming large amounts of tyramine-containing foods/beverages(>100mg tyramine per meal)

· It is a monoamine oxidase inhibitor (MAOI).

· 接受linezolid的病人應每週監測全血球計數，特別是治療超過兩週者、已有骨髓抑制狀況者、同時併用會造成骨髓抑制之藥物者、或先前已接受或同時接受抗生素治療的慢性感染病人。

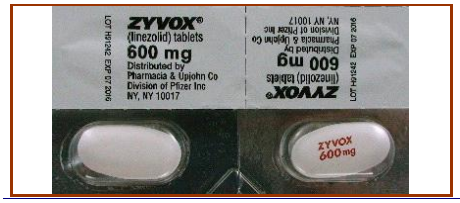
· 除非臨床情況適合，且能仔細監測病人的血清素徵象或症狀[包括高燒、僵直、肌陣攣、自律神經失調、精神狀態變化(包括極度躁動，(惡化為譫妄和昏迷))]，或者類抗精神病藥物惡性(類NMS)反應，否則linezolid不應該投予類癌症狀，或服用下列藥物的病人：血清素再吸收抑制劑、三環抗憂鬱劑、血清素5-HT1受體促效劑

(triptans)、meperidine、bupropion、buspirone。

藥名相似:

外觀相似:

外觀描述: 白色長橢圓形錠，有ZYVOX 600mg字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023181

06.06H3 Oxazolidinones

31062 C / Caution

ZYVOX INJECTION 采福適注射劑

Linezolid 2mg/mL, 300mL bag

Dosage: 1常備品 31062

Adult: IV infusion over 30-120mins
· Pneumonia, complicated skin and skin-structure infections: 600mg q12h for 10-14 days
· Vancomycin-resistant Enterococcus faecium infections(VRE): 600mg q12h for 14-28 days

Pediatric: IV infusion over 30-120mins
· Pre-term neonates (<34 wks): 10mg/kg q12h; If suboptimal responses or by 7 days of life, increase dose to 10mg/kg q8h
· Pneumonia, complicated skin and skin-structure infections:
0-11yrs: 10mg/kg q8h for 10-14 days
≧12yrs: 600mg q12h for 10-14 days
· Vancomycin-resistant Enterococcus faecium infections(VRE):
0-11yrs: 10mg/kg q8h for 14-28 days
≧12yrs: 600mg q12h for 14-28 days

Dosing adjustments in hepatic impairment:

Mild to moderate hepatic impairment (Child-Pugh class A or B): No dosage adjustment needed
Severe hepatic impairment: NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 600mg(21063); Inj: 2mg/mL, 300mL Bag(31062)

ADR:

COMMON
Rash, diarrhea, nausea, vomiting, headache, fever
SERIOUS
Lactic acidosis, myelosuppression, peripheral neuropathy, seizure, disorder of optic nerve, serotonin syndrome

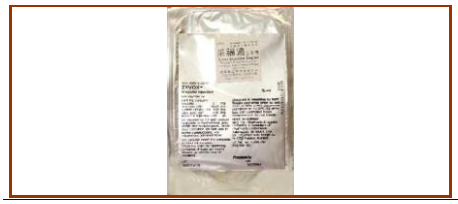
NOTE: 室溫儲存

· Avoid consuming large amounts of tyramine-containing foods/beverages(>100mg tyramine per meal)
· It is a monoamine oxidase inhibitor (MAOI).
· 仿單內容變更，摘述如下(版本 USPI 201305-2)
1.加註本藥使用超過28天的安全性和有效性，尚未在有對照組的臨床試驗中評估過。
2.增列末期腎病並接受血液透析治療者藥動學之相關資訊。
3.藥物交互作用：增列抗氧化劑(併用維生素C或維生素E時，不建議調整本藥劑量)。
4.更新抗藥性機轉相關資訊。
5.警語及注意事項：加註(A)兒科患者也有週邊神經病變與視神經病變的報告。(B)有些服用血清素抗抑鬱劑或buspirone者可能需要本藥緊急治療。如果無法取得替代藥物，且使用本藥的可能效益大於血清素症狀或類NMS反應的風險，則應立即停用血清素抗抑鬱劑。須監測患者2週(服用fluoxetine者需5週)，或直到投予最後一劑linezolid後24小時為止，以先發生者為準。也應監測患者抗憂鬱劑的停藥症狀。
6.患者須知：加註治療時可能發生低血糖反應(如發汗及震顫)及低血糖測量值之糖尿病患者。

藥名相似:

外觀相似:

外觀描述: 300mL透明微黃液體、塑膠軟袋銀色鋁箔外包



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023186

06.06H5 Polymyxins

31071 C /

T.T.Y. COLIMYCIN INJECTION 2000000 U (COLISTIN METHANESULFONATE) "台灣東洋" 克痢黴素注射劑 200萬單位（可麗基美壽）

Colistin base 66.8mg vial (=Colistimethate sodium(CMS) 160mg)

Dosage: 1常備品 31071

Adult (Dose is based on colistin base; weight-based dosing should utilize ideal body weight in obese patients)
MICROMEDEX:
· Disease due to Gram-negative bacteria, Pseudomonas aeruginosa, Enterobacter aerogenes, Escherichia coli, and Klebsiella pneumoniae: IM or IV, 2.5-5mg/kg/day in 2-4 divided doses, depending on severity of infection
熱病 2018:
· Loading dose: 4 x pt wt in kg, then start daily maintenance dose 12 hrs later, Max: 300mg
· Maintenance dose: 2.0 x ([1.5 x CrCl] +30) divided and give q8-12h

Pediatric (Dose is based on colistin base; weight-based dosing should utilize ideal body weight in obese patients)
· Disease due to Gram-negative bacteria, Pseudomonas aeruginosa, Enterobacter aerogenes, Escherichia coli, and Klebsiella pneumoniae: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

MICROMEDEX:
CrCl 50~79mL/min: 2.5-3.8 mg/kg/day in 2 divided doses
CrCl 30~49mL/min: 2.5 mg/kg qd or 2.5mg/kg/day in 2 divided doses
CrCl 10~29mL/min: 1.5 mg/kg q36h
熱病 2018:
IHD: non dialysis days: 130mg/day divided q12h;

dialysis days: 175mg for first dose after end of dialysis

P: Inj: 66.8mg Vial(31071)

ADR:

NOTE: 室溫儲存

· Each vial contains 2MU colistimethate sodium=160mg colistimethate sodium(CMS)=66.8mg colistin base

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『紅』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1024961

06.06H6 Cyclic Lipopeptides

31073 ɔt be ruled out / Infant risk can

Cubicin Injection 救必辛注射劑

Daptomycin inj 500mg pow in vial

Dosage: 1常備品 31073

Adult

·Complicated skin and skin structure infections: IV infusion over 30 mins, 4mg/kg qd for 7-14 days

·Bacteremia, right-sided endocarditis caused by methicillin-susceptible Staphylococcus aureus or methicillin-resistant Staphylococcus aureus: IV infusion over 30mins, 6mg/kg qd for 2-6 wks

Pediatric

Safety and efficacy have not been established in patients less than 1 year old

·Complicated skin and skin structure infections: IV infusion over 60mins (1-6 yrs) or 30mins(7-17 yrs)

1- <2 yrs: 10mg/kg qd for up to 14 days

2-6 yrs: 9mg/kg qd for up to 14 days

7-11 yrs: 7mg/kg qd for up to 14 days

12-17 yrs: 5mg/kg qd for up to 14 days

·Bacteremia due to Staphylococcus aureus: IV infusion over 60mins (1-6 yrs) or 30mins (7-17 yrs)

1-6 yrs: 12mg/kg qd for up to 42 days

7-11 yrs: 9mg/kg qd for up to 42 days

12-17 yrs: 7mg/kg qd for up to 42 days

Dosing adjustments in hepatic impairment:

Moderate impairment(Child-Pugh class B): No dosage adjustment needed

Dosing adjustments in renal impairment:

CrCl<30mL/min, hemodialysis, or continuous peritoneal dialysis (CAPD): Administer q48h

P: Inj: 500mg Vial(31073)

ADR:

COMMON

Hypertension, hypotension, pruritus, rash, abdominal pain, diarrhea, vomiting, dizziness, headache, insomnia, dyspnea, pain in throat, fever

SERIOUS

Disorder of muscle, increased creatine kinase level, rhabdomyolysis, renal failure, pulmonary eosinophilia, disease due to Gram-negative bacteria

NOTE: 冰箱儲存

·《Contraindications》Hypersensitivity to daptomycin

·Not indicated for the treatment of pneumonia

·daptomycin會分泌至人體乳汁，嬰兒暴露量約為母體的0.1%。

藥名相似:

外觀相似:

外觀描述: 黃色乾粉、『藍』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024565

06.06H7 Other Miscellaneous antibiotic Agents

21061 UK /

FUCIDIN TABLETS 服即淨錠

Fusidate sodium (Fusidic acid) 250mg tab

Dosage: 1常備品 21061

Adult

· Chronic osteomyelitis, skin and soft tissue infections: PO, 500mg q8h. The dose may be doubled for the treatment of fulminant infections

· Clostridium difficile associated diarrhea: PO, the dose of fusidic acid was 500mg tid for 10 days

Pediatric

· Skin and soft tissue infections, osteomyelitis: Children (<1yr): 49mg/kg/day div. into 3 equal doses; Children (1-5yr): 246mg tid; Children (6-12yr): 492mg tid. The dose may be doubled for the treatment of fulminant infections

Dosing adjustments in hepatic impairment:

Dosage adjustment required.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 250mg(21061); Cream: 2% 5g/tube(29304); Oph soln: 1% 5mL/bot(29296)

ADR:

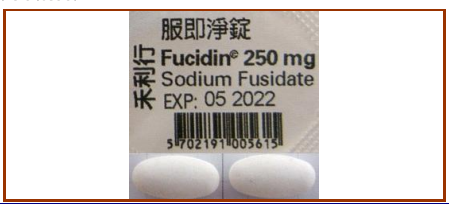
GI upset, hepatotoxicity, blurred vision, skin rash, pruritus

NOTE: 室溫儲存

藥名相似: Tab: 250mg(21061); Cream: 2% 5g/tube(293

外觀相似:

外觀描述: 白色橢圓形錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2019108

06.06H7 Other Miscellaneous antibiotic Agents

31170 UK / Unknown(有

UFO POWDER FOR INJECTION (FOSFOMYCIN) 優福乾粉注射劑（弗斯黴素）

Fosfomycin inj 2g pow in vial

Dosage: 1常備品 31170

Adult

· Susceptible infections: IV, 2-4g/day in 2 divided doses

Pediatric

· Susceptible infections: IV, 100-200mg/kg/day in 2 divided doses

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P: Granules: 3g/pk(21045); Inj: 2g Vial(31170)

ADR:

Elevations in hepatic enzymes, proteinuria, elevation in BUN, edema, cough, asthma attack, headache, mouth numbness, convulsion, granulocytopenia, anemia, eosinophilia, stomatitis, nausea, abdominal pain, anorexia, skin rash

NOTE: 室溫儲存

· Sodium contents: 29mEq/vial

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『淺藍』蓋透明玻璃小瓶，白底黑字標籤有"淺紫"色"UFO"及"優福"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1035049

06.08 Antifungal Agents

21100 C /

Flusine Tablets 弗路欣錠

Flucytosine (5 FC) 500mg tab

Dosage: 1常備品 21100

Adult

·Candidiasis, cryptococcosis, chromomycosis: PO, 50-150mg/kg/day in 4 divided doses

Pediatric

·Candidiasis, cryptococcosis, chromomycosis: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

CrCl 20-40mL/min: 12.5-37.5mg/kg q12h
CrCl 10-20mL/min: 12.5-37.5mg/kg q24h
CrCl <10mL/min: 12.5-37.5mg/kg q24-48h

P: Tab: 500mg(21100)

ADR:

COMMON
Abdominal pain, diarrhea, nausea, vomiting, confusion, headache, hallucinations
SERIOUS
Cardiotoxicity, gastrointestinal hemorrhage, leukopenia, myelosuppression, thrombocytopenia, renal failure

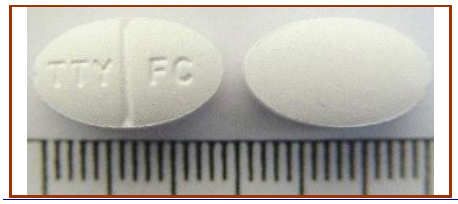
NOTE: 室溫儲存

·It should not be used alone in the treatment of severe infections

藥名相似:

外觀相似:

外觀描述: 白色橢圓錠，有TTY及FC字樣



06.08 Antifungal Agents

21102 C / Caution

NYSTATIN CAPSULES "YUNG SHIN" 寧司泰定膠囊

Nystatin 500,000 IU cap

Dosage: 1常備品 21102

Adult

· Gastrointestinal candidiasis(non-esophageal): PO, 1-2 tab (500,000-1,000,000 IU) 3 times per day

Pediatric

· Oral candidiasis: PO, infants, 200,000 IU 4 times/day, children 400,000-600,000 IU 4 times/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: 500,000 IU(21102); Pow: 100,000 IU/ds, 5ds/pk(28485); VT: 100,000 IU(29028)

ADR:

COMMON
Nausea and vomiting (with large doses (5 MU/day))

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 紅紫色/粉紅色膠囊,有"YSP"及"NYC"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1018895

06.08 Antifungal Agents

21103 demonstrated / Infant risk can

ICOMEIN CAPSULE 100MG "EVEREST" "永勝"易克黴膠囊１００毫克

Itraconazole 100mg cap

Dosage: 1常備品 21103

Adult
· Aspergillosis: PO, 200mg/day, Max. 200mg bid
· Aspergillosis/blastomycosis, life-threatening: PO, 200mg tid for 3 days, then 200mg/day for at least 3 mons
· Blastomycosis, histoplasmosis: PO, 200mg/day, Max. 200mg bid
· Dermatomycoses: PO, 200mg/day for 7 days

Pediatric
· Systemic fungal infections: PO, 6 mons-12yrs, 5mg/kg/day for 2 wks; 3-16 yrs, 100mg/day
· Candidiasis: PO, 10mg/kg/day in 2 div doses for 4 weeks

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: 100mg(21103)

ADR:

COMMON
Edema, hypertension, pruritus, rash, abdominal pain, diarrhea, nausea, vomiting, abnormal liver function, dizziness, headache, rhinitis, sinusitis, upper respiratory infection, fatigue, fever
SERIOUS
Congestive heart failure, pancreatitis, hepatotoxicity, anaphylaxis, peripheral nerve disease, hearing loss, pulmonary edema

NOTE: 室溫儲存

· 飯後立即服用，膠囊整粒吞服
· Patients with congestive heart failure or patients with a history of congestive heart failure should not be used unless the clinical benefit significantly exceeds their risk. If necessary, the signs and symptoms of septic heart failure should be monitored during treatment. If such signs and symptoms occur during treatment, they must be discontinued.

藥名相似:

外觀相似:

外觀描述: 藍色/透明紅色膠囊，有"ICOMEIN"及"EVERST"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046283

06.08 Antifungal Agents

21105 B / Unsafe

FUNGITECH* TABLETS 250MG "SINPHAR" "杏輝" 黴特克舒錠250公絲

Terbinafine HCl 250mg tab

Dosage: 1常備品 21105

Adult
· Onychomycosis: PO, 250mg daily for 6 wks for fingernails; 12 wks for toenails
· Tinea capitis: PO, 250mg once daily

Pediatric(>3 yrs)
· Tinea capitis: PO,
<20kg: 62.5mg once daily
20-40kg: 125mg once daily
>40kg: 250mg once daily

Dosing adjustments in hepatic impairment:

Chronic or active liver disease: Not recommended

Dosing adjustments in renal impairment:

Clcr <50mL/min: Not recommended

P:

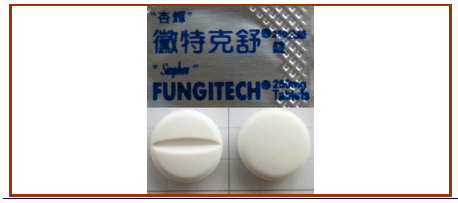
ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述:



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045950

06.08 Antifungal Agents

21106 D / Infant risk is

FLUENE CAPSULES 50MG (FLUCONAZOLE) "PURZER" "瑞安" 膚黴克膠囊５０公絲（氟可那挫）

Fluconazole 50mg cap

Dosage: 1常備品 21106

Adult: PO
· Cryptococcal meningitis: 400mg qd on the first day then 200-400mg daily for at least 10-12 wks after the CSF is sterile
· Oropharyngeal candidiasis: 200mg qd on the first day then 100mg qd for at least 2 wks
· Esophageal candidiasis: 200mg qd on the first day then 100mg-400mg qd for at least 3 wks and for at least 2 wks following the resolution of symptoms
· Systemic candidiasis: 400mg qd

Pediatric: PO
· Candidiasis, esophageal: 6mg/kg/day on day 1, then 3mg/kg/day (Max. 12mg/kg/day) qd for at least 3 weeks; continue treatment for 2 weeks following resolution of symptoms
· Candidiasis, oropharyngeal: 6mg/kg/day on day 1, then 3mg/kg/day qd for at least 2 weeks to decrease the likelihood of relapse
· Candidiasis, systemic: 6-12mg/kg/day
· Cryptococcal meningitis: 12mg/kg on day 1, then 6mg/kg/day (Max. 12mg/kg/day) for 10-12 weeks after the CSF is sterile

Dosing adjustments in hepatic impairment:

Discontinue fluconazole in patients who develop

signs and symptoms consistent with liver disease or elevations in hepatic function tests.

Dosing adjustments in renal impairment:

No dosage adjustment is needed in patients with renal impairment given single-dose therapy.
For multiple dosing, administer usual loading dose and subsequent doses should be adjusted according to Clcr:
Clcr > 50mL/min: No dosage adjustment needed
Clcr 21-50mL/min (no dialysis): Administer q48h or 50% of recommended dose
Clcr 11-20mL/min (no dialysis): Administer q96h or 25% of recommended dose
Patients receiving hemodialysis should receive 100% of the recommended dose after each dialysis treatment.

P: Cap: 50mg(21106); Inj: 100mg/50mL Vial(31106)

ADR:

NOTE: 室溫儲存

· Oral and IV dosage of fluconazole are identical, IV therapy is reserved for patient who do not tolerate or are unable to take the drug orally
· The pregnancy category for a single, low dose (150mg) of fluconazole remains category C. Indications (other than vaginal candidiasis) the pregnancy category has been changed from C to D.

藥名相似:

外觀相似:

外觀描述: 白/青色膠囊，膠囊上印有"PZP 17"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1041997

06.08 Antifungal Agents

21107 **D / Infant risk can**

VFEND FILM-COATED TABLETS 200MG 黴飛膜衣錠200毫克

Voriconazole 200mg tab

Dosage: 1常備品 21107

Adult
·Invasive aspergillosis, disseminated Candida infections and other serious fungal infection: PO, 200-300mg q12h for patients > 40kg; 100-150mg q12h for patients < 40kg

Pediatric
·Invasive aspergillosis, disseminated Candida infections and other serious fungal infection: PO
2-12 yrs and 12-14 yrs with BW< 50kg: 9mg/kg q12h; Max. 350mg/dose (Recommend to use oral suspension)
12-14 yrs with BW? 50kg; 15-17 yrs: Same as adult

Dosing adjustments in hepatic impairment:

Mild-to-moderate hepatic dysfunction: Following standard loading dose, reduce maintenance dosage by 50%
Severe hepatic impairment: Should only be used if benefit outweighs risk; monitor closely for toxicity.

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 200mg(21107); Inj: 200mg Vial(31108)

ADR:

COMMON
Diarrhea, nausea, vomiting, fever, headache, hallucinations, peripheral edema, rash, visual disturbances
SERIOUS
Cardiac arrest, cardiac dysrhythmia, prolonged QT interval, sudden cardiac death,Torsades de pointes, erythema multiforme, malignant melanoma, squamous cell carcinoma, Stevens-Johnson syndrome, toxic epidermal necrolysis, pancreatitis, cholestasis, fulminant hepatic failure, hepatitis, hyperbilirubinemia, increased liver function test, jaundice, anaphylactoid reaction, toxic encephalopathy, optic disc edema, optic neuritis, renal failure

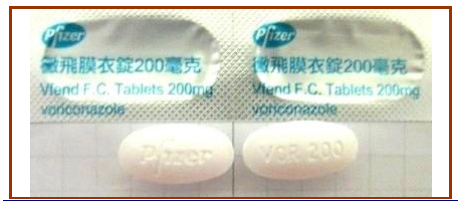
NOTE: 儲存於30°C以下

1. Food may decrease voriconazole absorption, should be taken 1 hr before or 1 hr after meals. Avoid grapefruit juice.
2.Bioequivalence between the oral tablet and suspension has not been determined; due to possible shortened gastric transit time in infants and children, absorption of tablets may be different than adults. It is recommended to use the oral suspension in children aged 2-12yrs.
3.仿單內容變更，摘述如下：(版本：CDS20150625-2)
特殊警語及使用時之特殊注意事項：小兒科使用增列在兒童族群中曾觀察到較高的肝臟酵素上升發生率。

藥名相似:

外觀相似:

外觀描述: 白色長橢圓形錠,有Pfizer及VOR200字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023646

06.08 Antifungal Agents

21108 **b3 / No report(毫**

GRISEOFULVIN TABLETS 250MG 灰黴素錠２５０公絲

Griseofulvin 250mg tab

Dosage: 1常備品 21108

Adult
· Tinea corporis, tinea cruris and tinea capitis: PO, 500mg/day; duration of therapy depends on the site of infection
· Onychomycosis, tinea pedis, tinea unguium or infections difficult to eradicate: PO, 1g/day; duration of therapy depends on the site of infection

Pediatric
· Antifungal: PO, 10-20mg/kg/day in single or 2 divided doses

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

COMMON
Photosensitivity, rash, urticaria, diarrhea, nausea, vomiting, headache
SERIOUS
Acroparesthesia (rare)

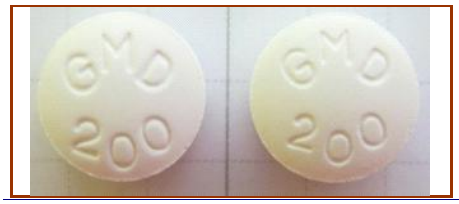
NOTE: 室溫儲存

· Additional contraceptive precautions should be taken during therapy and for 1 month following therapy
· Males should wait at least 6 months after therapy before fathering a child
· History of penicillin allergy
· Photosensitivity; avoid excessive exposure to sunlight
· You may take your medicine with food or milk to avoid stomach irritation

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠,兩面有"GMD200"字樣



06.08 Antifungal Agents

21109 **C / Caution**

POSANOL* TABLETS 100MG 波賽特錠劑100毫克

Posaconazole 100mg tab

Dosage: 1常備品 21109

· Treatment or prophylaxis of invasive Aspergillus and Candida infections: Loading dose: PO, 300mg bid on the first day; Maintenance dose: PO, 300mg qd, starting on the second day.

(≧13 yrs)
· Treatment or prophylaxis of invasive fungal infection: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 100mg(21109); Susp:40mg/mL, 105mL/B(28487); Inj: 300mg/16.7mL vial(急用藥, 37621)

ADR:

COMMON
Hypokalemia, diarrhea, nausea, vomiting, headache, fever
SERIOUS
Prolonged QT interval, Torsades de pointes, cholestasis, liver failure

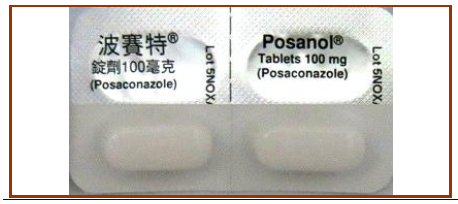
NOTE: 室溫儲存

· The delayed-release tab and oral suspension are not to be used interchangeably due to dosing differences for each formulation.

藥名相似:

外觀相似:

外觀描述: 黃色膠囊形膜衣錠，一面刻有100字樣



06.08 Antifungal Agents

28486 **C / Caution**

MYCOSTATIN FOR ORAL SUSPENSION 100,000 UNITS/ML (NYSTATIN) 滅菌靈懸液用粉劑１０萬單位/毫升（耐絲菌素）

Nystatin susp. 100,000 IU/mL, 24mL/bot

Dosage: 1常備品 28486

Adult
· Oropharyngeal candidiasis: Swish and swallow, 400,000-600,000 IU (4-6mL) qid (one-half of dose in each side of mouth)
· Intestinal candidiasis: Swish and swallow, 400,000-600,000 IU (4-6mL) qid

Pediatric
· Oropharyngeal candidiasis: Swish and swallow, one-half of dose in each side of mouth
Neonates(0~1 mon): 100,000 IU (1 mL) qid (avoid feeding for 5-10 mins)
Infants(1 mon~2 yrs): 200,000 IU (2 mL) qid
Children(>2 yrs): 400,000-600,000 IU (4-6mL) qid
· Intestinal candidiasis: Swish and swallow,
Infants(0 mon~2 yrs): 100,000-200,000 IU (1-2mL) qid
Children(>2 yrs): 400,000-600,000 IU (4-6mL) qid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: 500,000 IU(21102); Susp: 100,000 IU/mL, 24mL/bot(28486); VT: 100,000 IU(29028)

ADR:

COMMON
Skin irritation, hypersensitivity reaction
SERIOUS
Stevens-Johnson syndrome

NOTE: 室溫儲存

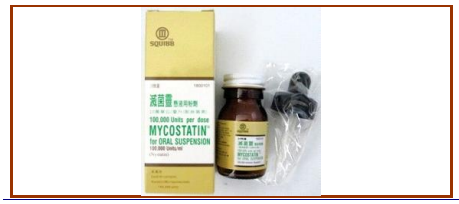
· 《Contraindications》hypersensitivity to nystatin products；
· 整瓶加23cc冷開水搖勻，泡製後室溫可保存7天。
· It should be retained in the mouth for as long as possible (several minutes) before swallowing.
· For neonates and infants, paint suspension into the mouth.

· Avoid taking food or drink for one hour after a dose.
· 本品賦形劑不含阿斯巴甜

藥名相似:

外觀相似:

外觀描述: 外包裝紙盒，內為24mL白色上蓋棕色玻璃瓶身，內含懸液用粉



06.08 Antifungal Agents

31100 B / Infant risk can

FUNGIZONE INTRAVENOUS INJECTION 防治黴靜脈凍晶注射劑

amphotericin B inj 50mg vial

Dosage: 1常備品 31100

Adult
· Fungal infection, systemic: IV infusion, test dose 1mg in 20 mL D5W over 20-30 mins; then 0.25-1mg/kg/day over 2-6hrs, Max. 1.5mg/kg/day

Pediatric
· Fungal infection, systemic: IV infusion, test dose 1mg in 20 mL D5W over 20-30 mins; then 0.25-1mg/kg/day over 2-6hrs, Max. 1.5mg/kg/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

GFR< 10mL/min: Administer q24-36h
Dialysis: The recommended intraperitoneal dose of amphotericin B for the treatment of peritoneal dialysis-related peritonitis in ANURIC patients (residual urine volume <100mL/day) is 1.5 mg/liter exchange

P: Inj: 50mg Vial(31100); Inj: liposomal 50mg Vial(31101)

ADR:

COMMON
Hypotension, thrombophlebitis, injection site pain, nausea, diarrhea, indigestion, loss of appetite, vomiting, normochromic, normocystic anemia, arthralgia, myalgia, headache, tachypnea, fever, infusion reaction, malaise, shivering
SERIOUS
Asystole, cardiac arrest, cardiac dysrhythmia, ventricular fibrillation, Stevens-Johnson syndrome, toxic epidermal necrolysis, hypokalemia, agranulocytosis, anaphylaxis, encephalopathy, seizure, nephrotoxicity

NOTE: 冰箱保存

·《Contraindications》Hypersensitivity to amphotericin B or any other component of the product ；
·Soln containing NaCl or a bacteriostatic agent (e.g. benzyl alcohol) may cause precipitation of the medication

藥名相似:

外觀相似:

外觀描述: 黃色乾粉、『綠』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2012258

06.08 Antifungal Agents

31101 B / Infant risk can

AMPHOLIPAD* LIPOSOME FOR INJECTION 50MG 安畢黴微脂粒凍晶注射劑50毫克

■Liposomal amphotericin B inj 50mg pow in vial

Dosage: 1常備品 31101

Adult: IV infusion over 120 mins
·Cryptococcal meningitis: 6mg/kg/day once daily
·Empiric therapy for febrile neutropenic patients: 3mg/kg/day once daily
·Systemic fungal infections: 3-5mg/kg/day once daily
·Visceral leishmaniasis-immunocompetent patients: 3mg/kg/day on days 1-5 and on days 14 and 21
·Visceral leishmaniasis-immunosuppressed patients: 4mg/kg/day on days 1-5 and on days 10, 17, 24, 31, and 38

Pediatric: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Dose reductions should be considered in newly-treated patients demonstrating an increase in serum creatinine to 2.5 or 3 mg/dL during therapy

P: Inj: 50mg Vial(31100); Inj: liposomal 50mg Vial(31101)

ADR:

NOTE: 室溫儲存。

1.Reconstitute with SWI, shake for 30 sec, filter with 5μm filter (use only one filter per vial), dilute further in D5W to a final concentration of 1-2mg/mL (0.2-0.5mg/mL may be appropriate for children), use within 6 hr
2.Infusion time may be reduced to 60 min if previous infusions well tolerated
3.Use separate line or flush line with D5W before infusion

藥名相似:

外觀相似:

外觀描述: 黃色乾粉、『藍』蓋透明玻璃小瓶，每小瓶附1個過濾器

06.08 Antifungal Agents

31106 D / Infant risk can

DIFLUCAN IV INJECTION 泰復肯靜脈注射劑

Fluconazole 100mg/50mL vial

Dosage: 1常備品 31106

Adult: IV infusion

· Cryptococcal meningitis: 400mg qd on the first day then 200-400mg daily for at least 10-12 wks after the CSF is sterile

· Oropharyngeal candidiasis: 200mg qd on the first day then 100mg qd for at least 2 wks

· Esophageal candidiasis: 200mg qd on the first day then 100mg qd (Max. 400mg/day) for at least 3 wks and for at least 2 wks following the resolution of symptoms

· Candidemia: 800mg qd on 1st day then 400mg qd. Treat for 14 days after resolution of symptoms

Pediatric: IV infusion

· Candidiasis, esophageal: 6mg/kg/day on day 1, then 3mg/kg/day (Max. 12mg/kg/day) qd for at least 3 weeks; continue treatment for 2 weeks following resolution of symptoms

· Candidiasis, oropharyngeal: 6mg/kg/day on day 1, then 3mg/kg/day qd for at least 2 weeks to decrease the likelihood of relapse

· Candidiasis, systemic: 6-12mg/kg/day

· Cryptococcal meningitis: 12mg/kg on day 1, then 6mg/kg/day (Max. 12mg/kg/day) for 10-12 weeks after the CSF is sterile

Dosing adjustments in hepatic impairment:

Discontinue fluconazole in patients who develop signs and symptoms consistent with liver disease or elevations in hepatic function tests.

Dosing adjustments in renal impairment:

No dosage adjustment is needed in patients with renal impairment given single-dose therapy.
For multiple dosing, administer usual loading dose and subsequent doses should be adjusted according to Clcr:
Clcr > 40mL/min: No dosage adjustment needed
Clcr 21-40mL/min (no dialysis): Administer q48h or 50% of recommended dose
Clcr 10-20mL/min (no dialysis): Administer q72h or 33% of recommended dose
Patients receiving hemodialysis should receive 100% of the recommended dose after each dialysis treatment.

P: Cap: 50mg(21106); Inj: 100mg/50mL Vial(31106)

ADR:

COMMON
Nausea, vomiting, headache
SERIOUS
Prolonged QT interval, Torsades de pointes, Stevens-Johnson syndrome, toxic epidermal necrolysis, agranulocytosis, anaphylaxis, seizure

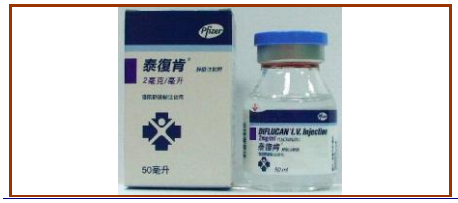
NOTE: 室溫儲存

· Oral and IV dosage of fluconazole are identical, IV therapy is reserved for patient who do not tolerate or are unable to take the drug orally.
· 懷孕時應避免使用，除非病人患有嚴重或可能危及生命的黴菌感染且預期其益處大於對胎兒可能的風險時，方可使用。
· 具生育能力女性應考慮採取有效避孕措施，並應於整個治療期間持續避孕至最後一劑後約1週。

藥名相似:

外觀相似:

外觀描述: 50mL透明注射液『藍』蓋透明玻璃瓶，蓋上有FLIP及OFF字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2018790

06.08 Antifungal Agents

31107 C / Caution

CANCIDAS INJECTION 50MG 黴息止注射劑50毫克

Caspofungin 50mg vial

Dosage: 1常備品 31107

Adult

· Invasive aspergillosis, candidemia, disseminated candidiasis, febrile neutropenia: Slow IV infusion over 1 hr, 70mg on day 1, then 50mg daily thereafter; duration of therapy depends upon clinical response

· Esophageal candidiasis: Slow IV infusion over 1 hr, 50mg daily

Pediatric

· Invasive aspergillosis, candidemia, disseminated candidiasis, esophageal candidiasis, febrile neutropenia: Slow IV infusion over 1 hr, 70mg/m2 on day 1, then 50mg/m2 daily thereafter; duration of therapy depends upon clinical response; Max. 70mg/day

Dosing adjustments in hepatic impairment:

Moderate hepatic insufficiency (Child Pugh Score 7-9): LD 70mg, then reduced daily dose to 35mg

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 50mg Vial(31107)

ADR:

NOTE: 冰箱儲存

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『紅』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023485

06.08 Antifungal Agents

31108 D / No report(毫

VFEND 200MG FOR SOLUTION FOR INFUSION --

Voriconazole inj 200mg pow in vial

Dosage: 1常備品 31108

Adult
·Invasive aspergillosis, disseminated candidiasis, fusarium infection, scedosporium apiospermum infection, infection prophylaxis in high-risk patients (including hematopoietic stem cell transplant recipients): IV infusion, initial 6mg/kg q12h for 2 doses, then 4mg/kg q12h; may switch to oral dosing as tolerated
·Candidemia: IV infusion, initial 6mg/kg q12h for 2 doses, then 3mg/kg q12h; may switch to oral dosing as tolerated

Pediatric
·Invasive aspergillosis, disseminated candidiasis, fusarium infection, scedosporium apiospermum infection: IV infusion,
2-12 yrs and 12-14 yrs with BW <50 kg: 9mg/kg q12h on day 1, followed by 8mg/kg q12h; may switch to oral dosing as tolerated
? 12 yrs: Same as adult

Dosing adjustments in hepatic impairment:

Mild to moderate dysfunction(Child-Pugh Class A and B): Standard loading dose, reduce maintenance dosage by 50%
Severe dysfunction: Should only be used if benefit outweighs risk; monitor closely for toxicity.

Dosing adjustments in renal impairment:

Clcr<50mL/min: Use oral formulation instead of IV to prevent accumulation of IV vehicle sulfobutyl ether beta-cyclodextrin sodium(SBECD)

P: Tab: 200mg(21107); Inj: 200mg Vial(31108)

ADR:

NOTE: 室溫儲存

· If unable to tolerate treatment, reduce the IV maintenance dose to 3mg/kg q12h
· The maintenance dose of voriconazole should be increased to 5mg/kg intravenously q12h when phenytoin is coadministered
· IV infusion over 1-2hrs; Max. infusion rate 3mg/kg/hr
· Must not dilute with 4.2% sodium bicarbonate
· 仿單內容變更，摘述如下：(版本：CDS20150625-2)
特殊警語及使用時之特殊注意事項：小兒科使用增列在兒童族群中曾觀察到較高的肝臟酵素上升發生率。

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『紅』蓋透明玻璃小瓶，白底深藍字標籤有淺藍色"200mg"字樣與區塊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023485

06.08 Antifungal Agents

31110 C / Caution

Mycamine for Injection 50mg/vial 米開民 注射劑

Micafungin 50mg vial

Dosage: 1常備品 31110

Adult: IV infusion over 1hr
· Candidemia, disseminated candidiasis: 100mg qd
· Esophageal candidiasis: 150mg qd
· Prophylaxis of Candida infections in hematopoietic stem cell transplantation: 50mg qd

Pediatric(≧4 mons): IV infusion over 1hr
· Candidemia, disseminated candidiasis: 2mg/kg qd; Max. 100mg/day
· Esophageal candidiasis: ≦30kg: 3mg/kg qd, >30kg: 2.5mg/kg qd; Max. 150mg/day
· Prophylaxis of Candida infections in hematopoietic stem cell transplantation: 1mg/kg qd; Max. 50mg/day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 50mg Vial(31110)

ADR:

COMMON
Hypokalemia, diarrhea, nausea, vomiting, headache, fever
SERIOUS
Anemia, hemolysis, hemolytic anemia, intravascular hemolysis, hepatitis, liver failure, anaphylaxis, acute renal failure, acute renal impairment, serum blood urea nitrogen raised, serum creatinine raised

NOTE: 室溫儲存

· Should be administered by IV infusion over 1hr. Rapid infusion may increase the risk of a histamine-mediated reaction.
· Do not mix or co-infuse Mycamine* with other medications. Flush line with NS prior to administration.

藥名相似:

外觀相似:

外觀描述: 白色乾粉，『藍』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024509

06.08 Antifungal Agents

31113 ɔt be ruled out / Infant risk can

Eraxis for Injection 100mg 助黴飛注射劑 100 毫克

Anidulafungin inj 100mg pow in vial

Dosage: 1常備品 31113

Adult
·Candidemia, intra-abdominal or peritoneal candiasis: IV infusion, 200mg on day 1, followed by 100mg qd for at least 14 days after the last positive culture

·Esophageal candidiasis: IV infusion, 100mg on day 1, followed by 50mg qd for at least 14 days and for at least 7 days after symptom resolution; or 200mg on day 1, followed by 100mg qd for 14-21 days

Pediatric
Safety and efficacy have not been established in patients less than 16 years old

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 100mg Vial(31113)

ADR:

COMMON
Hypokalemia, diarrhea
SERIOUS
Deep venous thrombosis, abnormal liver function, hepatic necrosis, anaphylaxis, hypersensitivity reaction, seizure

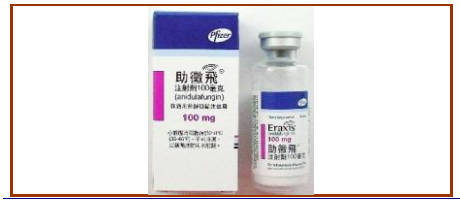
NOTE: 冰箱冷藏2-8oC，不可冷凍

· Infusion rate should not exceed 1.1mg/min. More rapid infusion may increase the risk of a histamine-mediated reaction.

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『灰』蓋透明玻璃小瓶



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024758

06.08 Antifungal Agents

37621 C / Infant risk can

POSANOL* 18mg/mL Concentrate for Solution for Infusion 波賽特 18毫克/毫升濃縮輸注液

急用Posaconazole 300mg/16.7mL vial

Dosage: 2急用藥 37621

Adult
· Second-line treatment for invasive aspergillosis in patients with disease refractory to or intolerant of conventional therapy, prophylaxis of invasive fungal infections in immunocompromised individuals: IV infusion over 90 mins via a central line with an in-line filter, 300mg bid on day 1 followed by 300mg qd thereafter

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

eGFR ≧ 50mL/min: No dosage adjustment needed
eGFR < 50mL/min: Avoid use unless benefit outweighs risk due to accumulation of IV vehicle sulfobutyl ether sodium. Monitor serum creatinine (SCr) levels closely; consider switch to oral therapy if SCr levels increase.

P: Tab: 100mg(21109); Susp: 40mg/mL, 105mL/B(28487); Inj: 300mg/16.7mL vial(急用藥, 37621)

ADR:

COMMON
Hypokalemia, diarrhea, nausea, vomiting, headache, fever
SERIOUS
Prolonged QT interval, Torsades de pointes, cholestasis (rare), liver failure (rare)

NOTE: 冰箱冷藏，不可冷凍。

· It is not indicated for the treatment of oropharyngeal candidiasis.
· Administer using a 0.22 micron polyethersulfone (PES) or polyvinylidene difluoride (PVDF) filter.
· Slow IV infusion over 90 mins via a central venous line (including a central venous catheter or peripherally inserted central catheter (PICC)). If a central venous catheter is unavailable, infusion through a peripheral line should only be used as a one-time infusion over 30 mins.

藥名相似:

外觀相似:

外觀描述: 透明注射液，『綠』蓋透明玻璃瓶

06.10 Antituberculosis Agents

21129 ɔt be ruled out / Infant risk can

(CDC二線TB)Delamanid 50mg tab

Dosage: 2衛福部提供 -CDC二線TB 21129

Adult
· Multidrug resistant tuberculosis: PO, 100mg bid for 24 wks in combination with an optimized MDR-TB regimen; continue optimized regimen after the 24-week delamanid treatment period

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild hepatic impairment: No dosage adjustment needed
Moderate to severe hepatic impairment: Use is not recommended

Dosing adjustments in renal impairment:

Mild or moderate renal impairment: No dosage adjustment needed
Severe renal impairment: Use is not recommended

P: Tab: 50mg(21129)

ADR:

COMMON
Palpitations, hyperuricemia, hypokalemia, decrease in appetite, diarrhea, nausea, upper abdominal pain,

vomiting, reticulocytosis, arthralgia, myalgia, asthenia, dizziness, headache, insomnia, paresthesia, tremor, tinnitus, hemoptysis
SERIOUS
Prolonged QT interval, drug resistance

NOTE: 室溫儲存

· It is recommended that electrocardiograms (ECG) should be obtained before initiation of treatment and monthly during treatment. If a QTcF >500 msec either before the first dose or during treatment, treatment with delamanid should either not be started or should be discontinued.

藥名相似:

外觀相似:

外觀描述:

06.10 Antituberculosis Agents

21130 C /

PYRAZINAMIDE TABLETS 500MG "P.L." "培力"匹井梭安錠５００毫克

Pyrazinamide 500mg (P.Z.A.)tab

Dosage: 1常備品 21130

Adult
· Tuberculosis: PO,
40-55kg: 1000mg qd, Max. 2g/day or 2000mg twice weekly, Max. 4g/dose or 1500mg three times weekly, Max. 3g/dose in combination with other antitubercular agents
56-75kg: 1500mg qd, Max. 2g/day or 3000mg twice weekly , Max. 4g/dose or 2500mg three times weekly, Max. 3g/dose in combination with other antitubercular agents
76-90kg: 2000mg qd, Max. 2g/day or 4000mg twice weekly, Max. 4g/dose or 3000mg three times weekly, Max. 3g/dose in combination with other antitubercular agents

Pediatric
· Tuberculosis: PO, 15-30mg/kg/day once daily, Max. 2g/day or 50mg/kg twice weekly up to a Max. 4g/dose in combination with other antitubercular agents

Dosing adjustments in hepatic impairment:

Dosage adjustment required.

Dosing adjustments in renal impairment:

Clcr 10-50mL/min: Use low end of the dosing range
Clcr <10mL/min: 7.5-15mg/kg/day
H/D: 25-35mg/kg tiw after dialysis
CAPD: No dosage adjustment needed

P: Tab: 500mg(21130); Tab: Rifater(21134)

ADR:

COMMON
Hyperuricemia, nausea, vomiting, arthralgia (40%)
SERIOUS
Anemia (rare), hepatotoxicity

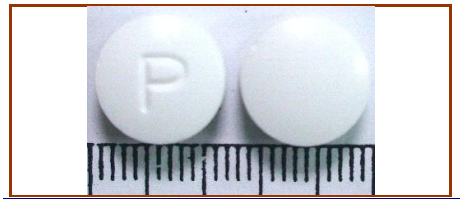
NOTE: 室溫儲存

Moniter liver function tests, serum uric acid

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有"P"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1038104

06.10 Antituberculosis Agents

21131 C / Infant risk is

RIFAMPIN CAPSULES 300MG "濟時"立汎黴素膠囊３００毫克

Rifampicin 300mg cap

Dosage: 1常備品 21131

Adult
· Tuberculosis: PO, ac, 10mg/kg/day qd or 10mg/kg/day twice weekly, Max. 600mg/day
· Latent tuberculosis(CDC建議適用對象為對isoniazid抗藥且rifampin敏感之接觸者-4R): PO, ac, 10mg/kg qd for 4 mons (120 days) by DOPT, Max. 600mg/day
· Prophylaxis for N. meningitidis: PO, 600mg q12h for 2 days, Max. 1200mg/day

Pediatric
· Tuberculosis: PO,ac, 10-20mg/kg/day div q12–24h or 10-20mg/kg/day twice weekly, Max. 600mg/day. Twice weekly therapy may be used after 1-2 mon of daily therapy
· Latent tuberculosis(CDC建議適用對象為對isoniazid抗藥且rifampin敏感之接觸者-4R): PO, ac, 10-20mg/kg qd for 4 mons (120 days) by DOPT, Max. 600mg/day
· Prophylaxis for N. meningitidis: PO,
0-1 mon: 10mg/kg/day div. q12h for 2 days
>1 mon: 20mg/kg/day div. q12h for 2 days

Dosing adjustments in hepatic impairment:

Serum bilirubin > 50 mmole/L: dosage reduction
Severe liver impairment : 6 to 8 mg/kg biweekly

Dosing adjustments in renal impairment:

· Not exceed 600mg/day
Clcr > 50mL/min: normal daily dose
Clcr 10-50mL/min: 50% to 100% of dose
Clcr < 10mL/min: 50% of dose

P: Cap: 150mg(21137), 300mg(21131); Tab: Rifater(21134); Inj: 500mg/10mL Amp(31120, 急用藥)

ADR:

NOTE: 室溫儲存

Rifampin usually should be administered 1 hour before or 2 hours after food to ensure max. absorption, adverse GI effects may be minimized by administering the drug during or immediately after a meal.

藥名相似:

外觀相似:

外觀描述: 紅色膠囊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1017594

06.10 Antituberculosis Agents

21132 **C / Infant risk is**

EPBUTOL TABLETS (ETHAMBUTOL) "YU SHENG" 易復癆錠（醫肺妥）

Ethambutol HCl (E.M.B.) 400mg tab

Dosage: 1常備品 21132

Adult & Children >13yrs
· Tuberculosis: PO, 15-25mg/kg/day, Max. 1.6g/day or 50mg/kg/dose twice weekly, 25-30mg/kg/dose, 3 times/week, Max. 2.4g/dose

Pediatric
Safety and efficacy have not been established in patients less than 13 years old

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 10-50mL/min: Administer q24-36h
Clcr< 10mL/min: Administer q48h

P: Tab: 400mg(21132)

ADR:

COMMON
Hyperuricemia, nausea, vomiting, mania
SERIOUS
Neutropenia, thrombocytopenia, anaphylactoid reaction, peripheral neuropathy, blindness and/or vision impairment level, optic neuritis

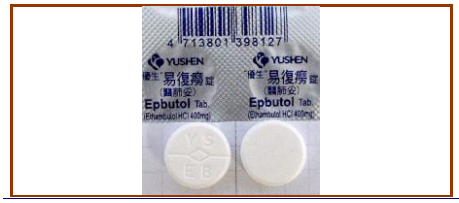
NOTE: 室溫儲存

·A four-drug regimen (isoniazid, rifampin, pyrazinamide, and either streptomycin or ethambutol) is preferred for the initial, empiric treatment of TB.
·視毒性-建議在病人開始治療前先進行視力檢查，治療期間宜每個月詢問病人是否有視力與辨色力障礙。使用劑量超過15mg/kg時，應每個月作視力檢查。

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面中央有菱形刻痕及YS及EB字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1019877

06.10 Antituberculosis Agents

21133 **C / Infant risk is**

ISONIAZIDE TABLETS 異菸鹼醯井錠

Isoniazid (INAH) 100mg tab

Dosage: 1常備品 21133

Adult
· Tuberculosis treatment: PO, 5mg/kg/day, Max. 300mg/day or 15mg/kg 2-3 times per week, Max. 900mg/dose
· Tuberculosis prophylaxis: PO, 300mg/day or 900mg twice weekly for 9 months

Pediatric
· Tuberculosis treatment: PO, 10-15mg/kg qd (Max. 300mg) or 20-30mg/kg twice weekly (Max. 900mg/dose)
· Tuberculosis prophylaxis: PO, 10-15mg/kg qd (Max. 300mg) or 20-30mg/kg twice weekly (Max. 900mg/dose) for 9 months

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 100mg(21133); Tab: Rifater(21134)

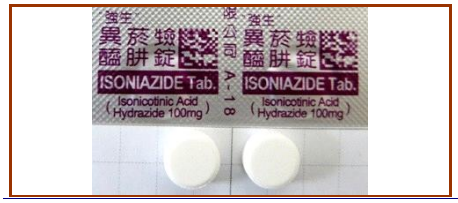
ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似: BETHANECHOL* 25mg Tab (22004)

外觀描述: 白色圓扁錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12000164

06.10 Antituberculosis Agents

21138 **B / Unsafe**

MYCOBUTIN 淨核膠囊150毫克

Rifabutin 150mg cap

Dosage: 1常備品 21138

Adult
· Prophylaxis of MAC infections in immunodepressed patients: PO, 300mg/day
· Non-tuberculosis mycobacterial disease (combination regimen): PO, 450~600mg/day
· Chronic multidrug-resistant pulmonary tuberculosis (combination regimen): PO, 300~450mg/day
· Newly-diagnosed pulmonary tuberculosis (combination regimen): PO, 150mg/day

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Clcr<30mL/min: Reduce dose by 50%

P: Cap: 150mg(21138)(27897, 二線TB用藥)

ADR:

NOTE: 室溫儲存

May discolor (brown-orange) bodily secretions; soft contact lens may be permanently stained

藥名相似:

外觀相似:

外觀描述: 咖啡色膠囊,有MYCOBUTIN及Pharmacia&Upjohn字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2020999

06.10 Antituberculosis Agents

21140 C / Caution

RINA CAPSULES "P.L." 利肺膠囊

Rifampicin 300mg [C], Isoniazid 150mg [a] cap

Dosage: 1常備品 21140

Adult

· Tuberculosis: PO, ac, 2 caps qd

Pediatric

Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Dosage should be adjusted with the individual components

Dosing adjustments in renal impairment:

NDA

P: Cap: Rina(21140); Tab: Rifater(21134); Tab: INAH 100mg(21133); Cap: RIF 150mg(21137), 300mg(21131); Inj: RIF 500mg/10mL Amp(31120, 急用藥)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 藍/紅色膠囊，有Peili C03字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1037167

06.10 Antituberculosis Agents

21170 C / Infant risk is

Isoniazid Tablets 300 mg "S.L.." "信隆" 異菸鹼醯肼錠300毫克

(CDC)Isoniazid (INAH) 300mg tab

Dosage: 2衛福部提供 21170

Adult

· Latent tuberculosis: PO, 15mg/kg in combination with rifapentine for 3 mons by DOT; Max. 900mg/dose

Pediatric

· Latent tuberculosis: PO, in combination with rifapentine for 3 mons by DOT
2-11 yrs: 25mg/kg qw; Max. 900mg/dose
≧12 yrs: 15 mg/kg qw; Max. 900mg/dose

Dosing adjustments in hepatic impairment:

3HP regimen for latent tuberculosis: NDA
Acute hepatic disease: Defer therapy for latent tuberculosis.

Dosing adjustments in renal impairment:

3HP regimen for latent tuberculosis: NDA

P: Tab: 100mg(21133), 300mg(21170,疾管署提供); Tab: Rifater(21134); Cap: Rina(21140)

ADR:

COMMON
Increased liver enzymes, neuropathy, neurotoxicity
SERIOUS
Rash, agranulocytosis, anemia, thrombocytopenia, severe hepatitis, hepatotoxicity, injury of liver, systemic lupus erythematosus, rhabdomyolysis, seizure

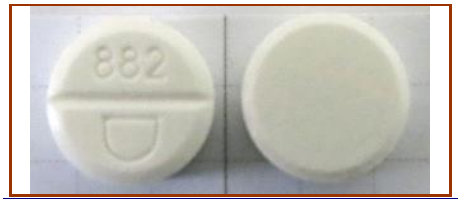
NOTE: 室溫儲存

· 3HP regimen: A combination regimen of isoniazid and rifapentine given weekly for 3 mons (12 wks) under directly observed therapy (DOT).
· The interval between doses must be > 72 hrs and there should be no more than 5 doses in a 28-day period.
· Recommended dose of rifapentine as 3HP regimen:
(1)Adults 25.1-32 kg: 600mg qw; 32.1-50kg: 750mg qw; >50kg: 900mg qw
(2)Children (? 2 yrs): 10-14kg: 300mg qw; 14.1-25kg: 450mg qw; 25.1-32 kg: 600mg qw; 32.1-50kg: 750mg qw; >50kg: 900mg

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠,一面有一刻痕和 882 字樣



06.10 Antituberculosis Agents

21171 C / Unsafe

PRIFTIN* 150mg film-coated tablets 肺挺膜衣錠150毫克

(CDC)Rifapentine 150mg tab

Dosage: 2衛福部提供 21171

Adult

· Latent tuberculosis: PO, in combination with isoniazid for 3 mons by DOT
25.1-32 kg: 600mg qw
32.1-50kg: 750mg qw
>50kg: 900mg qw

Pediatric (≧ 2 yrs)
· Latent tuberculosis: PO, in combination with isoniazid for 3 mons by DOT
10-14kg: 300mg qw
14.1-25kg: 450mg qw
25.1-32 kg: 600mg qw
32.1-50kg: 750mg qw
>50kg: 900mg

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 150mg(21171)

ADR:

COMMON
Rash, clostridium difficile diarrhea, anemia, ALT/SGPT level raised, AST/SGOT level raised, lymphocytopenia, arthralgia, headache, conjunctivitis, hemoptysis, red/orange discoloration of body tissues or fluids
SERIOUS
Neutropenia, hepatotoxicity, hypersensitivity reaction

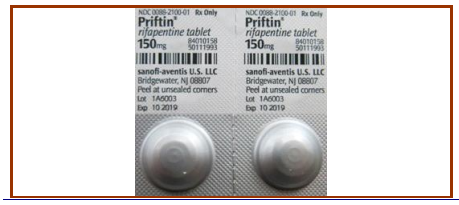
NOTE: 室溫儲存

· It may produce a red-orange discoloration of body fluids.
· 3HP regimen: A combination regimen of isoniazid and rifapentine given weekly for 3 mons (12 wks) under directly observed therapy (DOT).
· The interval between doses must be > 72 hrs and there should be no more than 5 doses in a 28-day period.
· Recommended dose of isoniazid as 3HP regimen:
(1)Adults and children ?12 yrs: 15 mg/kg qw; Max. 900mg/dose
(2)Children 2-11 yrs: 25mg/kg qw; Max. 900mg/dose

藥名相似:

外觀相似:

外觀描述:



06.10 Antituberculosis Agents

27640 ɔt be ruled out / Infant risk is

RIFINAH* 150 S.C.TABLETS 樂肺寧糖衣錠150毫克

急用⊙Rifampicin 150mg [C], Isoniazid 100mg [a] tab

Dosage: 2急用藥 27640

Adult (BW≦50 kg)
· Tuberculosis: PO, ac, 3 tabs qd

Pediatric (BW≦50 kg)
Same as Adult

Dosing adjustments in hepatic impairment:

Dosage should be adjusted with the individual components

Dosing adjustments in renal impairment:

NDA

P: P Tab: Rifinah(27640, 急用藥); Cap: Rina(21140); Tab: Rifater(21134); Tab: INAH 100mg(21133); Cap: RIF 300mg(21131); Inj: RIF 500mg/10mL Amp(31120, 急用藥)

ADR:

· Rifampicin
SERIOUS
Agranulocytosis, disseminated intravascular coagulation, hepatotoxicity, anaphylaxis, drug reaction with eosinophilia and systemic symptoms, hypersensitivity reaction, nephrotoxicity, renal failure
· Isoniazid
COMMON
Increased liver enzymes, neuropathy, neurotoxicity
SERIOUS
Rash, agranulocytosis, anemia, thrombocytopenia, severe hepatitis, hepatotoxicity, injury of liver, systemic lupus erythematosus, rhabdomyolysis, seizure

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 桃紅色圓凸糖衣錠

06.10 Antituberculosis Agents

27902 /

(CDC二線TB)Prothionamide 250mg tab

Dosage: 2衛福部提供 -CDC二線TB 27902

Adult
· Tuberculosis: PO, 15-20mg/kg/day divided in 2-3 doses; Max. 1g/day

Pediatric
· Tuberculosis: PO, 15-20mg/kg/day divided in 2-3 doses; Max. 1g/day

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Tab: 250mg(27902)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 橘色圓凸膜衣錠，一面中央有刻痕

06.10 Antituberculosis Agents

27955 C /

CYCLOCIN CAPSULES "P.L." "培力" 立環素膠囊

(CDC二線TB)Cycloserine 250mg cap

Dosage: 2衛福部提供 27955
-CDC二線TB

Adult
· Tuberculosis: PO, 10-15mg/kg/day in 2 divided doses, Max. 1g/day

Pediatric
· Tuberculosis: PO, 10-20mg/kg/day in 2 divided doses

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 10-50mL/min: Administer q12-24h
Clcr <10mL/min: Administer q24h

P: Cap: 250mg(27955)

ADR:

COMMON
Confusion, dizziness, headache, somnolence
SERIOUS
Seizure

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 紅色/橘色膠囊

06.10 Antituberculosis Agents

27965 C / Caution

Lamprene* 100mg cap 膠囊

(CDC二線TB)Clofazimine 100mg cap

Dosage: 2衛福部提供 27965
-CDC二線TB

Adult
·Erythema nodosum leprosum: PO, 100-200mg qd for up to 3 months to facilitate corticosteroid dose reduction or elimination; taper dose to 100mg as soon as reactive episode is controlled
·Tuberculosis: PO, 100-300mg/day (依治療計畫書)

Pediatric
·Tuberculosis: PO, 1mg/kg/day (依治療計畫書)

Dosing adjustments in hepatic impairment:

Severe hepatic impairment: Dose adjustments may be required

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: 100mg(27965)

ADR:

COMMON
Drug-induced pigmentation, dry skin, pruritus, rash, drug-induced gastrointestinal disturbance, nausea, vomiting, conjunctival pigmentation, corneal pigmentation, abnormal color of body fluids
SERIOUS
Bowel obstruction, gastrointestinal hemorrhage, severe gastrointestinal symptom, crystalline deposits of clofazimine, reactive depression due to skin discoloration, splenic infarction

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 褐色長橢圓形膠囊，有GEIGY及GM字樣

06.10 Antituberculosis Agents

27966 UK /

TERIZIDON* 250mg cap 膠囊

(CDC二線TB)Terizidone 250mg cap

Dosage: 2衛福部提供 27966
-CDC二線TB

Adult
· Tuberculosis: PO, 750-1000mg/day in 3-4 divided doses

Pediatric(≧14 yrs)
· Tuberculosis: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: 250mg(27966)

ADR:

Headache, dizziness, excitability, tremor, sleeplessness, sensation of inebriation, epileptoid convulsions, psychosis-like states, mild gastrointestinal discomfort (e.g. nausea, abdominal pain, flatulence, diarrhea, constipation), skin rash

NOTE:

藥名相似:

外觀相似:

外觀描述:

06.10 Antituberculosis Agents

27967 C / Caution

Paser* granules 4g/pack 顆粒劑

(CDC二線TB)P-aminosalicylic acid delayed release granules 4g/pack

Dosage: 2衛福部提供 -CDC二線TB 27967

Adult
· Tuberculosis: PO, 4g q8h

Pediatric
· Tuberculosis: PO, 200-300mg/kg/day in 2-4 divided doses

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Dosage adjustment required

P: Tab: 500mg(27903), Granules: 4g/pack(27967)

ADR:

COMMON
Abdominal pain, diarrhea, nausea, vomiting, immune hypersensitivity reaction, rash with fever
SERIOUS
Thrombocytopenia, hepatotoxicity

NOTE: 冰箱儲存

· Do not chew the granules
· It should be administered in an acidic food or drink having a pH<5, such as applesauce, yogurt or fruit juice(eg, tomato, orange, grapefruit, grape, cranberry, apple juice or fruit punch)
· Acidic foods or drinks will protect the acid-resistant coating for at least 2 hours
· It does not have to be taken with acidic food or drink if concurrent use with antacids

藥名相似:

外觀相似:

外觀描述: 白色紙包裝上有黑色"PASER"字樣

06.10 Antituberculosis Agents

27971 C / Unsafe

PAS Calcium Granules "P.L." "培力" 欣鈣派斯顆粒

(CDC二線TB)Calcium Para-aminosalicylate granules 5g/pack

Dosage: 2衛福部提供 -CDC二線TB 27971

Adult
· Tuberculosis: PO, 10-15g/day in 2-3 divided doses

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Dosage adjustment required

P: Granules: 5g/pack(27971)

ADR:

COMMON
Abdominal pain, diarrhea, nausea, vomiting, immune hypersensitivity reaction, rash with fever
SERIOUS
Thrombocytopenia, hepatotoxicity

NOTE: 25℃以下避光保存

· 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述:

06.10 Antituberculosis Agents

27999 ɔt be ruled out / Infant risk can

(CDC二線TB) Bedaquiline 100mg tab

Dosage: 2衛福部提供 -CDC二線TB 27999

Adult
· Tuberculosis: PO, 400 mg qd for 2 weeks, then 200 mg 3 times weekly (separated by at least 48 hours between doses) for 22 weeks (total duration of 24 weeks)

Pediatric
Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Mild to moderate impairment(Child-Pugh A or B):
No dosage adjustment needed
Severe impairment: Use with caution (has not been studied)

Hepatotoxicity during treatment:
New or worsening liver function (aminotransferase and total bilirubin > 2X ULN, aminotransferase elevations > 8X ULN, aminotransferase elevations > 5X ULN and persist for longer than 2 weeks):
Discontinue therapy

Dosing adjustments in renal impairment:

Mild to moderate impairment: No dosage adjustment needed
Severe impairment or ESRD requiring hemodialysis or peritoneal dialysis: Use with caution

P: Tab: 100mg(27999)

ADR:

COMMON
Chest pain, abdominal pain, nausea, arthralgia, headache, hemoptysis
SERIOUS
Prolonged QT interval, increased liver enzymes

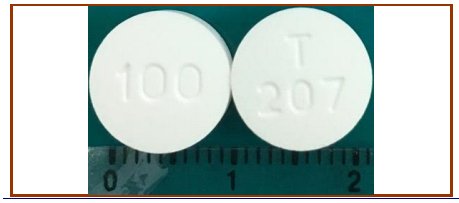
NOTE: 室溫儲存

· It should be swallowed whole.
· Use in combination with at least 3 other agents known to be active against the TB isolate. If susceptibility testing is not available, it may be used in combination with at least 4 other agents for which susceptibility is likely.
· Store tablets dispensed outside the original container in a tight light-resistant container with an expiration date not to exceed 3 months.

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有"100"字樣，另一面有"T 207"字樣



06.12A1 Antiretroviral Agents - NRTI

21150 **C / Unsafe**

COMBIVIR TABLETS 卡貝滋錠

Lamivudine 150mg & zidovudine 300mg tab

Dosage: 1常備品 21150

Adult
· HIV infection: PO, 1 tablet bid

Pediatric(≧30 kg)
· HIV infection: PO, 1 tablet bid

Dosing adjustments in hepatic impairment:

Fixed-dose combination is not recommended

Dosing adjustments in renal impairment:

Dosage adjustment required; use of each agent independently is indicated

P:

ADR:

COMMON
Rash, abdominal pain, diarrhea, loss of appetite, nausea, vomiting, musculoskeletal pain, myalgia, dizziness, headache, insomnia, neuropathy, sleep disorder, fatigue, cough, nasal symptoms OS, fever
SERIOUS
Erythema multiforme, Stevens-Johnson syndrome, lactic acidosis, pancreatitis, anemia, neutropenia, severe hepatomegaly, severe steatosis of liver, anaphylaxis, immune hypersensitivity reaction, rhabdomyolysis

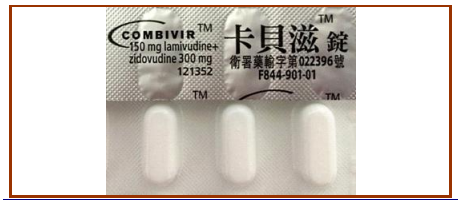
NOTE: 室溫儲存

1. It is not recommended in children under 12 years of age, patients with a body weight under 30kg or with a clinical need for dose adjustments (ie, renal or hepatic impairment or dose-limiting adverse effects).
2. It is contraindicated in patient with abnormally low neutrophil count (<0.75×109/L) or abnormally low haemoglobin levels (<7.5g/dL or 4.65mmol/L).

藥名相似:

外觀相似:

外觀描述: 白色長橢圓錠，有GX FC3字樣



06.12A1 Antiretroviral Agents - NRTI

27801 **C /**

RETROVIR 100MG CAPSULES 立妥威膠囊100毫克

急用Zidovudine (AZT) 100mg cap

Dosage: 2急用藥 27801

Adult
· HIV infection: PO, 600mg daily in divided dose.(200mg q8h or 300mg q12h).
· Prevention of maternal-fetal transmission: pregnant women, PO, initial 100mg 5 times or 200mg q8h at 14-34 weeks of pregnancy until labor.

Pediatric
· HIV infection:
Full-term neonates: PO, 2mg/Kg q6h
6wks -12yrs: PO, 160mg/m2 q8h; Max. 200mg/m2 q8h
>12yrs: PO, 600mg daily in divided dose.
· Prevention of maternal-fetal transmission:neonates, PO, initial 2mg/kg q6h as soon as possible after delivery continue through 6 weeks of age.

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

CLcr<15 mL/min: 100mg every 6-8 hours

P: Tab: Combivir(27809); Cap:100mg(27801, 急用藥); Syrup: 10mg/mL, 240mL/Bot (28994, 急用藥) (28990 CDC提供預防垂直感染); Inj: 200mg/20mL Vial(37753 CDC提供預防垂直感染)

ADR:

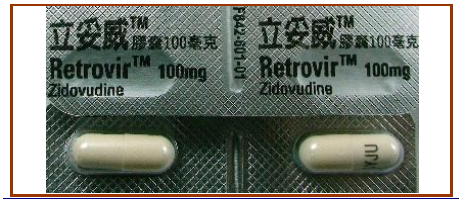
COMMON
Loss of appetite, nausea, vomiting, headache, cough, fever, malaise
SERIOUS
Lactic acidosis, anemia, granulocytopenic disorder, neutropenia, hepatomegaly, steatosis of liver, disorder of muscle

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色膠囊，有GSYJU字樣



06.12A1 Antiretroviral Agents - NRTI

27804 C / Unsafe

3TC FILM COATED TABLETS 150MG 速汰滋膜衣錠１５０毫克

Lamivudine 150mg FC tab

Dosage: 1常備品 27804

Adult
· HIV infection: PO, 150mg bid or 300mg qd

Pediatric
· HIV infection:
Neonates< 30 day: PO, 2mg/kg bid
3 mons-16 yrs: PO, 4mg/kg bid; Max. 150mg bid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

· HIV infection(>16 yrs):
Clcr 30-49mL/min: 150mg qd
Clcr 15-29mL/min: 150mg first dose, then 100mg qd Clcr 5-14mL/min: 150mg first dose, then 50mg qd
Clcr < 5mL/min: 50mg first dose, then 25mg qd

P: Tab: 100mg(21141), 150mg(27804); Tab: Combivir(27809), Kivexa(27815); Soln: 10mg/mL, 240mL/B(28995, 急用藥)

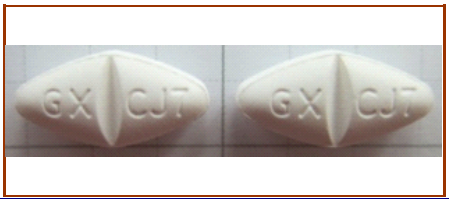
ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色菱形扁錠，中央有刻痕，有GX CJ7字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022075

06.12A1 Antiretroviral Agents - NRTI

27823 B / Unsafe

Viread Tablets 惠立妥膜衣錠

Tenofovir disoproxil fumarate 300mg tab

Dosage: 1常備品 27823

Adult
· HIV infection: PO, 300mg qd with other antiretroviral agents
· Chronic hepatitis B: PO, 300mg qd. The optimum duration is unknown

Pediatric(≧2yrs)
· HIV infection: PO, 8 mg/kg qd Max. 300 mg

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 30-49 mL/min: 300mg q48h
Clcr 10-29 mL/min: 300mg q72-96h
Clcr<10 mL/min: No dosing recommendation

P: Tab: 300mg (27823), Tab: ATRIPLA*(21153), COMPLERA*(21155), TRUVADA*(21152)

ADR:

COMMON
Pruritus, rash, abdominal pain, diarrhea, nausea, vomiting, asthenia, dizziness, headache, insomnia, depression, fever, pain
SERIOUS
Lactic acidosis, hepatitis B, hepatomegaly with steatosis, angioedema, immune reconstitution syndrome, acute renal failure, fanconi syndrome, nephrogenic diabetes insipidus, renal impairment, acute tubular necrosis

NOTE: 室溫儲存

· Tenofovir disoproxil fumarate 300mg is equivalent to tenofovir disoproxil 245mg.
· Do not use concurrently with adefovir or other tenofovir combination products.
·Avoid concurrent or recent use of nephrotoxic agents. (eg, high-dose or multiple NSAIDs)
·Proximal renal tubulopathy associated with osteomalacia may occur and may be characterized by pain in the extremities, worsening bone pain, fractures, muscular pain, or weakness; immediate evaluation of renal function recommended.

藥名相似:

外觀相似:

外觀描述: 淡藍色杏仁狀錠，一面有GILEAD 4331字樣，另一面有300字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024690

06.12A1 Antiretroviral Agents - NRTI

28990 C /

RETROVIR SYRUP 立妥威溶液劑

Zidovudine Syrup 10mg/mL, 240mL/bot

Dosage: 2衛福部提供 28990

Adult
· HIV infection: PO, 20mL(200mg) tid or 30mL(300mg) bid
· HIV infection, perinatal exposure; prophylaxis: PO,

10mL(100mg) 5 times/day or 20mL(200mg) tid or 30mL(300mg) bid (starting after week 14 of pregnancy) until labor, then 2mg/kg IV over 1hr followed by 1mg/kg/hr IV infusion during labor and until umbilical cord clamping

· HIV infection, perinatal exposure; prophylaxis (women with no prior antiretroviral therapy): PO, lamivudine 150mg plus zidovudine 60mL(600mg) to the mother at onset of labor, followed by lamivudine 150mg q12h plus zidovudine 30mL(300mg) q3h until delivery

Pediatric

· HIV infection:

Preterm neonates(< 35wks): PO, 2mg/kg q12h(if >30wks at birth, advance to q8h at 2 wks of age;if <30wks at birth, advance to q8h at 4 wks of age)

Full-term neonates: PO, 2mg/kg q6h

6 wks-12 yrs: PO, 160mg/m(2) q8h; Max. 200mg q8h

· HIV infection, perinatal exposure; prophylaxis: PO, full term neonate should receive 2mg/kg q6h starting 12 hours after birth, continuing until 6 weeks of age; the preterm neonate should receive 2mg/kg q12h(if >30wks at birth, advance to q8h at 2 wks of age;if <30wks at birth, advance to q8h at 4 wks of age)

· HIV infection, perinatal exposure; prophylaxis (women with no prior antiretroviral therapy): PO, postpartum, the neonate should receive lamivudine 2mg/kg plus zidovudine 4mg/kg q12h for 7 days

Dosing adjustments in hepatic impairment:

50% decrease in dose or double dosing interval in patients with cirrhosis

Dosing adjustments in renal impairment:

Clcr<15mL/min (maintained on H/D or P/D): 100mg q6-8h

P: Tab: Combivir(27809); Cap:100mg(27801, 急用藥); Syrup: 10mg/mL, 240mL/Bot (28994, 急用藥) (28990 CDC提供預防垂直感染); Inj: 200mg/20mL Vial(37753 CDC提供預防垂直感染)

ADR:

COMMON

Constipation, loss of appetite, nausea, vomiting, asthenia, headache, insomnia, malaise

SERIOUS

Lactic acidosis, anemia, neutropenia, hepatomegaly, steatosis of liver, drug-induced myopathy

NOTE: 室溫儲存

· Contraindication: Hb<7.5g/dL or neutrophil< 750 cells/mm(3)

· 本品賦形劑不含阿斯巴甜

藥名相似:

外觀相似:

外觀描述: 240mL溶液,白色塑膠瓶,藍底白字及黑字標簽

06.12A1 Antiretroviral Agents - NRTI

28994 C /

RETROVIR SYRUP 立妥威溶液劑

急用Zidovudine Syrup 10mg/mL, 240mL/bot

Dosage: 2急用藥 28994

Adult

· HIV infection: PO, 20mL(200mg) tid or 30mL(300mg) bid

· HIV infection, perinatal exposure; prophylaxis: PO, 10mL(100mg) 5 times/day or 20mL(200mg) tid or 30mL(300mg) bid (starting after week 14 of pregnancy) until labor, then 2mg/kg IV over 1hr followed by 1mg/kg/hr IV infusion during labor and until umbilical cord clamping

· HIV infection, perinatal exposure; prophylaxis (women with no prior antiretroviral therapy): PO, lamivudine 150mg plus zidovudine 60mL(600mg) to the mother at onset of labor, followed by lamivudine 150mg q12h plus zidovudine 30mL(300mg) q3h until delivery

Pediatric

· HIV infection:

Preterm neonates(< 35wks): PO, 2mg/kg q12h(if >30wks at birth, advance to q8h at 2 wks of age;if <30wks at birth, advance to q8h at 4 wks of age)

Full-term neonates: PO, 2mg/kg q6h

6 wks-12 yrs: PO, 160mg/m(2) q8h; Max. 200mg q8h

· HIV infection, perinatal exposure; prophylaxis: PO, full term neonate should receive 2mg/kg q6h starting 12 hours after birth, continuing until 6 weeks of age; the preterm neonate should receive 2mg/kg q12h(if >30wks at birth, advance to q8h at 2 wks of age;if <30wks at birth, advance to q8h at 4 wks of age)

· HIV infection, perinatal exposure; prophylaxis (women with no prior antiretroviral therapy): PO, postpartum, the neonate should receive lamivudine 2mg/kg plus zidovudine 4mg/kg q12h for 7 days

Dosing adjustments in hepatic impairment:

50% decrease in dose or double dosing interval in patients with cirrhosis

Dosing adjustments in renal impairment:

Clcr<15mL/min (maintained on H/D or P/D): 100mg q6-8h

P: Tab: Combivir(27809); Cap:100mg(27801, 急用藥); Syrup: 10mg/mL, 240mL/Bot (28994, 急用藥) (28990 CDC提供預防垂直感染); Inj: 200mg/20mL Vial(37753 CDC提供預防垂直感染)

ADR:

COMMON

Constipation, loss of appetite, nausea, vomiting, asthenia, headache, insomnia, malaise

SERIOUS

Lactic acidosis, anemia, neutropenia, hepatomegaly, steatosis of liver, drug-induced myopathy

NOTE: 室溫儲存

· Contraindication: Hb<7.5g/dL or neutrophil< 750 cells/mm(3)

· 本品賦形劑不含阿斯巴甜

藥名相似:

外觀相似:

外觀描述: 240mL溶液,白色塑膠瓶,藍底白字黑字標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022014

06.12A1 Antiretroviral Agents - NRTI

28995 **C / Unsafe**

3TC ORAL SOLUTION 速汰滋 內服液劑

急用Lamivudine soln 10mg/mL, 240mL/bot

Dosage: 2急用藥 28995

Adult

· HIV infection: PO, 15mL(150mg) bid or 30mL (300mg) qd

· HIV infection, perinatal exposure; prophylaxis: PO, lamivudine 15mL(150mg) plus zidovudine 600mg to the mother at onset of labor, followed by lamivudine 15mL(150mg) q12h plus zidovudine 300mg q3h until delivery

Pediatric

· HIV infection:

Neonates< 30 days: PO, 2mg/kg bid

3 mons-16 yrs: PO, 4mg/kg bid; Max. 150mg bid

· HIV infection, perinatal exposure; prophylaxis: PO, postpartum, the neonate should receive lamivudine 2mg/kg plus zidovudine 4mg/kg q12h for 7 days

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

· HIV infection(>16 yrs):

Clcr 30-49mL/min: 150mg qd

Clcr 15-29mL/min: 150mg first dose, then 100mg qd Clcr 5-14mL/min: 150mg first dose, then 50mg qd

Clcr < 5mL/min: 50mg first dose, then 25mg qd

· HIV infection(pediatric): Dose adjustment and/or an increase in the dosing interval should be considered

P: Tab: 100mg(21141), 150mg(27804); Tab: Combivir(27809), Kivexa(27815); Soln: 10mg/mL, 240mL/B(28995, 急用藥)

ADR:

COMMON

Lipodystrophy, fatigue, headache, decrease in appetite, nausea, vomiting

SERIOUS

Lactic acidosis, hepatomegaly, relapsing type B viral hepatitis, pancreatitis

NOTE: 室溫儲存

· 本品賦形劑不含阿斯巴甜

藥名相似:

外觀相似:

外觀描述: 240mL溶液,白色塑膠瓶,白底黑字標籤有淺綠色區塊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022074

06.12A1 Antiretroviral Agents - NRTI

37753 **C /**

Zidovudine 200mg/20mL vial

Dosage: 2衛福部提供 37753

Adult

· HIV infection: IV, 1mg/kg 5-6 times/day

· HIV infection, perinatal exposure; prophylaxis: IV, 2mg/kg over 1hr followed by 1mg/kg/hr IV infusion during labor and until umbilical cord clamping

· HIV infection, perinatal exposure; prophylaxis (women with no prior antiretroviral therapy): IV, zidovudine 2mg/kg over 1 hr followed by 1mg/kg/hr until delivery, and nevirapine 200mg orally as a single dose at onset of labor

Pediatric

· HIV infection:

Preterm neonates(<35 wks): IV, 1.5mg/kg q12h(if >30wks at birth, advance to q8h at 2 wks of age;if <30wks at birth, advance to q8h at 4 wks of age)

Full-term neonates: IV, 1.5mg/kg q6h

>90 days: IV, 120mg/m(2) q6h or 20mg/m(2)/hr by continuous infusion

· HIV infection, perinatal exposure; prophylaxis: IV, full term neonate should receive 1.5mg/kg q6h starting 12 hours after birth, continuing until 6 weeks of age; the preterm neonate should receive 1.5mg/kg q12h(if >30wks at birth, advance to q8h at 2 wks of age;if <30wks at birth, advance to q8h at 4 wks of age)

Dosing adjustments in hepatic impairment:

50% decrease in dose or double dosing interval in patients with cirrhosis

Dosing adjustments in renal impairment:

Clcr<15mL/min (maintained on H/D or P/D): 1mg/kg q6-8h

P: Tab: Combivir(27809); Cap:100mg(27801, 急用藥); Syrup: 10mg/mL, 240mL/Bot (28994, 急用藥) (28990 CDC提供預防垂直感染); Inj: 200mg/20mL Vial(37753 CDC提供預防垂直感染)

ADR:

COMMON

Constipation, loss of appetite, nausea, vomiting, asthenia, headache, insomnia, malaise

SERIOUS

Lactic acidosis, anemia, neutropenia, hepatomegaly, steatosis of liver, drug-induced myopathy

NOTE: 室溫儲存

1.Contraindication: Hb<7.5g/dL or neutrophil< 750 cells/mm(3)

2.Infuse over 1 hour; avoid rapid infusion or bolus injection; do not give IM

藥名相似:

外觀相似:

外觀描述:

06.12A2 Antiretroviral Agents - NNRTI

27830 **B / Unsafe**

Intelence Tablets 100mg 英特萊錠 100 毫克

急用Etravirine 100mg tab

Dosage: 2急用藥 27830

Adult

· HIV infection in treatment-experienced patients: PO, 200mg bid with other antiretroviral agents

Pediatric(≧6 yrs)

· HIV infection in treatment-experienced patients: PO,
16-20 kg: 100mg bid with other antiretroviral agents
20-25 kg: 125mg bid with other antiretroviral agents
25-30 kg: 150mg bid with other antiretroviral agents
≧30 kg: Same as adult

Dosing adjustments in hepatic impairment:

Mild to moderate hepatic impairment(Child-Pugh class A to B): No dosage adjustment needed; use with caution in patients with moderate impairment
Severe hepatic impairment (Child-Pugh class C): Not recommended

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 100mg(27830)

ADR:

COMMON
Rash, ALT/SGPT level raised, AST/SGOT level raised, paresthesia, peripheral neuropathy
SERIOUS
Myocardial infarction, erythema multiforme, rash, Stevens-Johnson syndrome, toxic epidermal necrolysis, hepatitis, hypersensitivity reaction, immune reconstitution syndrome

NOTE: 室溫儲存

· Swallow whole. If unable to swallow, disperse the tablets in a glass of water, stir well and drink immediately. Rinse glass several times to ensure administration of complete dose.

藥名相似:

外觀相似:

外觀描述: 白色橢圓形錠,有T125及100字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025081

06.12A2 Antiretroviral Agents - NNRTI

28997 **B /**

VIRAMUNE ORAL SUSPENSION 50MG/5ML 衛滋 內服懸液

急用Nevirapine susp 10mg/mL, 240mL/bot

Dosage: 2急用藥 28997

Adult

· HIV infection: PO, 20mL(200mg) qd for 14 days, then 20mL(200mg) bid

· HIV infection, Perinatal exposure; Prophylaxis (women with no prior antiretroviral therapy) - 1: PO, single dose 20mL(200mg) at the onset of labor

· HIV infection, Perinatal exposure; Prophylaxis (women with no prior antiretroviral therapy) - 2: zidovudine IV 2mg/kg over 1 hr followed by 1mg/kg/hr until delivery, and nevirapine PO, 200 mg as a single dose at onset of labor

Pediatric

· HIV infection:
Neonates(<2 mons): PO, 120mg/m2 (or 5mg/kg) qd for 14 days, then 120mg/m2 q12h for 14 days, then 200 mg/m2 q12h
2 mons-8 yrs: PO, 4mg/kg (or 120mg/m2) qd, (Max. 200mg/day) for 14 days, then 7mg/kg (or 120-200mg/m2) bid (Max. 200mg bid)
8 yrs and older: PO, 4mg/kg qd for 14 days then 4 mg/kg bid; Max. 400mg/day.

· HIV infection, Perinatal exposure; Prophylaxis (women with no prior antiretroviral therapy) - 1: PO, 2mg/kg dose administered to the newborn within 48-72 hours of birth; if nevirapine was administered to the mother less than 1 hour prior to delivery, the newborn should receive 2 mg/kg as soon as possible after birth and again at 48-72 hours after birth

· HIV infection, Perinatal exposure; Prophylaxis (women with no prior antiretroviral therapy) - 2: PO, postpartum, the neonate should receive zidovudine 2mg/kg q6h for 6 wks and nevirapine 2mg/kg as a single dose at age 48-72 hr

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Clcr 20mL/min or greater: No dosage adjustment needed
Clcr <20mL/min(not receiving dialysis): NDA

P: Tab: 200mg(27808); Susp: 10mg/mL, 240mL/Bot(28992 CDC提供預防垂直感染) (28997, 急用藥)

ADR:

COMMON
Headache, fatigue,diarrhea, nausea, rash (most common), fat redistribution (less common)
SERIOUS
Hepatitis, hepatic failure, severe skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis)

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023049

06.12A3 Antiretroviral Agents - PI

27816 **C / Unsafe**

Kaletra Tablets 快利佳錠劑

Lopinavir 200mg & Ritonavir 50mg tab

Dosage: 1常備品 27816

Adult
· HIV infection(therapy-na?ve): PO, 400/100mg (2 tablets) twice daily or 800/200mg (4 tablets) once daily
· HIV infection(therapy-experienced): PO, 400/100mg (2 tablets) twice daily
· HIV infection(concurrent with efavirenz, fosamprenavir, nevirapine or nelfinavir): PO, 400/100mg (2 tablets) twice daily in therapyl-na?ve patients; 600/150mg (3 tablets) twice daily in therapy-experienced patients

Pediatric (6mons-18yrs)
· HIV infection: PO,
<15kg: 12mg/kg of lopinavir and 3mg/kg of ritonavir bid
15-40kg: 10mg/kg of lopinavir and 2.5mg/kg of ritonavir bid
>40kg: 400mg of lopinavir and 100mg of ritonavir bid
· HIV infection(concurrent with efavirenz, fosamprenavir, nevirapine or nelfinavir): PO,
<15kg: 13mg/kg of lopinavir and 3.25mg/kg of ritonavir bid
15-45kg: 11mg/kg of lopinavir and 2.75mg/kg of ritonavir bid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: Lopinavir 200mg & Ritonavir 50mg(27816); Cap: Ritonavir 100mg(27807)

ADR:

COMMON
Asthenia, headache, diarrhea, nausea, lipodystrophy
SERIOUS
Diabetes mellitus, hyperglycemia, hypertriglyceridemia, serum total cholesterol raised, hepatotoxicity, pancreatitis

NOTE: 室溫貯存

· Swallow whole; do not break, crush or chew (Crushing is not recommended by the manufacturer as pre-clinical studies showed poor absorption with this method of administration)
· Once-daily dosing is not recommended in therapy-experienced adult patients or when used concurrently with efavirenz, nevirapine, (fos)amprenavir or nelfinavir

藥名相似: Tab: Lopinavir 200mg & Ritonavir 50mg(2781

外觀相似: Stocrit* 600mg(27813)

外觀描述: 土黃色長橢圓錠，有KA字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024560

06.12A3 Antiretroviral Agents - PI

27818 **B / Infant risk can**

REYATAZ CAPSULES 200MG 瑞塔滋膠囊

Atazanavir 200mg cap

Dosage: 1常備品 27818

Adult
· HIV infection(antiretroviral-na?ve): PO, 300mg qd plus ritonavir 100mg qd or 400mg qd with meals in patients unable to tolerate ritonavir
· HIV infection(antiretroviral-experienced): PO, 300mg qd and ritonavir 100mg qd with meals
· HIV infection(coadministration with efavirenz): PO, 400mg qd and ritonavir 100mg qd and efavirenz 600mg qd; atazanavir without ritonavir should not be coadministered with efavirenz

Pediatric
· HIV infection(≧6y): PO,
15-20kg: atazanavir 150mg qd and ritonavir 100mg qd
20-40kg: atazanavir 200mg qd and ritonavir 100mg qd
≧40kg: atazanavir 300mg qd and ritonavir 100mg qd
· HIV infection(antiretroviral-naive): PO,
≧13yrs, ≧40kg: 400mg qd in patients unable to tolerate ritonavir

Dosing adjustments in hepatic impairment:

Moderate impairment (Child-Pugh Class B): 300mg qd
Severe impairment (Child-Pugh Class C): Not recommended

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: 150mg(27814), 200mg(27818)

ADR:

COMMON
Rash, abdominal pain, diarrhea, nausea,vomiting, ALT/SGPT level raised, hyperbilirubinemia, jaundice, serum amylase raised, myalgia, headache, scleral icterus, cough, fever
SERIOUS
Atrioventricular block, prolonged PR interval, erythema multiforme, Stevens-Johnson syndrome, diabetes mellitus, hyperglycemia, blood coagulation disorder, decreased hemoglobin (grade 3 or 4), neutropenia (grade 3 or 4), cholelithiasis, drug reaction with eosinophilia and systemic symptoms, immune reconstitution syndrome, nephrolithiasis

NOTE: 室溫儲存

· Administer atazanavir at least 2 hrs prior and at least 10 hrs after the H2- receptor antagonist
· Administer atazanavir at least 2 hrs before or 1 hr after Al-, Ca- or Mg-containing antacids

藥名相似:

外觀相似:

外觀描述: 藍色膠囊，有BMS 200mg及3631字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024093

06.12A3 Antiretroviral Agents - PI

27838 **C / Unsafe**

Prezista Tablets 400mg 普利他膜衣錠400毫克

急用Darunavir 400mg tab

Dosage: 2急用藥 27838

Adult
· HIV infection in treatment-experienced patients: PO, 600mg bid with ritonavir 100mg bid
· HIV infection in treatment-na?ve patients: PO, 800mg qd with ritonavir 100mg qd

Pediatric(≧6 yrs)
· HIV infection in treatment-experienced patients: PO,
20-30kg: 375mg darunavir/50mg ritonavir bid
30-40kg: 450mg darunavir/60mg ritonavir bid
≧40kg: Same as adult
Do not use once daily dosing in pediatric patients

Dosing adjustments in hepatic impairment:

Mild to moderate hepatic impairment: No dosage adjustment needed
Severe hepatic impairment: Not recommended

Dosing adjustments in renal impairment:

Mild to moderate renal impairment: No dosage adjustment needed
Severe renal impairment: NDA

P: Tab: 600mg(27840), 400mg(27838)

ADR:

COMMON
Rash, hypertriglyceridemia, serum cholesterol raised, abdominal pain, diarrhea, nausea, vomiting, headache
SERIOUS
Acute generalized exanthematous pustulosis, severe skin reaction, Stevens-Johnson syndrome, toxic epidermal necrolysis, diabetes mellitus, acute pancreatitis, hepatitis

NOTE: 室溫儲存

· Coadministration with ritonavir and food is required

藥名相似:

外觀相似:

外觀描述: 橙色橢圓形錠，一面有400MG字樣，另一面有TMC字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025286

06.12A3 Antiretroviral Agents - PI

27840 **C / Unsafe**

Prezista Tablets 600mg 普利他膜衣錠600毫克

急用Darunavir 600mg tab

Dosage: 2急用藥 27840

Adult
· HIV infection in treatment-experienced patients: PO, 600mg bid with ritonavir 100mg bid and other antiretroviral agents
· HIV infection in treatment-na?ve patients: PO, 800mg qd with ritonavir 100mg qd and other antiretroviral agents

Pediatric(≧6 yrs)
· HIV infection in treatment-experienced patients: PO,
20-30kg: 375mg darunavir/50mg ritonavir bid and other antiretroviral agents
30-40kg: 450mg darunavir/60mg ritonavir bid and other antiretroviral agents
≧40kg: Same as adult
Do not use once daily dosing in pediatric patients

Dosing adjustments in hepatic impairment:

Mild to moderate hepatic impairment: No dosage adjustment needed
Severe hepatic impairment: Not recommended

Dosing adjustments in renal impairment:

Mild to moderate renal impairment: No dosage adjustment needed
Severe renal impairment: NDA

P: Tab: 600mg(27840), 400mg(27838)

ADR:

COMMON
Rash, hypertriglyceridemia, serum cholesterol raised, abdominal pain, diarrhea, nausea, vomiting, headache
SERIOUS
Acute generalized exanthematous pustulosis, severe skin reaction, Stevens-Johnson syndrome, toxic epidermal necrolysis, diabetes mellitus, acute pancreatitis, hepatitis

NOTE: 室溫儲存

· Coadministration with ritonavir and food is required

藥名相似:

外觀相似:

外觀描述: 橘色橢圓形錠，一面有600字樣，另一面有TMC字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025192

06.12A5 Antiretroviral Agents - Integrase Inhibitors

27512 ɔt be ruled out / Infant risk can

TIVICAY* Film-Coated Tablets 50mg 汰威凱膜衣錠50毫克

Dolutegravir 50mg tab

Dosage: 1常備品 27512

Adult
· HIV infection: PO, in combination with other antiretroviral agents
(1)Treatment naive or treatment-experienced integrase strand transfer inhibitor (INSTI)-naive: 50mg qd
(2)Integrase Strand Inhibitor (INSTI)-experienced with known or suspected INSTI-associated resistance: 50mg bid
(3)Treatment naive or treatment-experienced INSTI-naive when coadministered with certain UGT1A or CYP3A inducers (i.e., carbamazepine, efavirenz, fosamprenavir/ritonavir, tipranavir/ritonavir or rifampin): 50mg bid

Pediatric (≧12 yrs & BW≧40kg)
· HIV infection: PO, in combination with other antiretroviral agents
(1)Treatment naive or treatment-experienced integrase strand transfer inhibitor (INSTI)-naive: 50mg qd
(2)Treatment naive or treatment-experienced INSTI-naive when coadministered with certain UGT1A or CYP3A inducers (i.e., carbamazepine, efavirenz, fosamprenavir/ritonavir, tipranavir/ritonavir or rifampin): 50mg bid

Dosing adjustments in hepatic impairment:

Mild to moderate impairment (Child-Pugh A or B): No dosage adjustment needed
Severe impairment (Child-Pugh C): Use is not recommended (has not been studied)

Dosing adjustments in renal impairment:

(1) Treatment-naive or treatment-experienced INSTI-naive:
Mild to severe impairment: No dosage adjustment needed
(2) INSTI-experienced patients with known or suspected resistance:
Mild to moderate impairment: No dosage adjustment needed
Severe impairment: Use with caution

P: Tab: 50mg(27512); TRIUMEQ*(21156)

ADR:

COMMON
Hyperglycemia, increased serum lipase level, headache, insomnia
SERIOUS
ALT/SGPT level raised, AST/SGOT level raised, drug-induced liver disease, acute hepatic failure, hepatitis, hepatotoxicity, serum bilirubin raised, hypersensitivity reaction, immune reconstitution syndrome, renal impairment

NOTE: 室溫儲存

· Administer 2 hours before or 6 hours after cation-containing antacids or laxatives, sucralfate, oral supplements containing iron or calcium, or buffered medications. Alternatively, dolutegravir and supplements containing calcium or iron can be taken together with food.

藥名相似:

外觀相似:

外觀描述: 黃色圓型錠，一面有SV 572字樣，另一面有50字樣

06.12A5 Antiretroviral Agents - Integrase Inhibitors

27821 C / Unsafe

Isentress Film Coated Tablets 400 mg 宜昇瑞 膜衣錠400 毫克

Raltegravir 400mg tab

Dosage: 1常備品 27821

Adult
· HIV infection: PO, 400mg bid

Pediatric(≧6 yrs weighing at least 25 kg)
· HIV infection: Same as adult

Dosing adjustments in hepatic impairment:

Mild to moderate hepatic impairment: No dosage adjustment needed
Severe hepatic impairment: NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 400mg(27821)

ADR:

COMMON
Nausea, moderate to severe asthenia, dizziness, headache, fatigue
SERIOUS
Suicidal, renal failure

NOTE: 儲存30℃以下

· When coadministered with rifampin, the recommended raltegravir dose is 800mg bid
· 藥品仿單變更，摘述如下：(版本S-WPC-MK0518-T-052013/0518-TWN-2015-010376)
1.更新藥物動力學之相關資訊(小兒族群及身體質量指數)。
2.增列小兒科病患之臨床研究、不良反應經驗。
3.用法用量：增列6歲以上兒童和青少年(至少體重25公斤)之使用劑量。
4.特殊警語與注意事項：增列不建議本藥和含鋁及/或鎂的制酸劑併用投藥。

5.藥物交互作用：(A)增列本藥與含有二價金屬陽離子的制酸劑併用可能因螯合作用會降低本藥的吸收，而降低血中濃度。因此，不建議本藥併用含鋁和/或鎂的制酸劑。(B)更新其它藥物對本藥藥物動力學的影響說明。

藥名相似:

外觀相似:

外觀描述: 粉紅色橢圓錠，有227字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024988

06.12A6 Antiretroviral Agents- Combinations

21152 **B / Infant risk can**

TRUVADA* TABLETS 舒發泰膜衣錠

Emtricitabine 200mg & Tenofovir disoproxil fumarate 300mg tab

Dosage: 1常備品 21152

Adult

· HIV infection: PO, 1 tab qd with or without food, in combination with other antiretroviral agents

· Preexposure prophylaxis (PrEP) for prevention of HIV infection in HIV-1-negative adults at high risk: PO, 1 tab qd with or without food

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Hepatic impairment: Has not been studied.
The impact of liver impairment during the administration of TRUVADA* is expected to be limited.

Dosing adjustments in renal impairment:

· HIV-1 infection:
CrCl 30-49 mL/min: 1 tab q48h
CrCl <30 mL/min: Not recommended

· Preexposure prophylaxis (PrEP) for prevention of HIV infection in uninfected high-risk individuals:
CrCl <60 mL/min: Not recommended

P: Tab: TRUVADA*(21152), ATRIPLA(21153), COMPLERA*(21155), Tab: Tenofovir disoproxil fumarate 300mg(27823)

ADR:

COMMON
Rash, lactic acidosis, abdominal pain, diarrhea, nausea, serum amylase raised, backache, myalgia, osteopenia, dizziness, headache, insomnia, peripheral neuropathy, depression, dream disorder, pneumonia, fatigue
SERIOUS
Pancreatitis, hepatomegaly with steatosis, hepatotoxicity, reactivation of hepatitis B viral hepatitis, immune reconstitution syndrome, rhabdomyolysis, fanconi syndrome, renal failure, renal impairment

NOTE: 儲存30℃以下

· For pre-exposure prophylaxis (PrEP)
(1)Do not initiate TRUVADA* if signs or symptoms of acute HIV-1 infection are present unless negative infection status is confirmed.
(2)Do not use TRUVADA* in individuals with unknown or positive HIV-1 status.
(3)HIV-1 screening tests should be repeated at least every 3 mons during therapy.
· Do not use with drugs containing emtricitabine, tenofovir or lamivudine.
· Do not administer in combination with adefovir.
· Due to the risk of postnatal transmission of HIV, the CDC does not recommend breastfeeding for HIV-infected mothers, including those who are receiving combination antiretroviral therapy or prophylaxis.

藥名相似:

外觀相似:

外觀描述: 藍色長橢圓錠，一面有"701"字樣，另一面有"GILEAD"字樣

06.12A6 Antiretroviral Agents- Combinations

21153 **D / Unsafe**

ATRIPLA TABLETS 亞翠佩膜衣錠

Efavirenz 600mg, Emtricitabine 200mg & Tenofovir disoproxil fumarate 300mg tab

Dosage: 1常備品 21153

Adult

· HIV infection: PO, ac, 1 tab qd, preferably at bedtime

Pediatric (≧12 years and ≧40 kg)

· HIV infection: Same as adult

Dosing adjustments in hepatic impairment:

Mild hepatic impairment (Child-Pugh class A): Use with caution
Moderate or severe hepatic impairment (Child-Pugh class B, C): Use not recommended

Dosing adjustments in renal impairment:

CrCl<50mL/min: Use not recommended

P: Tab: ATRIPLA*(21153),COMPLERA*(21155), TRUVADA*(21152), Tab: Efavirenz 600mg(27813), Tenofovir disoproxil fumarate 300mg(27823)

ADR:

COMMON
Rash, diarrhea, nausea, decreased bone mineral density, dizziness, headache, anxiety, depression, dream disorder, increased creatine kinase level, sinusitis, upper respiratory infection, fatigue
SERIOUS
Prolonged QT interval, Torsades de pointes, lactic acidosis, hepatitis, exacerbation of hepatitis B, hepatomegaly with steatosis, reactivation of hepatitis B viral hepatitis, osteomalacia, severe depression, suicidal thoughts, acute renal failure, fanconi syndrome, proximal renal tubular acidosis

NOTE: 室溫儲存

· Administration at bedtime may improve the tolerability of nervous system symptoms.

藥名相似:

外觀相似:

外觀描述: 粉紅色長橢圓型錠，一面有123字樣

06.12A6 Antiretroviral Agents- Combinations

21155 **B / Unsafe**

Complera Film-coated Tablets "康普萊"膜衣錠

Emtricitabine 200mg, Rilpivirine 25mg & Tenofovir disoproxil fumarate 300mg tab

Dosage: 1常備品 21155

Adult

· HIV infection: PO, 1 tab qd with food

Pediatric

Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild to moderate impairment (Child-Pugh class A or B): No dosage adjustments needed

Severe impairment (Child-Pugh class C): NDA

Dosing adjustments in renal impairment:

CrCl <50 mL/minute: Use is not recommended

P: Tab: Rilpivirine 25mg(27831), Tenofovir disoproxil fumarate 300mg(27823), COMPLERA*(21155), ATRIPLA*(21153), TRUVADA*(21152)

ADR:

COMMON

Diarrhea (grade 2 to 4), nausea, dizziness, headache (grade 2 to 4), depression, dream disorder (grade 2 to 4), insomnia (grade 2 to 4)

SERIOUS

Severe disorder of skin, rash (grade 2 to 4), lactic acidosis, exacerbation of hepatitis B, hepatomegaly with steatosis, hepatotoxicity, drug hypersensitivity syndrome, hypersensitivity reaction, Fanconi syndrome

NOTE: 室溫儲存

· If it is used for patients receiving rifabutin, patients should receive an additional rilpivirine 25 mg/day to provide a total rilpivirine dosage of 50 mg/day. Decrease back to 25 mg/day following rifabutin discontinuation.

· Avoid concurrent use with adefovir or lamivudine-containing products or other emtricitabine-, rilpivirine-, and/or tenofovir-containing products.

藥名相似:

外觀相似:

外觀描述: 淡紫紅色長橢圓錠，一面有GSI字樣

06.12A6 Antiretroviral Agents- Combinations

21156 **C / Unsafe**

Triumeq Film-Coated Tablets 三恩美膜衣錠

Dolutegravir 50mg, Abacavir 600mg & Lamivudine 300mg tab

Dosage: 1常備品 21156

Adult

· HIV infection: PO, 1 tab qd

Pediatric (≧12 yrs)

· HIV infection: PO, 1 tab qd

Dosing adjustments in hepatic impairment:

Mild impairment (Child-Pugh class A): Use is not recommended. (Use dose-adjusted individual component drugs)

Moderate to severe impairment (Child-Pugh class B or C): Use is contraindicated.

Dosing adjustments in renal impairment:

CrCl <50 mL/min: Use is not recommended. (Use dose-adjusted individual component drugs)

P: Tab: Lamivudine - 150mg(27804), 100mg(21141); Abacavir - 300mg(27822, 急用藥); TRIUMEQ*(21156), KIVEXA*(27815), DUOVIR-N(21154),COMBIVIR*(21150); Soln: Lamivudine - 10mg/mL, 240mL/B(28995, 急用藥)(28991, CDC)

ADR:

SERIOUS

Myocardial infarction, lactic acidosis, hepatitis B exacerbation, hepatomegaly with steatosis, hypersensitivity reaction (1%~8% (abacavir only)), immune reconstitution syndrome

NOTE: 室溫儲存

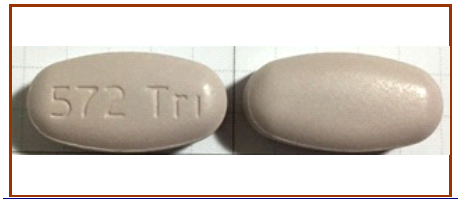
· Screen patient for presence of the HLA-B*5701 allele prior to initiation or reinitiation of therapy.

· Concomitant use of other abacavir-, lamivudine-, or dolutegravir-containing products with TRIUMEQ* should be avoided.

藥名相似:

外觀相似:

外觀描述: 紫色橢圓形錠，一面有 572 Tri字樣



06.12A6 Antiretroviral Agents- Combinations

21158 **ɔt be ruled out / Infant risk can**

PREZCOBIX* Flim-Coated Tablets 普澤力膜衣錠

Darunavir 800mg & Cobicistat 150mg tab

Dosage: 1常備品 21158

Adult
· HIV infection: PO, 1 tab qd with food, in combination with other antiretrovirals

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

· Mild (Child-Pugh class A) to moderate (Child-Pugh class B): No dosage adjustment needed
· Severe impairment (Child-Pugh class C): Use is not recommended

Dosing adjustments in renal impairment:

NDA
CrCl<70 mL/min: Co-administered with tenofovir disoproxil fumarate is not recommended

P: P Tab: PREZCOBIX*(21158); Tab: Darunavir 400mg(27838,急用藥), Darunavir 600mg(27840,急用藥)

ADR:

COMMON
Rash, abdominal pain, diarrhea, nausea, vomiting, headache
SERIOUS
Skin reaction extreme, Stevens-Johnson syndrome

NOTE: 室溫儲存

(1)Assess estimated creatinine clearance prior to initiation of therapy.
(2)HIV genotype testing is recommended for antiretroviral treatment-experienced patients; if testing is not feasible, use is recommended in protease-inhibitor naive patients only.
(3)Consider interrupting or discontinuing therapy if new or worsening liver dysfunction is suspected.
(4)Use with caution in patients with sulfonamide allergy (darunavir contains sulfa moiety).
(5)It is not recommended for use during pregnancy because of substantially lower exposures of darunavir and cobicistat during pregnancy. Recommend an alternative regimen for women who become pregnant while on cobicistat/darunavir therapy.
(6)Contraindications(according to package insert):
· Alpha 1-adrenoreceptor antagonist: alfuzosin
· Antianginal: ranolazine
· Antiarrhythmic: dronedarone
· Anticonvulsants: carbamazepine, phenobarbital, phenytoin
· Anti-gout: colchicine, in patients with renal/and or hepatic impairment
· Antimycobacterial: rifampin
· Antipsychotics: lurasidone, pimozide
· Ergot derivatives, e.g. dihydroergotamine, ergotamine, methylergonovine
· GI motility agent: cisapride
· Herbal product: St. John's wort (Hypericum perforatum)
· Hepatitis C direct acting antiviral: elbasvir/grazoprevir
· Lipid modifying agents: lomitapide, lovastatin, simvastatin
· PDE-5 inhibitor: sildenafil when used for treatment of pulmonary arterial hypertension
· Sedatives/hypnotics: orally administered midazolam, triazolam
(7)Additional or alternative (non-hormonal) forms of contraception should be considered when estrogen-containing contraceptives are co-administered with PREZCOBIX. For co-administration with drospirenone, clinical monitoring is recommended due to the potential for hyperkalemia.

藥名相似:

外觀相似:

外觀描述: 粉紅色橢圓膜衣錠，一面有"TG"字樣，另一面有"800"字樣

06.12A6 Antiretroviral Agents- Combinations

21159 **ɔt be ruled out / Infant risk can**

GENVOYA* Film-coated Tablets 捷扶康 膜衣錠

Tenofovir alafenamide fumarate 10mg, Emtricitabine 200mg, Elvitegravir 150mg & Cobicistat 150mg

Dosage: 1常備品 21159

Adult
· HIV infection: PO, 1 tab qd with food

Pediatric (≧12 yrs and ≧35kg)
· HIV infection: Same as adult

Dosing adjustments in hepatic impairment:

· Mild to moderate impairment (Child-Pugh class A or B): No dosage adjustment needed
· Severe impairment (Child-Pugh class C): Use is not recommended

Dosing adjustments in renal impairment:

· CrCl ≧ 30 mL/min: No dosage adjustment needed
· CrCl< 30 mL/min: Use is not recommended

P: P Tab: GENVOYA*(21159); TRUVADA*(21152); ATRIPLA*(21153); COMPLERA*(21155); Tab: Tenofovir disoproxil fumarate 300mg(27823); Tab: Tenofovir alafenamide 25mg(21160, 急用藥)

ADR:

COMMOM

Nausea

SERIOUS
Hypervolemia, hyperkalemia, lactic acidosis, exacerbation of hepatitis B, hepatomegaly with steatosis, immune reconstitution syndrome, decreased bone mineral density, osteomyelitis, acute renal failure, Fanconi syndrome, renal impairment,
pneumonia

NOTE: 室溫儲存

· Swallow the tablet whole. Do not crush, break, or chew it.

· Prior to initiation, patients should be tested for hepatitis B infection.
· It is not indicated for the treatment of chronic hepatitis B virus infection and the safety and efficacy have not been established in patients coinfected with HIV-1 and HBV.
· Close monitor hepatic function with clinical and laboratory follow-up for at least several months after it is discontinued in patients coinfected with HIV and HBV.
· If appropriate, anti-hepatitis B therapy may be warranted, especially in patients with advanced liver disease or cirrhosis.
· Concomitant use with alfuzosin, carbamazepine, cisapride, dihydroergotamine, ergotamine, lovastatin, lurasidone, methylergonovine, oral midazolam, phenobarbital, phenytoin, pimozide, rifampin, sildenafil used for treatment of pulmonary arterial hypertension, simvastatin, St John's wort or triazolam is contraindicated.
· 本藥不可併用含有tenofovir alafenamide、tenofovir disoproxil、lamivudine或adefovir dipivoxil成分的HBV治療用藥。

藥名相似:

外觀相似:

外觀描述: 粉綠色橢圓扁錠，一面有"GSI"字樣，另一面有"510"字樣

06.12A6 Antiretroviral Agents- Combinations

21181 **ɔt be ruled out / Infant risk can**

Odefsey* Film-coated tablets 安以斯膜衣錠

Rilpivirine 25mg, Emtricitabine 200mg & Tenofovir alafenamide fumarate 25mg tab

Dosage: 1常備品 21181

Adult
· HIV infection: PO, 1 tab qd with food

Pediatric (≧12 years and ≧35 kg)
· HIV infection: Same as adult

Dosing adjustments in hepatic impairment:

Mild to moderate impairment (Child-Pugh Class A or B): No dosage adjustment needed
Severe impairment (Child-Pugh Class C): NDA (has not been studied)

Dosing adjustments in renal impairment:

CrCl ≧ 30 mL/min: No dosage adjustment needed
CrCl < 30 mL/min: Use is not recommended

P: P Tab: ODEFSEY*(21181); BIKTARVY*(21182); GENVOYA*(21159); TRUVADA*(21152)(27599, 疾管署提供用於PrEP計畫); ATRIPLA*(21153); COMPLERA*(21155); Tab: Tenofovir disoproxil fumarate 300mg(27823); Tab: Tenofovir alafenamide 25mg(21160); Tab: Rilpivirine 25mg(27831)

ADR:

COMMON
Nausea, headache, somnolence
SERIOUS
Disorder of skin (severe), lactic acidosis, exacerbation of hepatitis B , Hepatomegaly with steatosis, hepatotoxicity, drug reaction with eosinophilia and systemic symptoms, hypersensitivity reaction, immune reconstitution syndrome, fracture of bone, depression, injury due to suicide attempt, suicidal thoughts, acute renal failure, Fanconi syndrome, renal impairment

NOTE: 室溫儲存

· Prior to initiation, patients should be tested for hepatitis B infection.
· Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue this drug. If appropriate, initiation of anti-hepatitis B therapy may be warranted, especially in patients with advanced liver disease or cirrhosis, since post treatment exacerbation of hepatitis may lead to hepatic decompensation and liver failure.
· For patients taking this medicine prior to pregnancy who are already virally suppressed, continue with 1 tablet once daily and closely monitor viral load, as lower rilpivirine exposure may occur during pregnancy.
· Concomitant use with proton pump inhibitors is contraindicated.
· The antacid should be given at least 2 hours before or 4 hours after the drug is administered;The H2 blocker should be given at least 12 hours before or 4 hours after the drug is administered.

藥名相似:

外觀相似:

外觀描述:

06.12A6 Antiretroviral Agents- Combinations

21182 **ɔt be ruled out / Infant risk can**

Biktarvy* Tablets 吉他韋 膜衣錠

Bictegravir 50mg, Emtricitabine 200mg & Tenofovir alafenamide fumarate 25mg tab

Dosage: 1常備品 21182

Adult
· HIV infection: PO, 1 tab qd with or without food

Pediatric (≧25kg)
· HIV infection: Same as adult

Dosing adjustments in hepatic impairment:

Mild to moderate impairment (Child-Pugh Class A or B): No dosage adjustment needed
Severe impairment (Child-Pugh Class C): Use is not recommended (has not been studied)

Dosing adjustments in renal impairment:

CrCl ≧ 30 mL/min: No dosage adjustment needed
CrCl < 30 mL/min: Use is not recommended

P: P Tab: BIKTARVY*(21182); ODEFSEY*(21181); GENVOYA*(21159); TRUVADA*(21152)(27599, 疾管署提供用於PrEP計畫); ATRIPLA*(21153); COMPLERA*(21155); Tab: Tenofovir disoproxil fumarate 300mg(27823); Tab: Tenofovir alafenamide 25mg(21160)

ADR:

COMMON
Diarrhea, nausea, headache
SERIOUS
Lactic acidosis, exacerbation of hepatitis B, hepatomegaly with steatosis, immune reconstitution syndrome, acute renal failure, Fanconi syndrome, renal impairment

NOTE: 室溫儲存

· Prior to initiation, patients should be tested for hepatitis B infection.
· Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue this drug. If appropriate, initiation of anti-hepatitis B therapy may be warranted, especially in patients with advanced liver disease or cirrhosis, since post treatment exacerbation of hepatitis may lead to hepatic decompensation and liver failure.
· It can be taken at least 2 hours before or 6 hours after taking antacids containing aluminum, magnesium.

藥名相似:

外觀相似:

外觀描述:

06.12A6 Antiretroviral Agents- Combinations

27599 **B / Infant risk can**

TRUVADA* TABLETS 舒發泰膜衣錠

(公費)Emtricitabine 200mg & Tenofovir disoproxil fumarate 300mg tab

Dosage: 2衛福部提供 27599

Adult
· Preexposure prophylaxis (PrEP) for prevention of HIV infection in HIV-1-negative adults at high risk: PO, 1 tab qd or on-demand dosing (event-based) with or without food

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Hepatic impairment: Has not been studied.
The impact of liver impairment during the administration of TRUVADA* is expected to be limited.

Dosing adjustments in renal impairment:

· Preexposure prophylaxis (PrEP) for prevention of HIV infection in uninfected high-risk individuals:
CrCl <60 mL/min: Not recommended

P: Tab: TRUVADA*(21152), ATRIPLA(21153), COMPLERA*(21155), Tab: Tenofovir disoproxil fumarate 300mg(27823)

ADR:

COMMON
Rash, lactic acidosis, abdominal pain, diarrhea, nausea, serum amylase raised, backache, myalgia, osteopenia, dizziness, headache, insomnia, peripheral neuropathy, depression, dream disorder, pneumonia, fatigue
SERIOUS
Pancreatitis, hepatomegaly with steatosis, hepatotoxicity, reactivation of hepatitis B viral hepatitis, immune reconstitution syndrome, rhabdomyolysis, fanconi syndrome, renal failure, renal impairment

NOTE: 儲存30℃以下

· 公費條件:
(1)愛滋感染者之年滿 18 歲的社會網絡(如配偶或性伴侶等，尤以女性為優先)，且為愛滋檢驗陰性及高風險行為指標達30分(含)以上者。
(2)弱勢之年輕族群-須為18至30歲(未滿31歲)，且為愛滋檢驗陰性及高風險行為指標達30分(含)以上者。
(3)已加入「105-106年愛滋病毒篩檢與暴露前預防性投藥(PrEP)前驅計畫」，至106年底尚未服藥滿1年者，可加入本計畫至服藥滿1年。

· On-demand dosing:
(1)單次性行為: 使用者在可能發生不安全性行為前2至24小時服用2顆，服藥後的24小時與48小時，各服用1顆。
(2)連續性行為: 使用者在可能發生不安全性行為的前2至24小時服用2顆後，服藥後每隔24小時服藥1顆，直到最後一次性行為後兩日為止。
(3)若使用者在最後一次服藥距離當次性行為時間間隔小於7天，當次性行為前2至24小時僅須服用1顆，並在服藥後的24小時、48小時服藥，完成此次依需求使用暴露前預防性投藥。
在此強調第2日起的服藥時刻是依據首次服藥日的時刻而定，而非性行為發生的時刻。

· For pre-exposure prophylaxis (PrEP)
(1)Do not initiate TRUVADA* if signs or symptoms of acute HIV-1 infection are present unless negative infection status is confirmed.
(2)Do not use TRUVADA* in individuals with unknown or positive HIV-1 status.
(3)HIV-1 screening tests should be repeated at least every 3 mons during therapy.
· Do not use with drugs containing emtricitabine, tenofovir or lamivudine.
· Do not administer in combination with adefovir.
· Due to the risk of postnatal transmission of HIV, the CDC does not recommend breastfeeding for HIV-infected mothers, including those who are receiving combination antiretroviral therapy or prophylaxis.

藥名相似:

外觀相似:

外觀描述: 藍色長橢圓錠，一面有"701"字樣，另一面有"GILEAD"字樣

06.12A6 Antiretroviral Agents- Combinations

27832 ɔt be ruled out / Infant risk can

JULUCA film coated tablets 滋若愷膜衣錠

^急用Dolutegravir 50mg & Rilpivirine 25mg FC tab

Dosage: 2急用藥 27832

Adult

· HIV infection (replace current stable antiretroviral regimen): PO, 1 tab qd with meal; coadministration with rifabutin, 1 tab with an additional rilpivirine 25 mg tab qd with meal during the rifabutin regimen

Pediatric

· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild to moderate impairment (Child-Pugh Class A or B): No dosage adjustment needed
Severe impairment (Child-Pugh Class C): NDA (has not been studied)

Dosing adjustments in renal impairment:

CrCl ≧ 30 mL/min: No dosage adjustment needed
CrCl< 30 mL/min or ESRD: Increased monitoring for adverse events recommended

P: P Tab: JULUCA*(DTG+RPV, 27832), TIVICAY*(DTG, 27512), TRIUMEQ*(DTG+ABC+3TC, 21156), EDURANT*(RPV, 27831), COMPLERA*(FTC+RPV+TDF, 21155), ODEFSEY*(RPV+FTC+TAF, 21181)

ADR:

COMMON
Diarrhea, headache
SERIOUS
Hepatitis, hepatotoxicity, drug-induced liver injury, drug reaction with eosinophilia and systemic symptoms, hypersensitivity reaction, depression

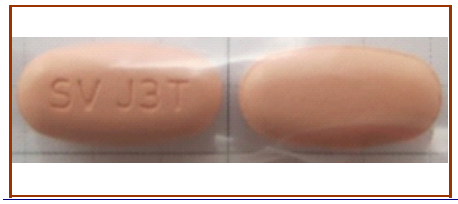
NOTE: 室溫儲存

· Prior to switching to dolutegravir/rilpivirine, patients must be virologically suppressed(HIV-1 RNA< 50 copies/mL) on a stable antiretroviral regimen for ≧6 months with no history of treatment failure and no known resistance to dolutegravir or rilpivirine.
· Perform pregnancy testing before initiation of dolutegravir/rilpivirine in adolescents and adults of childbearing potential.
· A protein supplement drink alone does not replace a meal.
· Concomitant use with dofetilide, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifapentine, dexamethasone (>1 dose), or proton pump inhibitors are contraindicated.
· Underlying hepatitis B or C or elevated transaminases prior to initiation increase risk for new or worsening elevated transaminases (sometimes consistent with immune reconstitution syndrome or hepatitis B reactivation, particularly if anti-hepatitis therapy was withdrawn); monitoring recommended
· Administer at least 4 hours before or 6 hours after oral antacids, laxatives, or other products that contain aluminum, calcium, magnesium, or sucralfate.
· Administer at least 4 hours before or 12 hours after oral cimetidine, famotidine, nizatidine, ranitidine.
· Administer at least 4 hours before or 6 hours after oral iron or taken together with food.

藥名相似:

外觀相似:

外觀描述: 粉紅色橢圓形膜衣錠，一面刻有"SV J3T"字樣



06.12B Adamantanes

27227 C / Unsafe

AMANDA* F.C. TABLETS 100MG "WEIDAR" (AMANTADINE) "衛達"安滿達膜衣錠１００毫克

Amantadine sulphate 100mg FC tab

Dosage: 1常備品 27227

Adult

· Influenza A virus infection: PO, 100mg bid or 200mg qd
· Parkinsonism syndrome: PO, initial 100mg bid; MD, up to 400mg/day in div. doses; when used with levodopa, doses should remain at 100mg qd-bid
· Drug-induced extrapyramidal reactions: PO, 200mg/day in div. doses; Max. 300mg/day in div. doses

Pediatric

· Influenza A virus infection: PO,
1-9yrs: 5mg/kg/day in 2 divided doses (manufacturers range: 4.4-8.8mg/kg/day); Max. 150mg/day
≧10yrs and <40kg: 5mg/kg/day in 2 divided doses
≧10yrs and ≧40kg: 100mg bid; Max. 200mg/day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 30-50mL/min: 200mg on first day then 100mg/day
Clcr 15-29mL/min: 200mg on first day then 100mg qod
Clcr<15mL/min: 200mg on first day then 200mg q7d
Hemodialysis: 200mg q7d

P: Tab: 100mg(27227); Inj: 200mg/Bot(31629)

ADR:

COMMON
Dizziness, agitation, anxiety, ataxia, confusion, depression, dream disorder, fatigue, feeling nervous, hallucinations, irritability, headache, insomnia, somnolence, nausea, loss of appetite, constipation, diarrhea, xerostomia, orthostatic hypotension, peripheral edema
SERIOUS
Cardiac arrest, cardiac dysrhythmia, congestive heart failure, hypotension, tachycardia, malignant melanoma, agranulocytosis, leukopenia, neutropenia, immune hypersensitivity reaction, neuroleptic malignant syndrome, suicidal intent, acute respiratory failure, pulmonary edema

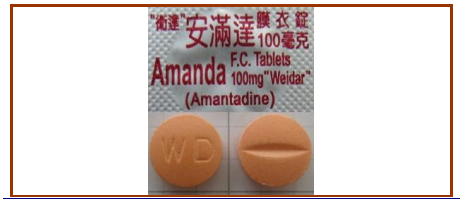
NOTE: 室溫儲存

1. If insomnia occurs, the last daily dose should be taken several hours before retiring.
2. Safety and efficacy of amantadine in children younger than 1 yr of age have not been established.
3. Geriatric patients (65 years and older): PO, 100mg qd

藥名相似:

外觀相似: LABTAL* 200mg FC Tab (22468)

外觀描述: 橘色圓扁錠，一面中央有刻痕，另一面有"WD"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1030257

06.12B Adamantanes

37604 **C / Unknown(有**

Cymevene Lyophilized IV Injection 500mg/Vial 西美芬凍晶靜脈注射劑500毫克/小瓶（義大利廠）

急用Ganciclovir inj 500mg pow in vial

Dosage: 2急用藥 37604

Adult
·CMV retinitis: induction, slow IV infusion over 1hr, 5mg/kg q12 hr for 14-21 days; MD, 5mg/kg once daily for 7 days/week, or 6mg/kg once daily for 5 days/week
·CMV disease prevention: slow IV infusion over 1hr, 5mg/kg q12 hr for 7-14 days, then 5mg/kg once daily for 7 days/week, or 6mg/kg once daily for 5 days/week; duration of therapy dependent on degree and duration of immunosuppression

Pediatric
Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

IV induction dose: Clcr 50-69mL/min, 2.5mg/kg q12h; Clcr 25-49mL/min, 2.5mg/kg q24h; Clcr 10-24mL/min, 1.25mg/kg q24h; Clcr<10mL/min, 1.25mg/kg 3 times a week following hemodialysis

IV maintenance dose: Clcr 50-69mL/min, 2.5mg/kg q24h; Clcr 25-49mL/min, 1.25mg/kg q24h; Clcr 10-24mL/min, 0.625mg/kg q24h; Clcr<10mL/min, 0.625mg/kg 3 times a week following hemodialysis

P: Inj: 500mg Vial(37604)

ADR:

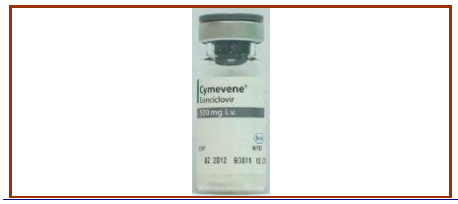
COMMON
Pruritus, sweating, diarrhea, loss of appetite, vomiting, anemia, neutropenia, thrombocytopenia, infectious disease, neuropathy, serum creatinine raised, fever, shivering
SERIOUS
Cardiac arrest, torsades de pointes, stevens-johnson syndrome, gastrointestinal perforation, pancreatitis, liver failure, anaphylaxis, sepsis, rhabdomyolysis, cerebrovascular accident, retinal detachment, renal failure, multiple organ failure

NOTE: 室溫儲存30°C以下

藥名相似:

外觀相似:

外觀描述: 白色乾粉，灰蓋玻璃小瓶



06.12C Monoclonal Antibodies

37836 **C / Caution**

SYNAGIS 100mg/ml solution for injection 西那吉斯注射液劑100毫克/毫升

Palivizumab inj 50mg/0.5mL vial

Dosage: 1常備品 37836

--

Pediatric
· Prevention of respiratory syncytial virus(RSV) disease in high-risk infants(such as those with chronic lung disease of prematurity, serious congenital heart disease and a history of prematurity): IM, 15mg/kg monthly

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 50mg Vial(37836)

ADR:

COMMON
Rash, diarrhea, gastroenteritis, vomiting, otitis media, cough, rhinitis, upper respiratory infection, wheezing, fever
SERIOUS
Thrombocytopenia, anaphylaxis, hypersensitivity reaction

NOTE: 儲存2-8℃

· 《Contraindications》Previous significant

hypersensitivity reaction to palivizuma ;
· For infants and children requiring cardiopulmonary bypass should receive a supplemental 15mg/kg dose as soon as possible after the procedure

藥名相似:

外觀相似:

外觀描述: 澄清注射液，『粉紅』蓋透明玻璃小瓶，蓋上有FLIP及OFF字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=60001010

06.12D Nucleoside and Nucleotides

21141 **C / Unsafe**

ZEFFIX TABLETS 100MG 干安能 錠１００毫克

Lamivudine 100mg FC tab

Dosage: 1常備品 21141

Adult
· HBV infection: PO, 100mg qd

Pediatric(2-17yrs)
· HBV infection: PO, 3mg/kg qd; Max. 100mg/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

HBV infection
Clcr 30-49mL/min: 100mg first dose, then 50mg qd
Clcr 15-29mL/min: 100mg first dose, then 25mg qd
Clcr 5-14mL/min: 35mg first dose, then 15mg qd
Clcr < 5mL/min: 35mg first dose, then 10mg qd

P: Tab: 100mg(21141), 150mg(27804); Tab: Combivir(27809), Kivexa(27815); Soln: 10mg/mL, 240mL/B(28995, 急用藥)

ADR:

COMMON
Lipodystrophy, fatigue, headache, decrease in appetite, nausea, vomiting
SERIOUS
Lactic acidosis, hepatomegaly, relapsing type B viral hepatitis, pancreatitis

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 暗磚紅色橢圓錠，有GXCG5字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043302

06.12D Nucleoside and Nucleotides

21142 **X / Unsafe**

ROBATROL CAPSULES 200MG 羅拔除膠囊200毫克

Ribavirin 200mg cap

Dosage: 1常備品 21142

Adult
· Chronic hepatitis C infection: (in combination with interferon alfa-2b at 3 million units 3 times/wk SC)
≦75kg: PO, 400mg AM and 600mg PM
> 75kg: PO, 600mg bid
· Chronic hepatitis C infection: (in combination with peg-interferon alfa-2b):
≦65kg: PO, 400mg bid
66-85kg: PO, 400mg AM and 600mg PM
86-105kg: PO, 600mg bid
>105kg: PO, 600mg AM and 800mg PM

Pediatric
· Chronic hepatitis C infection: (in combination with interferon alfa-2b)
>61kg: same as adult
50-61kg: PO, 400mg bid
37-49kg: PO, 200mg AM and 400mg PM
25-36kg: PO, 200mg bid

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

CLcr <50mL/min: Ribavirin should not be used

P: Cap: 200mg(21142), (27845, 急用藥); Inhalation powder: 6g Vial(29079, 急用藥)

ADR:

COMMON
Pruritus, rash, indigestion, loss of appetite, nausea, headache, conjunctivitis, fatigue
SERIOUS
Cardiac arrest, hypotension, pancreatitis, hemolytic anemia, cardiac and pulmonary events, thrombotic thrombocytopenic purpura, hepatotoxicity, hyperammonemia, hyperbilirubinemia, increased erythrocyte destruction, liver failure (in combination with peginterferon alfa-2a), bacterial infectious disease (in combination with peginterferon alfa-2a), suicide (in combination with peginterferon alfa-2a), complication of respiratory therapy procedure, drug precipitation, respiratory complication

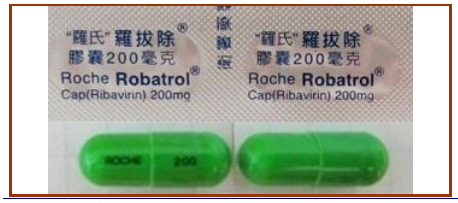
NOTE: 室溫儲存

1. Ribavirin should not be given as monotherapy for hepatitis C.
2. Oral ribavirin can be taken (consistently) with or without food

藥名相似:

外觀相似:

外觀描述: 『綠』色膠囊，一端有"ROCHE"，另一端有"200"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044650

06.12D Nucleoside and Nucleotides

21143 C / Unsafe

HEPSERA TABLETS 干適能錠

Adefovir dipivoxil 10mg tab

Dosage: 1常備品 21143

Adult
·Chronic hepatitis B infection with evidence of active viral replication (in both lamivudine-resistant and treatment-na?ve patients): PO, 10mg once daily

Pediatric(≧12 yrs)
·Chronic hepatitis B infection with evidence of active viral replication (in both lamivudine-resistant and treatment-na?ve patients): Same as adult

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 30-49mL/min: 10mg q48h
Clcr 10-29mL/min: 10mg q72h
Clcr <10mL/min: No recommendation available
Hemodialysis: 10mg every 7 days following dialysis

P: Tab: 10mg(21143)

ADR:

COMMON
Asthenia, serum creatinine raised
SERIOUS
Hypophosphatemia, lactic acidosis, ALT (SGPT) level raised, hepatitis, hepatomegaly with steatosis, nephrotoxicity, renal failure

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，GS KNU字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023920

06.12D Nucleoside and Nucleotides

21144 C / Unsafe

Baraclude Tablets 0.5mg 貝樂克膜衣錠0.5毫克

Entecavir 0.5mg tab

Dosage: 1常備品 21144

Adult
·Chronic hepatitis B infection in nucleoside-treatment-na?ve patients with compensated liver disease: PO, ac, 0.5mg once daily
·Chronic hepatitis B infection in patients with a history of hepatitis B viremia while receiving lamivudine or known lamivudine resistant mutations: PO, ac, 1mg once daily
·Chronic hepatitis B infection in patients with decompensated liver disease: PO, ac, 1mg once daily

Pediatric (≧ 2 yrs)
·Chronic hepatitis B infection: PO, ac,

Weight (kg)	nucleoside-treatment-naive	lamivudine-experienced
10-11	0.15mg qd	0.3mg qd
>11-14	0.2mg qd	0.4mg qd
>14-17	0.25mg qd	0.5mg qd
>17-20	0.3mg qd	0.6mg qd
>20-23	0.35mg qd	0.7mg qd
>23-26	0.4mg qd	0.8mg qd
>26-30	0.45mg qd	0.9mg qd
>30	0.5mg qd	1.0mg qd

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr(mL/min)	Treatment-naive	Lamivudine-Refractory or Decompensated Liver Disease
30-50	0.25mg qd or 0.5mg q48h	0.5mg qd or 1mg q48h
10-30	0.15mg qd or 0.5mg q72h	0.3mg qd or 1mg q72h
<10	0.05mg qd or 0.5mg qw	0.1mg qd or 1mg qw
H/D* or CAPD	0.05mg qd or 0.5mg qw	0.1mg qd or 1mg qw

*on hemodialysis days, administer after hemodialysis

P: Tab: 0.5mg(21144), 1mg(27536)

ADR:

COMMON
Nausea, dizziness, headache, fatigue
SERIOUS
Lactic acidosis, severe hepatomegaly with steatosis, recurrent hepatitis, anaphylactoid reaction

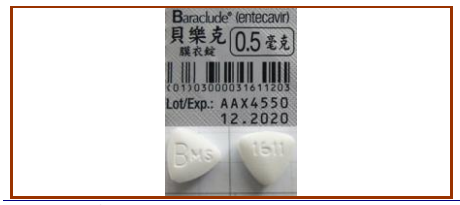
NOTE: 室溫儲存

1.Administer on an empty stomach (at least 2h before or 2h after a meal)
2.Hepatic function should be monitored for at least several months after discontinue anti-hepatitis B therapy

藥名相似:

外觀相似:

外觀描述: 白色三角形扁錠，有BMS及1611字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024469

06.12D Nucleoside and Nucleotides

21145 **B / Unsafe**

Sebivo 600mg film-coated tablets 喜必福 膜衣錠 600 毫克

Telbivudine 600mg tab

Dosage: 1常備品 21145

Adult
·Chronic hepatitis B infection: PO, 600mg qd

Pediatric (≧16 yr)
Same as adult

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 30-49mL/min: Administer q48h
Clcr <30mL/min: Administer q72h
Hemodialysis: Administer q96h after the dialysis

P: Tab: 600mg(21145)

ADR:

COMMON
Increase creatine kinase level, headache, cough, fatigue, influenza
SERIOUS
Lactic acidosis, AST/ALT level abnormal (grade 3 or 4), hepatomegaly, steatosis of liver, disorder of muscle, rhabdomyolysis

NOTE: 室溫儲存

·此藥不建議用於對lamivudine具抗藥性者；另有實驗證據顯示，本品亦不適用對entecavir具抗藥性者
·Hepatic function should be monitored for at least several months after stopping treatment

藥名相似:

外觀相似:

外觀描述: 白色長橢圓扁錠，有LDT字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024662

06.12D Nucleoside and Nucleotides

21160 **ɔt be ruled out / Infant risk can**

VEMLIDY* film-coated Tablets 韋立得膜衣錠

Tenofovir Alafenamide 25mg tab

Dosage: 1常備品 21160

Adult
· Chronic hepatitis B: PO, 25mg qd with food

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild impairment (Child-Pugh class A): No dosage adjustment needed
Decompensated (Child-Pugh B or C): Use is not recommended

Dosing adjustments in renal impairment:

Mild, moderate or severe renal impairment: No dosage adjustment needed
End-stage renal disease(CrCl <15 mL/min): Use is not recommended

P: Tab: Tenofovir alafenamide 25mg(21160), Tenofovir disoproxil fumarate 300mg(27823)

ADR:

COMMON
Abdominal pain, backache, headache, fatigue
SERIOUS
Lactic acidosis, pancreatitis, hepatomegaly with steatosis, acute renal failure, Fanconi syndrome, renal impairment

NOTE: 30℃以下

· Tenofovir alafenamide fumarate 28mg is equivalent to tenofovir alafenamide 25mg.
· Assess serum creatinine, phosphorus, creatinine clearance, urine glucose, and urine protein before initiation and during therapy.

藥名相似:

外觀相似:

外觀描述: 黃色圓形錠，一面有GSI字樣，另一面有25字樣

06.12D Nucleoside and Nucleotides

21162 **C / Unsafe**

Becavir F.C. Tablets 0.5mg 貝甘欣膜衣錠0.5毫克

Entecavir 0.5mg tab

Dosage: 1常備品 21162

Adult
·Chronic hepatitis B infection in nucleoside-treatment-na?ve patients with compensated liver disease: PO, ac, 0.5mg once daily
·Chronic hepatitis B infection in patients with a history of hepatitis B viremia while receiving lamivudine or known lamivudine resistant mutations: PO, ac, 1mg once daily
·Chronic hepatitis B infection in patients with decompensated liver disease: PO, ac, 1mg once daily

Pediatric (≧ 2 yrs)
·Chronic hepatitis B infection: PO, ac,

Weight (kg)	nucleoside-treatment-naive	lamivudine-experienced
10-11	0.15mg qd	0.3mg qd
>11-14	0.2mg qd	0.4mg qd
>14-17	0.25mg qd	0.5mg qd
>17-20	0.3mg qd	0.6mg qd
>20-23	0.35mg qd	0.7mg qd
>23-26	0.4mg qd	0.8mg qd
>26-30	0.45mg qd	0.9mg qd
>30	0.5mg qd	1.0mg qd

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr(mL/min)	Treatment-naive Lamivudine-Refractory or Decompensated Liver Disease
30-50	0.25mg qd or 0.5mg q48h 0.5mg qd or 1mg q48h
10-30	0.15mg qd or 0.5mg q72h 0.3mg qd or 1mg q72h
<10	0.05mg qd or 0.5mg qw 0.1mg qd or 1mg qw
H/D* or CAPD	0.05mg qd or 0.5mg qw 0.1mg qd or 1mg qw

*on hemodialysis days, administer after hemodialysis

P: Tab: 0.5mg(21144)(21162), 1mg(27536)

ADR:

COMMON
Nausea, dizziness, headache, fatigue
SERIOUS
Lactic acidosis, severe hepatomegaly with steatosis, recurrent hepatitis, anaphylactoid reaction

NOTE: 室溫儲存25℃以下

1.Administer on an empty stomach (at least 2h before or 2h after a meal)
2.Hepatic function should be monitored for at least several months after discontinue anti-hepatitis B therapy

藥名相似:

外觀相似:

外觀描述: 白色三角形扁錠，一面有"AX 133"字樣，另一面有"5"字樣

06.12D Nucleoside and Nucleotides

21164 **B / Infant risk is**

ACYLETE* TABLETS 400MG (ACYCLOVIR) 敵疱治錠４００公絲（艾可賽威）

Acyclovir 400mg tab

Dosage: 1常備品 21164

Adult
· Chickenpox (varicella): PO, 800mg qid for 5 days
· Genital herpes: initial infection, PO, 200mg 5 times/day for 10 days; intermittent therapy of recurrence, PO, 200mg 5 times/day for 5 days; chronic suppressive therapy of recurrence, PO, 400mg bid for up to 12 mons
· Herpes zoster: PO, 800mg 5 times/day for 7-10 days

Pediatric
· Chickenpox (varicella)(≧2 yrs): PO, 20mg/kg qid for 5 days, Max. 800mg/dose; children>40kg, 800mg qid for 5 days

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

· If normal dose is 200mg 5 times/day
Clcr≧10mL/min: Give usual dose and interval
Clcr<10mL/min: 200mg q12h
· If normal dose is 400mg q12h
Clcr≧10mL/min: Give usual dose and interval
Clcr<10mL/min: 200mg q12h
· If normal dose is 800mg 5 times/day
Clcr>25mL/min: Give usual dose and interval
Clcr 10-25mL/min: 800mg q8h
Clcr<10mL/min: 800mg q12h

P: Tab: 200mg(27226), 400mg(21164); Oph Oint: 3% 4.5g(29194); Inj: 250mg Vial(37605)

ADR:

COMMON
Diarrhea, nausea, vomiting, headache, malaise,
SERIOUS
Thrombotic thrombocytopenic purpura, hemolytic uremia syndrome, renal failure

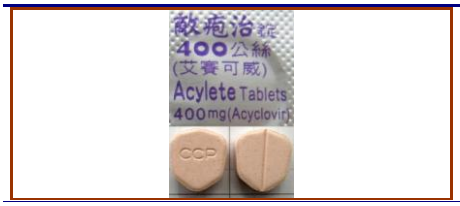
NOTE: 室溫儲存

1. Patients receiving acyclovir should be well hydrated and have adequate urine output
2. May be administered with or without food

藥名相似:

外觀相似:

外觀描述: 淡紅橙色六邊形錠，一面有 CCP 字樣，另一面中央有刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1034583

06.12D Nucleoside and Nucleotides

27226 B / Infant risk is

VIRLESS TABLETS 200MG (ACYCLOVIR) "YUNG SHIN"
剋疱錠２００公絲（艾賽可威）〝永信〞

Acyclovir 200mg tab

Dosage: 1常備品 27226

Adult
· Chickenpox (varicella): PO, 800mg qid for 5 days
· Genital herpes: initial infection, PO, 200mg 5 times/day for 10 days; intermittent therapy of recurrence, PO, 200mg 5 times/day for 5 days; chronic suppressive therapy of recurrence, PO, 400mg bid for up to 12 mons
· Herpes zoster: PO, 800mg 5 times/day for 7-10 days

Pediatric
· Chickenpox (varicella)(≧2 yrs): PO, 20mg/kg qid for 5 days, Max. 800mg/dose; children>40kg, 800mg qid for 5 days

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

· If normal dose is 200mg 5 times/day
Clcr≧10mL/min: Give usual dose and interval
Clcr<10mL/min: 200mg q12h
· If normal dose is 400mg q12h
Clcr≧10mL/min: Give usual dose and interval
Clcr<10mL/min: 200mg q12h
· If normal dose is 800mg 5 times/day
Clcr>25mL/min: Give usual dose and interval
Clcr 10-25mL/min: 800mg q8h
Clcr<10mL/min: 800mg q12h

P: Tab: 200mg(27226), 400mg(21164); Oph Oint: 3% 4.5g(29194); Inj: 250mg Vial(37605)

ADR:

COMMON
Diarrhea, nausea, vomiting, headache, malaise,
SERIOUS
Thrombotic thrombocytopenic purpura, hemolytic uremia syndrome, renal failure

NOTE: 室溫儲存

1. Patients receiving acyclovir should be well hydrated and have adequate urine output
2. May be administered with or without food

藥名相似:

外觀相似:

外觀描述: 藍色圓扁錠，一面有"YUNG"及"SHIN"字樣，另一面有刻痕

06.12D Nucleoside and Nucleotides

27229 B / Caution

FAMVIR 抗濾兒膜衣錠２５０毫克

Famciclovir 250mg FC tab

Dosage: 1常備品 27229

Adult
· Herpes zoster: PO, 500mg q8h for 7 days
· First episode genital herpes simplex infection: PO, 500mg bid for 5-14 days in HIV-infected patients; 250mg tid for 7-10 days in immunocompetent patients
· Recurrent genital herpes: PO, 500mg bid for 5-10 days in HIV-infected patients; 1g bid for 1 day or 125mg bid for 5 days in immunocompetent patients
· Suppression of recurrent genital herpes: PO, 500mg bid in HIV-infected patients; 250mg bid for up to 1 yr in immunocompetent patients
· Recurrent mucocutaneous herpes simplex (orolabial or anogenital) infections: PO, 500mg bid for 7 days in HIV-infected patient

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

· Herpes zoster:
Clcr ≧ 60mL/min: Usual dose
Clcr 40-59mL/min: 500mg q12h
Clcr 20-39mL/min: 500mg qd
Clcr < 20mL/min: 250mg qd
· Recurrent genital herpes:
Clcr ≧60mL/min: 1g q12h for 1 day
Clcr 40-59mL/min: 500mg q12h for 1 day
Clcr 20-39mL/min: 500mg as a single dose
Clcr < 20mL/min: 250mg as a single dose
· Suppression of recurrent genital herpes:
Clcr ≧40mL/min: 250mg q12h
Clcr 20-39mL/min: 125mg q12h
Clcr < 20mL/min: 125mg qd
· Recurrent orolabial or genital herpes in HIV infected patients:
Clcr≧40mL/min: 500mg q12h
Clcr 20-39mL/min: 500mg qd
Clcr < 20mL/min: 250mg qd

P: Tab: 250mg(27229)

ADR:

COMMON
Diarrhea, flatulence, nausea, vomiting, headache, dysmenorrhea
SERIOUS
Erythema multiforme, Stevens-Johnson syndrome

NOTE: 室溫儲存

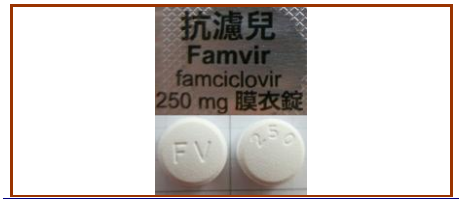
1. Take with or without food

2. Safety and efficacy in children less than 18 yrs of age have not been established.

藥名相似: Tab: 250mg(27229)

外觀相似:

外觀描述: 白色圓扁錠，有250及FV字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022179

06.12D Nucleoside and Nucleotides

27526 **C / Infant risk can**

VALCYTE FILM-COATED TABLETS 450MG 克毒癒 膜衣錠 4 5 0 毫克

Valganciclovir 450mg tab

Dosage: 1常備品 27526

Adult

·Cytomegaloviral retinitis: PO, initial 900mg bid for 21 days; MD 900mg qd

·Cytomegalovirus infection; prophylaxis: PO, 900mg qd; therapy should begin within 10 days of transplantation and continue through day 100 posttransplantation

Pediatric

· Congenital CMV infection (<1 yr): PO, 16mg/kg q12h

· Prevention of CMV disease following heart transplantation (1 mons-16 yrs): PO, once daily dose (mg) = 7 x body surface area x creatinine clearance(using modified Schwartz formula, Max. 150 mL/min/1.73 m2); begin therapy within 10 days of transplantation and continued until 100 days post transplantation; Max. 900mg/day

· Prevention of CMV disease following kidney transplantation(4 mons-16 yrs): PO, once daily dose (mg) = 7 x body surface area x creatinine clearance(using modified Schwartz formula, Max. 150 mL/min/1.73 m2); begin therapy within 10 days of transplantation and continued until 200 days post transplantation; Max. 900mg/day

Clcr = [k x height (cm)] ÷ serum creatinine (mg/dL)

k= 0.33 for patients < 1 yr with low birth weight for gestational age; 0.45 for patients < 1 yr with birth weight appropriate for gestational age; 0.45 for patients 1-2 yrs; 0.55 for boys age 2-13 yrs; 0.55 for girls age 2-16 yrs; 0.7 for boys age 13-16 yrs

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

	Induction	Maintenance
Clcr 40-59 mL/min	450 mg bid	450 mg qd
Clcr 25-39 mL/min	450 mg qd	450 mg qod
Clcr 10-24 mL/min	450 mg qod	450 mg biw

P: Tab: 450mg(27526)

ADR:

COMMON

Diarrhea, nausea, vomiting, headache, tremor, urinary tract infectious disease, upper respiratory infection, fatigue, fever

SERIOUS

Anemia, aplastic anemia, bone marrow depression, leukopenia, neutropenia, pancytopenia, thrombocytopenia

NOTE: 室溫儲存

·Do not break or crush tablets.

·Avoid direct contact of broken or crushed tablets with skin or mucous membranes (potential teratogen and carcinogen).

·Women of childbearing age should use effective contraception, and men should use barrier contraception when receiving valganciclovir and should continue to do so for 90 days following treatment.

藥名相似:

外觀相似:

外觀描述: 粉紅色長橢圓錠,有VGC及450字樣

06.12D Nucleoside and Nucleotides

27536 **C / Unsafe**

Baraclude Tablets 1mg 貝樂克膜衣錠1毫克

Entecavir 1mg tab

Dosage: 1常備品 27536

Adult

·Chronic hepatitis B infection in nucleoside-treatment-na?ve patients with compensated liver disease: PO, ac, 0.5mg once daily

·Chronic hepatitis B infection in patients with a history of hepatitis B viremia while receiving lamivudine or known lamivudine resistant mutations: PO, ac, 1mg once daily

·Chronic hepatitis B infection in patients with decompensated liver disease: PO, ac, 1mg once daily

Pediatric (≧ 2 yrs)

·Chronic hepatitis B infection: PO, ac,

Weight (kg)	nucleoside-treatment-naive	lamivudine-experienced
10-11	0.15mg qd	0.3mg qd
>11-14	0.2mg qd	0.4mg qd
>14-17	0.25mg qd	0.5mg qd
>17-20	0.3mg qd	0.6mg qd
>20-23	0.35mg qd	0.7mg

qd
>23-26 0.4mg qd 0.8mg qd
>26-30 0.45mg qd 0.9mg qd
>30 0.5mg qd 1.0mg qd

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr(mL/min)	Treatment-naive	Lamivudine-Refractory or Decompensated Liver Disease
30-50	0.25mg qd or 0.5mg q48h	0.5mg qd or 1mg q48h
10-30	0.15mg qd or 0.5mg q72h	0.3mg qd or 1mg q72h
<10	0.05mg qd or 0.5mg qw	0.1mg qd or 1mg qw
H/D* or CAPD	0.05mg qd or 0.5mg qw	0.1mg qd or 1mg qw

*on hemodialysis days, administer after hemodialysis

P: Tab: 0.5mg(21144)(21162), 1mg(27536)

ADR:

COMMON
Nausea, dizziness, headache, fatigue
SERIOUS
Lactic acidosis, severe hepatomegaly with steatosis, recurrent hepatitis, anaphylactoid reaction

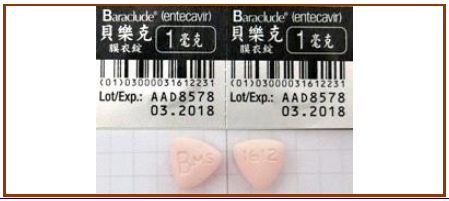
NOTE: 室溫儲存

1.Administer on an empty stomach (at least 2h before or 2h after a meal)
2.Hepatic function should be monitored for at least several months after discontinue anti-hepatitis B therapy

藥名相似:

外觀相似:

外觀描述: 粉紅色三角形扁錠，有BMS及1612字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024468

06.12D Nucleoside and Nucleotides

27848 **demonstrated / Infant risk can**

ZEPATIER* (elbasvir and grazoprevir) Tablet 賀肝樂膜衣錠

Elbasvir 50mg & Grazoprevir 100mg tab

Dosage: 1常備品 27848

Adult
· Chronic hepatitis C genotype 1 or 4 infection: PO, 1 tab qd with or without ribavirin, for 12 or 16 wks, depending on HCV genotype and certain patient factors (e.g., previous treatment experience, presence of baseline polymorphisms)

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild impairment (Child-Pugh A): No dosage adjustment needed
Moderate or severe impairment (Child-Pugh B or C): Use is contraindicated

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: ZEPATIER* (27848)

ADR:

COMMON
Nausea, headache, fatigue
SERIOUS
ALT/SGPT level raised, liver failure, reactivation of hepatitis B viral hepatitis

NOTE: 室溫儲存

· 健保給付治療組合：(1)Zepatier +/- ribavirin治療基因型1a型，無抗藥性病毒株，12週療程，(2)Zepatier +/- ribavirin治療基因型1b型，12週療程，(3)Zepatier治療基因型第4型，12週療程，支付價格2976元/日。Zepatier + ribavirin治療基因型1a型，有抗藥性病毒株，16週療程，支付價格2232元/日。(含ribavirin者，不得另申報ribavirin費用)
· Testing patients with HCV genotype 1a infection for the presence of virus with NS5A resistance-associated polymorphisms is recommended prior to treatment initiation to determine regimen and duration.
· 合併感染HCV與HBV之病人，發生B型肝炎病毒再活化的風險提高，建議HCV開始治療前，增加HBV感染檢測(HBsAg和HBc抗體)，在治療期間與治療後，應追蹤監測是否出現肝炎爆發與HBV再活化的徵兆。 (仿單內容更新- OA文號乙1070002026)

藥名相似:

外觀相似:

外觀描述: 米色橢圓形膜衣錠，一面有 770 字樣

06.12D Nucleoside and Nucleotides

27849 **demonstrated / Infant risk can**

MAVIRET* Film-Coated Tablets 100mg/40mg 艾百樂膜衣錠100毫克/40毫克

Glecaprevir 100mg & Pibrentasvir 40mg tab

Dosage: 1常備品 27849

Adult
· Chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

infection: PO, 3 tabs qd with food, treatment duration as below:
(1) treatment-naive without cirrhosis: 8 wks
(2) treatment-naive with compensated cirrhosis(Child-Pugh A): 12 wks
(3) treatment-experienced:
(a)Genotype 1:
·Prior treatment with an NS5A inhibitor containing regimen without an NS3/4A protease inhibitor: 16 wks
· Prior treatment with an NS3/4A protease inhibitor containing regimen without an NS5A inhibitor: 12 wks
(b)Genotype 1, 2, 4, 5, or 6:
·Prior treatment with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment with an HCV NS3/4A PI or NS5A inhibitor: 8 wks (without cirrhosis) or 12 wks (with compensated cirrhosis)
(c)Genotype 3:
·Prior treatment with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment with an HCV NS3/4A PI or NS5A inhibitor: 16 wks

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild impairment (Child-Pugh A): No dosage adjustment needed
Moderate impairment (Child-Pugh class B): Use is not recommended
Severe impairment (Child-Pugh class C): Use is contraindicated

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: P Tab: MAVIRET* (27849)

ADR:

COMMON
Nausea, headache, fatigue
SERIOUS
Reactivation of hepatitis B viral hepatitis

NOTE: 室溫儲存

·健保給付治療組合：Maviret治療基因型第1、2、3、4、5或6型，8週療程，支付價格4464元/日。Maviret治療基因型第1、2、3、4、5或6型，12週療程，支付價格2976元/日。(含ribavirin者，不得另申報ribavirin費用)

藥名相似:

外觀相似:

外觀描述: 粉紅色橢圓形膜衣錠，一面有NXT字樣

06.12D Nucleoside and Nucleotides

27850 ɔt be ruled out / Infant risk can

Epclusa Film-Coated Tablets 宜譜莎 膜衣錠

Sofosbuvir 400mg & Velpatasvir 100mg tab

Dosage: 1常備品 27850

Adult
· Chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6 infection: PO, 1 tab qd, treatment duration as below:
(1)Treatment-naive and treatment-experienced, without cirrhosis and with compensated cirrhosis (Child-Pugh A): 12 wks
(2)Treatment-naive and treatment-experienced, with decompensated cirrhosis (Child-Pugh class B or C): in combination with weight-based ribavirin for 12 wks
(3)Prior treatment failure with sofosbuvir- or NS5A-based regimens: 24 wks

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Mild or moderate impairment: No dosage adjustment needed
Severe impairment (eGFR <30 mL/minute/1.73 m2): NDA

P: Tab: EPCLUSA* (27850)

ADR:

COMMON
Nausea, headache, fatigue
SERIOUS
Bradyarrhythmia, liver failure, reactivation of hepatitis B viral hepatitis

NOTE: 室溫儲存

· The solubility of velpatasvir decreases as pH increases. Therefore, drugs that increase gastric pH are expected to decrease the concentrations of velpatasvir.
(1)Administration of sofosbuvir/velpatasvir and antacids (e.g., aluminum and magnesium hydroxides) should be separated by 4 hours.
(2)H2-receptor antagonists may be administered concurrently with or 12 hours apart from sofosbuvir/velpatasvir; dosage of the H2-receptor antagonist should not exceed dosages comparable to famotidine 40 mg twice daily.
(3)Concomitant use of sofosbuvir/velpatasvir and proton-pump inhibitors (e.g., omeprazole) is not recommended. If concomitant use of sofosbuvir/velpatasvir and omeprazole is considered necessary, sofosbuvir/velpatasvir should be administered with food 4 hours before omeprazole 20 mg. Use of sofosbuvir/velpatasvir with other proton-pump inhibitors has not been studied.

藥名相似:

外觀相似:

外觀描述: 淺粉紅色菱形錠，一面刻有"GSI"字樣，另一面刻有"7916"字樣

06.12D Nucleoside and Nucleotides

37605 B / Infant risk is

ACICLOVIR* INTRAVENOUS INFUSION "DBL" 岱比博〝爾速可愈〞注射液

Acyclovir inj 250mg/10mL vial

Dosage: 1常備品 37605

Adult
· Herpes simplex virus infection(≧12 yrs): IV infusion, Genital herpes: 5mg/kg over 1 hr q8h for 5-7 days
Encephalitis: 10mg/kg q8h for 10 days
Mucosal and cutaneous herpes in immuno-compromised patients: 5mg/kg q8h for 7 days
· Varicella zoster infections in immuno-compromised patients: 10mg/kg q8h for 7 days

Pediatric
· Herpes simplex virus infection(≧12 yrs): IV infusion, Genital herpes: 5mg/kg q8h for 5 days
Mucosal and cutaneous herpes in immuno-compromised patients: <12 yrs, 10mg/kg q8h for 7 days; ≧12 yrs, 5mg/kg q8h for 7 days
Encephalitis: 3 mons-12 yrs, 20mg/kg q8h for 10 days; ≧12 yrs, 10mg/kg q8h for 10 days
Neonatal herpes simplex: 0-3 mons, 10mg/kg q8h for 10 days; doses of 15- 20mg/kg have been used
· Varicella zoster infections in immuno-compromised patients: <12 yrs, 20mg/kg q8h for 7 days; ≧12 yrs, 10mg/kg q8h for 7 days

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr>50mL/min: Usual dose and interval
Clcr 25-50mL/min: Administer q12h
Clcr 10-25mL/min: Administer qd
Clcr<10mL/min: 50% of usual dose qd

P: Tab: 200mg(27226); Oph Oint: 3% 4.5g(29194); Inj: 250mg Vial(37605)

ADR:

COMMON
Diarrhea, nausea, vomiting, central nervous system effects, agitation, confusion, dizziness, hallucinations, somnolence, malaise, injection site phlebitis, increased serum creatinine and BUN
SERIOUS
Thrombotic thrombocytopenic purpura, confusion, lethargy, tremor, agitation, hemolytic uremic syndrome, renal impairment

NOTE: 室溫儲存25℃以下

1. Patients receiving acyclovir should be well hydrated and have adequate urine output
2. IV infusion over 1 hour (bolus injection can cause precipitation of acyclovir crystals in renal tubules), max. concentration 7mg/mL.
3. Avoid subcutaneous or intramuscular injection
4.本藥的pH值約為11.0，不能經由口服給藥。不慎注入血管外組織時會出現嚴重的局部發炎反應，有時會導致皮膚破裂。
5.治療免疫不全病人可能會發生導致死亡之血栓性血小板減少性紫斑/溶血性尿毒症候群。
6.腎功能不全者需調整劑量，以避免在體內累積。應保持充足的水分補充。治療過程中發生腎功能損傷時，通常在重新補充水份和/或降低藥物劑量或停藥後會改善。但有罕見的案例會發展成急性腎衰竭。

藥名相似:

外觀相似:

外觀描述: 10mL透明注射液，『黑』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022251

06.12E Neuraminidase

27231 C /

Eraflu Capusle 75mg "Yung Shin" "永信"易剋冒膠囊75毫克

公費Oseltamivir phosphate 75mg cap

Dosage: 2衛福部提供 27231

Adult
· Influenza treatment: PO, 75mg bid for 5 days
· Influenza prophylaxis: PO, 75mg qd for at least 7 days (up to 6 wks).

Pediatric
· Influenza treatment(children < 1 yrs):
6-11months: PO, 25mg bid for 5 days
3-5months: PO, 20mg bid for 5 days
< 3months: PO, 12mg bid for 5 days
· Influenza prophylaxis(children < 1 yrs):
6-11months: PO, 25mg qd for 10 days
3-5months: PO, 20mg qd for 10 days
< 3months: not recommended, unless clinical critical
· Influenza treatment(children > 1 yrs):
<15kg: PO, 30mg bid for 5 days
15-23kg: PO, 45mg bid for 5 days
23-40kg: PO, 60mg bid for 5 days
> 40kg: PO, 75mg bid for 5 days
· Influenza prophylaxis(children >1 yrs):
<15kg: PO, 30mg qd for 10 days
15-23kg: PO, 45mg qd for 10 days
23-40kg: PO, 60mg qd for 10 days
> 40kg: PO, 75mg qd for 10 days

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

· Influenza treatment:
Clcr 30-60mL/min: 30mg bid for 5 days
Clcr 10-30mL/min: 30mg qd for 5 days
ESRD not on dialysis: Use is not recommended
· Influenza prophylaxis:
Clcr 30-60mL/min: 30mg qd
Clcr 10-30mL/min: 30mg qod
ESRD not on dialysis: Use is not recommended

P:

ADR:

OMMON
Nausea, vomiting, headache
SERIOUS
Cardiac dysrhythmia, erythema multiforme(rare), facial swelling, Stevens-Johnson syndrome(rare), toxic epidermal necrolysi(rare), gastrointestinal hemorrhage, hemorrhagic colitis, hepatitis, anaphylaxis(rare), seizure, abnormal behavior, delirium

NOTE: 室溫儲存25℃以下

·The safety and efficacy of oseltamivir phosphate in pediatric patients < 1 yr have not been established.
·自109年1月24日延長至109年3月31日，公費藥劑使用對象，擴大使用條件：類流感病人，臨床評估符合流感診斷者(不論國籍)

藥名相似:

外觀相似:

外觀描述: 白色/黃色膠囊，有YSP OVC及75mg字樣

06.12E Neuraminidase

27243 C /

TAMIFLU CAPSULES 75MG 克流感膠囊 75 毫克 (法國廠)

Oseltamivir 75mg cap

Dosage: 1常備品 27243

Adult
· Influenza treatment: PO, 75mg bid for 5 days
· Influenza prophylaxis: PO, 75mg qd for at least 7 days (up to 6 wks).

Pediatric
· Influenza treatment(children < 1 yrs): PO, 3mg/kg bid for 5 day
· Influenza prophylaxis(children < 1 yrs): PO, 3mg/kg qd for 10 day
· Influenza treatment(children > 1 yrs):
<15kg: PO, 30mg bid for 5 days
15-23kg: PO, 45mg bid for 5 days
23-40kg: PO, 60mg bid for 5 days
> 40kg: PO, 75mg bid for 5 days
· Influenza prophylaxis(children >1 yrs):
<15kg: PO, 30mg qd for 10 days
15-23kg: PO, 45mg qd for 10 days
23-40kg: PO, 60mg qd for 10 days
> 40kg: PO, 75mg qd for 10 days

Dosing adjustments in hepatic impairment:

Mild to moderate impairment (Child-Pugh score ?9): No dosage adjustment needed
Severe impairment: Has not been studied

Dosing adjustments in renal impairment:

· Influenza treatment:
Clcr 30-60mL/min: 30mg bid for 5 days
Clcr 10-30mL/min: 30mg qd for 5 days
ESRD not on dialysis: Use is not recommended
· Influenza prophylaxis:
Clcr 30-60mL/min: 30mg qd
Clcr 10-30mL/min: 30mg qod
ESRD not on dialysis: Use is not recommended

P:

ADR:

COMMON
Nausea, vomiting, headache
SERIOUS
Cardiac dysrhythmia, erythema multiforme(rare), facial swelling, Stevens-Johnson syndrome(rare), toxic epidermal necrolysi(rare), gastrointestinal hemorrhage, hemorrhagic colitis, hepatitis, anaphylaxis(rare), seizure, abnormal behavior, delirium

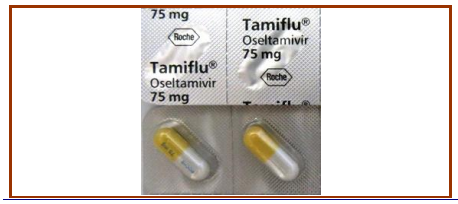
NOTE: 室溫儲存

The safety and efficacy of oseltamivir phosphate in pediatric patients < 1 yr have not been established.

藥名相似:

外觀相似:

外觀描述: 灰色/黃色膠囊，有ROCHE及75mg字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025285

06.12E Neuraminidase

29951 C /

RELENZA ROTADISKS 瑞樂沙旋達碟

Zanamivir Inh powder 5mg/cap, 20cap/B

Dosage: 2衛福部提供 29951

Adult
· Influenza treatment: Inhalation, 2 inhalations (5 mg/inhalation) via Diskhaler q12h for 5 days; administer 2 doses on day 1, at least 2 h apart
· Influenza prophylaxis: Inhalation, 2 inhalations (5 mg/inhalation) via Diskhaler qd for 10 days (up to 28 days)

Pediatric(≧5 yrs)
Same as adult

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P:

ADR:

COMMON
Diarrhea, nausea, headache, cough, nasal symptom
SERIOUS
Bronchospasm, respiratory depression

NOTE: 室溫儲藏

· Do not puncture any Rotadisk blister until loaded into the diskhaler
· If patients scheduled to take inhaled drugs (e.g.

fast acting bronchodilators) at the same time, bronchodilator inhalation should be used before zanamivir
·自109年1月24日延長至109年3月31日，公費藥劑使用對象，擴大使用條件：類流感病人，臨床評估符合流感診斷者(不論國籍)
·據108年9月27日台北市衛生局函示，藥物配置點之分配與管控標準，於108年12月23日配置瑞樂沙1500支予本院，對於 5 歲以上無禁忌症使用對象，請優先開立瑞樂沙。

藥名相似:

外觀相似:

外觀描述: 外用吸入膠囊，請配合碟型吸入器使用

06.12E Neuraminidase

31178 **C / Infant risk can**

RAPIACTA for Intravenous Drip Infusion 300mg 瑞貝塔點滴靜脈注射液

Peramivir inj 300mg/60mL bag

Dosage: 1常備品 31178

Adult
· Acute , uncomplicated influenza A or B virus infections: IV infusion over at least 15 mins, 300mg (to a maximum of 600 mg)(仿單) or 600mg(美國建議劑量) as a single dose within 2 days of symptom onset
· Hospitalized influenza A or B virus infections: IV infusion over at least 15 mins, 600mg qd or 300mg bid for 5 days; if clinically unstable on day 4, continue on 600 mg qd for 5 additional days (10 days total)(Micromedex資料-off-labeled use)

Pediatric
· Acute , uncomplicated influenza A or B virus infections: IV infusion over at least 15 mins, 10mg/kg (> 1 mon, insufficient clinical data available in children less than 2 yrs, 仿單)or 12mg/kg(>2yrs, 美國建議劑量) as a single dose within 2 days of symptom onset, Max. 600mg

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr≧50mL/min: No dosage adjustment needed
Clcr 30-50mL/min: 100mg(仿單) or 200mg(美國建議劑量) as a single dose
Clcr 10-30mL/min: 50mg(仿單) or 100mg(美國建議劑量) as a single dose
There are no clinical data available in children with renal impairment.

P: Inj: 300mg/60mL Bag(31178, 自費)(39332, 公費)

ADR:

COMMON
Diarrhea
SERIOUS
Stevens-Johnson syndrome, anaphylaxis, abnormal behavior, hallucinations

NOTE: 室溫儲存

· Efficacy has not been established for patients with serious influenza requiring hospitalization.
· Each 60mL bag contains 540mg sodium chloride.

藥名相似:

外觀相似:

外觀描述: 60mL透明液，點滴注射用軟袋

06.12E Neuraminidase

39332 **UK / Unsafe**

RAPIACTA for Intravenous Drip Infusion 300mg 瑞貝塔點滴靜脈注射液

通報Peramivir inj 300mg/60mL bag(公費)

Dosage: 2衛福部提供 39332

Adult
· Influenza A or B virus infections: IV infusion over longer than 15 mins, In general, 300mg as a single dose; 600mg as a single dose for patients at high-risk, but multiple daily doses are also used depending on the condition. The dosage should be adjusted according to the age or condition of the patient.

Pediatric
· Influenza A or B virus infections: IV infusion over longer than 15 mins, 10mg/kg qd; Max. 600mg/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

	General	High-risk
Clcr 30-50mL/min:	100mg	200mg
Clcr 10-30mL/min:	50mg	100mg

P: Inj: 5mg/mL, 60mL Bag(39332)

ADR:

COMMON
Diarrhea, nausea, neutropenia
SERIOUS
Psychiatric sign or symptom

NOTE:

· Each 60mL bag contains 540mg sodium chloride. Use with caution in patients with cardiovascular or renal function impairment.

藥名相似:

外觀相似:

外觀描述: 點滴用注射袋

06.14A Quinolones, parenteral

31182 **C / Unknown(有**

AVELOX INFUSION SOLUTION 400MG/250ML 威洛速靜脈輸注液４００毫克　２５０毫升

Moxifloxacin 400mg/250mL bot

Dosage: 1常備品 31182

Adult
· Chronic bronchitis, community-acquired pneumonia, acute bacterial sinusitis, skin and skin structure infection, intra-abdominal infection: IV infusion over 60mins, 400mg qd for 5-21 days; duration of therapy depends on the type of infection
· Tuberculosis: IV infusion over 60mins, 400mg qd

Pediatric
Safety and efficacy have not been established in pediatric patients less than 18 years old

Dosing adjustments in hepatic impairment:

No dosage adjustment needed; Use with caution secondary to the risk of QT prolongation

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 400mg(21269)(27898, 二線TB用藥); Inj: 400mg/250mL Bot(31182)

ADR:

COMMON
Hypokalemia, abdominal pain, constipation, diarrhea, nausea, vomiting, ALT/SGPT level abnormal, dizziness, headache
SERIOUS
Aortic aneurysm or dissection, prolonged QT interval, Torsades de pointes, rash, Stevens-Johnson syndrome, toxic epidermal necrolysis, hyperglycemia, hypoglycemia, Clostridium difficile diarrhea, agranulocytosis, aplastic anemia, hemolytic anemia, pancytopenia, thrombocytopenia, hepatic necrosis, hepatitis, liver failure, anaphylactoid reaction, hypersensitivity reaction, exacerbations of myasthenia gravis, rupture of tendon, tendinitis, disorientated, disturbance of attention, Guillain-Barre syndrome, memory impairment, peripheral neuropathy, pseudotumor cerebri, raised intracranial pressure, seizure, retinal detachment, agitation, feeling nervous, paranoid disorder, suicidal, renal failure, extrinsic allergic alveolitis, serum sickness due to drug

NOTE: 室溫保存

1.The intravenous dose should be administered over 60 minutes; rapid infusion or bolus administration should be avoided. Increased drug concentrations or increased infusion rates may increase the magnitude of QT prolongation
2.This medicine may make your skin more sensitive to sunlight. Use a sunscreen when you are outdoors. Avoid sunlamps and tanning beds.
3.Fluoroquinolones have been associated with disturbances in glucose regulation, including hyperglycemia and hypoglycemia. These events have occurred most often in patients receiving concomitant oral hypoglycemic agents or insulin. Severe cases of hypoglycemia, including coma and death, have been reported. Diabetic patients should be monitored closely for signs/symptoms of disordered glucose regulation.Discontinue if a hypoglycemic reaction occurs and immediately initiate appropriate therapy.
4.Quinolone 類藥品警語：
(1)沒有其他替代治療選擇時，才用於下列適應症：慢性支氣管炎急性惡化、急性非複雜性膀胱炎。
(2)過去使用quinolone或fluoroquinolone類曾發生嚴重不良反應，應避免使用，應先確認沒有替代治療選擇並謹慎評估效益/風險。
(3)肌腱炎及肌腱斷裂(好發於阿基里斯腱)，有時為雙側，可能於使用48小時內發生，也可能停藥數月後才發生。老年人、腎功能不良、曾進行器官移植或同時併用皮質類固醇會增加風險，故應避免併用皮質類固醇。
(4)精神相關不良反應，包括中毒性精神病、精神病反應進展至自殺意念/想法、幻覺或妄想；憂鬱或自殘行為如企圖自殺或完成自殺；焦慮、躁動或緊張；精神混亂、瞻妄、失去方向感或注意力無法集中；失眠或做惡夢；記憶力受損。可能發生在第一次投藥後。倘出現前述不良反應，應停用並開始適當治療。應特別注意治療的精神病或有精神疾病史的病人。
(5)癲癇(痙攣)風險、增加顱內壓(假性腦腫瘤)、頭暈和顫抖有關。如發生應停用並開始適當治療。
(6)血糖異常，曾有嚴重低血糖導致昏迷或死亡通報案例。如發生應停用並立即開始適當的治療。
(7)增加主動脈瘤及主動脈剝離相關風險，尤其老年人。有動脈瘤疾病之家族史，或已有主動脈瘤及/或主動脈剝離，或具有加重主動脈瘤及主動脈剝離之危險時，需謹慎評估其效益及風險與其他治療方式。建議病人如有突發性腹痛、胸或背痛，應立即就醫。

藥名相似:

外觀相似:

外觀描述: 250mL淡黃透明注射液『暗紅』色蓋透明玻璃瓶，蓋上有FLIP及OFF字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023712

06.14A Quinolones, parenteral

31184 **C / Unsafe**

BACFLOCIN* I.V. solution for infusion 5mg/ml 倍樂欣靜脈輸液5毫克/毫升

Levofloxacin inj 250mg/50mL vial

Dosage: 1常備品 31184

Adult: IV infusion over 60mins
·Acute exacerbation of chronic bronchitis: 500mg q24h for 7 days
·Chronic bacterial prostatitis: 500mg q24h for 28 days
·Bacterial sinusitis: 750mg q24h for 5 days or 500mg

q24h for 10-14 days
·Community acquired pneumonia: 500mg q24h for 7-14 days or 750mg q24h for 5 days
·Infection of skin: complicated, 750mg q24h for 7-14 days; uncomplicated, 500 mg q24h for 7-10 days
·Nosocomial pneumonia: 750 mg q24h for 7-14 days
·Pyelonephritis: 750mg q24h for 5 days
·Urinary tract infections: complicated, 250 mg q24h for 10 days or 750mg q24h for 5 days; uncomplicated, 250mg q24h for 3 days
·Tuberculosis: 500mg-1000mg qd

Pediatric: (Use may be justified if the benefits outweigh the risks)
·Community acquired pneumonia, acute otitis media: IV infusion over 60mins,
6 mons-5 yrs: 8-10mg/kg q12h; Max. 750mg/day
5 yrs-16 yrs: 8-10mg/kg qd; Max. 750mg/day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

·Normal renal function dosing of 750mg/day:
Clcr 20-49mL/min: Initial 750mg, then 750mg q48h
Clcr 10-19mL/min: Initial 750mg, then 500mg q48h
·Normal renal function dosing of 500mg/day:
Clcr 20-49mL/min: Initial 500mg, then 250mg q24h
Clcr 10-19mL/min: Initial 500mg, then 250mg q48h
·Normal renal function dosing of 250mg/day:
Clcr 20-49mL/min: No dosage adjustment needed
Clcr 10-19mL/min: Initial 250mg, then 250mg q48h
(No dosage adjustment is required in uncomplicated UTI)

P: Tab: 500mg(21270)(27899, 二線TB用藥), 750mg(27896, 二線TB用藥); Oph Soln: 0.5%, 5mL(29205); Inj: 250mg/50mL Vial(31184)

ADR:

COMMON
Diarrhea, nausea, headache
SERIOUS
Cardiac arrest, prolonged QT interval, Torsades de pointes, ventricular tachycardia, erythema multiforme, Stevens-Johnson syndrome, hypoglycemia, aplastic anemia, pancytopenia, thrombocytopenic purpura, hepatitis, liver failure, anaphylactoid reaction, immune hypersensitivity reaction, rupture of tendon, tendinitis, seizure, acute renal failure

NOTE: 室溫避光

·It should be used immediately (within 3 hrs) after perforation of the rubber stopper
·Shelf life after removal of the outer packaging: 3 days (under indoor light conditions)
·兒童患者比未使用者更易發生肌肉骨骼疾病之不良反應。
·Fluoroquinolones have been associated with disturbances in glucose regulation, including hyperglycemia and hypoglycemia. These events have occurred most often in patients receiving concomitant oral hypoglycemic agents or insulin. Severe cases of hypoglycemia, including coma and death, have been reported. Diabetic patients should be monitored closely for signs/symptoms of disordered glucose regulation.Discontinue if a hypoglycemic reaction occurs and immediately initiate appropriate therapy.
·Quinolone 類藥品警語：
(1)過去使用quinolone或fluoroquinolone類曾發生嚴重不良反應，應避免使用，應先確認沒有替代治療選擇並謹慎評估效益/風險。
(2)肌腱炎及肌腱斷裂(好發於阿基里斯腱)，有時為雙側，可能於使用48小時內發生，也可能停藥數月後才發生。老年人、腎功能不良、曾進行器官移植或同時併用皮質類固醇會增加風險，故應避免併用皮質類固醇。
(3)精神相關不良反應，包括中毒性精神病、精神病反應進展至自殺意念/想法、幻覺或妄想；憂鬱或自殘行為如企圖自殺或完成自殺；焦慮、躁動或緊張；精神混亂、瞻妄、失去方向感或注意力無法集中；失眠或做惡夢；記憶力受損。可能發生在第一次投藥後。倘出現前述不良反應，應停用並開始適當治療。應特別注意治療的精神病或有精神疾病史的病人。
(4)癲癇(痙攣)風險、增加顱內壓(假性腦腫瘤)、頭暈和顫抖有關。如發生應停用並開始適當治療。
(5)血糖異常，曾有嚴重低血糖導致昏迷或死亡通報案例。如發生應停用並立即開始適當的治療。
(6)增加主動脈瘤及主動脈剝離相關風險，尤其老年人。有動脈瘤疾病之家族史，或已有主動脈瘤及/或主動脈剝離，或具有加重主動脈瘤及主動脈剝離之危險時，需謹慎評估其效益及風險與其他治療方式。建議病人如有突發性腹痛、胸或背痛，應立即就醫。

藥名相似:

外觀相似:

外觀描述: 50mL澄清淡黃色注射液，『灰』蓋玻璃瓶，包裝有"倍樂欣"、"Bacflocin"及紫紅色圖區塊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1056750

06.14A Quinolones, parenteral

31185 **C / Unsafe**

CIPROXIN INF. SOL. 50ML/100MG、100ML/200MG、200ML/400MG 速博新靜脈輸液0．1、0．2、0．4公克

Ciprofloxacin 200mg/100mL vial

Dosage: 1常備品 31185

Adult: IV infusion over 60 mins,
· Susceptible infections: 400mg q8-12h
· Anthrax: 400mg q12h for 60 days
· Bone and joint infection: Mild/moderate, 400mg q12h for 4-6 wks; severe/complicated, 400mg q8h for 4-6 wks
· Febrile neutropenia: 400mg q8h for 7-14 days, in combination with piperacillin 50mg/kg q4h(Max. 24g/day)
· Intra-abdominal infection: 400mg q12h for 7-14 days, in combination with metronidazole
· Lower respiratory infection, skin/skin structure infection: Mild/moderate, 400mg q12h for 7-14

days; severe/complicated, 400mg q8h for 7-14 days
· Urinary tract infection: Mild/moderate, 200mg q12h for 7-14 days; severe/complicated, 400mg q12h for 7-14 days
· Nosocomial pneumonia: 400mg q8h for 10-14 days
· Chronic bacterial prostatitis: 400mg q12h for 28 days
· Sinusitis: 400mg q12h for 10 days

Pediatric: IV infusion over 60 mins,
· Anthrax: 10-15mg/kg q12h for 60 days, Max. 400mg/dose
· Cystic fibrosis: 30mg/kg/day div. q8h; Max. 1.2g/day
· Complicated urinary tract infection: 6-10mg/kg q8h for 10-21 days, Max. 400mg/dose

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr >30mL/min: Usual dose
Clcr 5-29mL/min: 200-400mg q18-24h

P: Tab: 250mg(20839); Inj: 200mg/100mL vial(31185)

ADR:

COMMON
Rash, diarrhea, nausea, vomiting, headache, irritability, nasal discharge, nasopharyngitis
SERIOUS
Aortic aneurysm or dissection, cardiorespiratory arrest, myocardial infarction, prolonged QT interval, syncope, Torsades de pointes, photosensitivity, Stevens-Johnson syndrome, toxic epidermal necrolysis, hypoglycemia, Clostridium difficile colitis, Clostridium difficile diarrhea, gastrointestinal hemorrhage, pancreatitis, agranulocytosis, aplastic anemia, bone marrow depression, hemolytic anemia, leukopenia, pancytopenia, thrombocytopenia, hepatic necrosis, hepatitis, hepatotoxicity, liver failure, hypersensitivity reaction, exacerbations of myasthenia gravis, rupture of tendon, tendinitis, disorientated, disturbance of attention, Guillain-Barre syndrome, memory impairment, peripheral neuropathy, pseudotumor cerebri, raised intracranial pressure, seizure, retinal detachment, delirium, depression, hallucinations, paranoid disorder, psychotic disorder, suicidal behavior, acute renal failure, hemorrhagic cystitis, interstitial nephritis

NOTE: 室溫避光

· The following regimens are equivalent:
Ciproxin tablet 250mg q12h = IV 200mg q12h
Ciproxin tablet 500mg q12h = IV 400mg q12h
Ciproxin tablet 750mg q12h = IV 400mg q8h
· Fluoroquinolones have been associated with disturbances in glucose regulation, including hyperglycemia and hypoglycemia. These events have occurred most often in patients receiving concomitant oral hypoglycemic agents or insulin. Severe cases of hypoglycemia, including coma and death, have been reported. Diabetic patients should be monitored closely for signs/symptoms of disordered glucose regulation.Discontinue if a hypoglycemic reaction occurs and immediately initiate appropriate therapy.
· Quinolone 類藥品警語：
(1)沒有其他替代治療選擇時，才用於下列適應症：慢性支氣管炎急性惡化、急性非複雜性膀胱炎、非複雜性泌尿道感染、急性鼻竇炎。
(2)過去使用quinolone或fluoroquinolone類曾發生嚴重不良反應，應避免使用，應先確認沒有替代治療選擇並謹慎評估效益/風險。
(3)肌腱炎及肌腱斷裂(好發於阿基里斯腱)，有時為雙側，可能於使用48小時內發生，也可能停藥數月後才發生。老年人、腎功能不良、曾進行器官移植或同時併用皮質類固醇會增加風險，故應避免併用皮質類固醇。
(4)精神相關不良反應，包括中毒性精神病、精神病反應進展至自殺意念/想法、幻覺或妄想；憂鬱或自殘行為如企圖自殺或完成自殺；焦慮、躁動或緊張；精神混亂、瞻妄、失去方向感或注意力無法集中；失眠或做惡夢；記憶力受損。可能發生在第一次投藥後。倘出現前述不良反應，應停用並開始適當治療。應特別注意治療的精神病或有精神疾病史的病人。
(5)癲癇(痙攣)風險、增加顱內壓(假性腦腫瘤)、頭暈和顫抖有關。如發生應停用並開始適當治療。
(6)血糖異常，曾有嚴重低血糖導致昏迷或死亡通報案例。如發生應停用並立即開始適當的治療。
(7)增加主動脈瘤及主動脈剝離相關風險，尤其老年人。有動脈瘤疾病之家族史，或已有主動脈瘤及/或主動脈剝離，或具有加重主動脈瘤及主動脈剝離之危險時，需謹慎評估其效益及風險與其他治療方式。建議病人如有突發性腹痛、胸或背痛，應立即就醫。

藥名相似:

外觀相似:

外觀描述: 100mL透明注射液『藍』蓋透明玻璃瓶

TFDA許可證
http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2018095

06.14A Quinolones, parenteral

31186 **C / Unsafe**

CRAVIT* IV Solution for Infusion 5mg/ml "台灣第一三共"可樂必妥靜脈輸液5毫克/毫升

Levofloxacin inj 250mg/50mL vial

Dosage: 1常備品 31186

Adult: IV infusion over 60mins
·Acute exacerbation of chronic bronchitis: 500mg q24h for 7 days
·Chronic bacterial prostatitis: 500mg q24h for 28 days
·Bacterial sinusitis: 750mg q24h for 5 days or 500mg q24h for 10-14 days
·Community acquired pneumonia: 500mg q24h for 7-14 days or 750mg q24h for 5 days
·Infection of skin: complicated, 750mg q24h for 7-14 days; uncomplicated, 500 mg q24h for 7-10 days
·Nosocomial pneumonia: 750 mg q24h for 7-14 days
·Pyelonephritis: 750mg q24h for 5 days
·Urinary tract infections: complicated, 250 mg q24h for 10 days or 750mg q24h for 5 days; uncomplicated, 250mg q24h for 3 days
·Tuberculosis: 500mg-1000mg qd

Pediatric: (Use may be justified if the benefits outweigh the risks)

·Community acquired pneumonia, acute otitis media: IV infusion over 60mins,
6 mons-5 yrs: 8-10mg/kg q12h; Max. 750mg/day
5 yrs-16 yrs: 8-10mg/kg qd; Max. 750mg/day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

·Normal renal function dosing of 750mg/day:
Clcr 20-49mL/min: Initial 750mg, then 750mg q48h
Clcr 10-19mL/min: Initial 750mg, then 500mg q48h
·Normal renal function dosing of 500mg/day:
Clcr 20-49mL/min: Initial 500mg, then 250mg q24h
Clcr 10-19mL/min: Initial 500mg, then 250mg q48h
·Normal renal function dosing of 250mg/day:
Clcr 20-49mL/min: No dosage adjustment needed
Clcr 10-19mL/min: Initial 250mg, then 250mg q48h
(No dosage adjustment is required in uncomplicated UTI)

P: Tab: 500mg(21270)(27899, 二線TB用藥), 750mg(27896, 二線TB用藥); Oph Soln: 0.5%, 5mL(29205); Inj: 250mg/50mL Vial(31184)

ADR:

COMMON
Diarrhea, nausea, dizziness, headache, insomnia
SERIOUS
Aortic aneurysm or dissection, cardiac arrest, prolonged QT interval, Torsades de pointes, ventricular tachycardia, erythema multiforme, Stevens-Johnson syndrome, hypoglycemia, aplastic anemia, pancytopenia, thrombocytopenic purpura, hepatitis, liver failure, anaphylactoid reaction, hypersensitivity reaction, exacerbations of myasthenia gravis, rupture of tendon, tendinitis, disorientated, disturbance of attention, Guillain-Barre syndrome, memory impairment, peripheral neuropathy, pseudotumor cerebri, raised intracranial pressure, seizure, retinal detachment, delirium, depression, hallucinations, paranoid disorder, psychotic disorder, suicidal, acute renal failure, unterstitial nephritis

NOTE: 室溫避光

·It should be used immediately (within 3 hrs) after perforation of the rubber stopper
·Shelf life after removal of the outer packaging: 3 days (under indoor light conditions)
·兒童患者比未使用者更易發生肌肉骨骼疾病之不良反應。

·Fluoroquinolones have been associated with disturbances in glucose regulation, including hyperglycemia and hypoglycemia. These events have occurred most often in patients receiving concomitant oral hypoglycemic agents or insulin. Severe cases of hypoglycemia, including coma and death, have been reported. Diabetic patients should be monitored closely for signs/symptoms of disordered glucose regulation.Discontinue if a hypoglycemic reaction occurs and immediately initiate appropriate therapy.

·Quinolone 類藥品警語：
(1)過去使用quinolone或fluoroquinolone類曾發生嚴重不良反應，應避免使用，應先確認沒有替代治療選擇並謹慎評估效益/風險。
(2)肌腱炎及肌腱斷裂(好發於阿基里斯腱)，有時為雙側，可能於使用48小時內發生，也可能停藥數月後才發生。老年人、腎功能不良、曾進行器官移植或同時併用皮質類固醇會增加風險，故應避免併用皮質類固醇。
(3)精神相關不良反應，包括中毒性精神病、精神病反應進展至自殺意念/想法、幻覺或妄想；憂鬱或自殘行為如企圖自殺或完成自殺；焦慮、躁動或緊張；精神混亂、瞻妄、失去方向感或注意力無法集中；失眠或做惡夢；記憶力受損。可能發生在第一次投藥後。倘出現前述不良反應，應停用並開始適當治療。應特別注意治療的精神病或有精神疾病史的病人。
(4)癲癇(痙攣)風險、增加顱內壓(假性腦腫瘤)、頭暈和顫抖有關。如發生應停用並開始適當治療。
(5)血糖異常，曾有嚴重低血糖導致昏迷或死亡通報案例。如發生應停用並立即開始適當的治療。
(6)增加主動脈瘤及主動脈剝離相關風險，尤其老年人。有動脈瘤疾病之家族史，或已有主動脈瘤及/或主動脈剝離，或具有加重主動脈瘤及主動脈剝離之危險時，需謹慎評估其效益及風險與其他治療方式。建議病人如有突發性腹痛、胸或背痛，應立即就醫。

藥名相似:

外觀相似:

外觀描述: 50mL澄清、『黃綠』色注射液『藍』蓋玻璃瓶

06.14B Quinolones, oral

20835 **UK / No report(毫**

DOLCOL FILM COATING TABLETS 250MG 圖留康膜衣錠 250毫克

Pipemidic acid 250mg FC tab

Dosage: 1常備品 20835

Adult
· G.U. infection: PO, 0.5-2g/day div. into 3-4 doses
· Otitis media: PO, 1.5-2g/day div. into 3-4 doses

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr>30mL/min: No dosage adjustment needed
Severe renal failure: Dose reduction is advisable

P: Tab: 250mg(20835)

ADR:

Anorexia, epigastric pain, heartburn, nausea, vomiting, feeling of abdominal distension or abdominal pain, diarrhea, constipation, rash

NOTE: 室溫儲存

· 仿單說明：孕婦、授乳婦的投與
(1)對於孕婦、授乳婦之服用本劑，其安全性未予確定
· 故孕婦或可能懷孕的婦人，請勿給藥。

(2)有對母乳中移行之報告，故對授乳婦給藥時，停止授乳。

· Avoid excessive exposure to sunlight and UV lights to prevent possible phototoxicity reactions

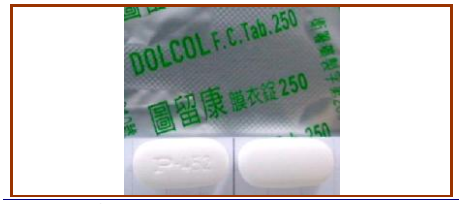
· Should be taken on a full stomach

· Fluoroquinolones have been associated with disturbances in glucose regulation, including hyperglycemia and hypoglycemia. These events have occurred most often in patients receiving concomitant oral hypoglycemic agents or insulin. Severe cases of hypoglycemia, including coma and death, have been reported. Diabetic patients should be monitored closely for signs/symptoms of disordered glucose regulation.Discontinue if a hypoglycemic reaction occurs and immediately initiate appropriate therapy.

藥名相似: Tab: 250mg(20835)

外觀相似:

外觀描述: 白色長橢圓扁錠，有P-452字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1020910

06.14B Quinolones, oral

20839 C / Caution

CINOLONE F.C. TABLET 250MG "信東"信諾隆膜衣錠 250毫克

Ciprofloxacin 250mg FC tab

Dosage: 1常備品 20839

Adult

· Anthrax: PO, 500mg q12h for at least 60 days

· Bone and joint infection: PO, mild/moderate, 500mg q12h for 4-6 wks; severe/complicated, 750mg q12h for 4-6 wks

· Gonorrhea: PO, 250mg as a single dose

· Infectious diarrhea: PO, 500mg q12h for 5-7 days

· Intra-abdominal infection: PO, 500mg q12h for 7-14 days, in combination with metronidazole

· Lower respiratory tract infection, skin/skin structure infection: PO, 500-750mg q12h for 7-14 days

· Urinary tract infection: PO, 250-500mg q12h for 7-14 days

· Prostatitis, chronic bacterial: PO, 500mg q12h for 28 days

· Sinusitis, typhoid fever: PO, 500mg q12h for 10 days

Pediatric

· Susceptible infections: PO, 20-30mg/kg/day div. q12h; Max. 1.5g/day

· Anthrax: PO, 10-15mg/kg bid for at least 60 days; Max. 500mg/dose

· Cystic fibrosis: PO, 40mg/kg/day div. q12h; Max. 2g/day

· Complicated urinary tract infection: 10-20mg/kg q12h for 10-21 days, Max. 750mg/dose

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr ≧ 50mL/min: usual dose
Clcr 30-50mL/min: 250-500mg q12h
Clcr 5-29mL/min: 250-500mg q18h

P:

ADR:

COMMON
Rash, diarrhea, nausea, vomiting, headache, irritability, nasal discharge, nasopharyngitis
SERIOUS
Aortic aneurysm or dissection, cardiorespiratory arrest, myocardial infarction, prolonged QT interval, syncope, Torsades de pointes, photosensitivity, Stevens-Johnson syndrome, toxic epidermal necrolysis, hypoglycemia, Clostridium difficile colitis, Clostridium difficile diarrhea, gastrointestinal hemorrhage, pancreatitis, agranulocytosis, aplastic anemia, bone marrow depression, hemolytic anemia, leukopenia, pancytopenia, thrombocytopenia, hepatic necrosis, hepatitis, hepatotoxicity, liver failure, hypersensitivity reaction, exacerbations of myasthenia gravis, rupture of tendon, tendinitis, disorientated, disturbance of attention, Guillain-Barre syndrome, memory impairment, peripheral neuropathy, pseudotumor cerebri, raised intracranial pressure, seizure, retinal detachment, delirium, depression, hallucinations, paranoid disorder, psychotic disorder, suicidal behavior, acute renal failure, hemorrhagic cystitis, interstitial nephritis

NOTE: 室溫儲存

· Swallow whole; do not crush or chew

· Alkalinized urine; may result in crystalluria

· Excessive sunlight; may cause phototoxicity

· CDC: due to resistance, quinolone antibiotics should not be used to treat gonococcal infections acquired in Asia, the Pacific, England, Wales and in the states of Hawaii and California

· Not FDA-approved in children under 18 yrs of age (except for inhalational anthrax and complicated urinary tract infections)

· Fluoroquinolones have been associated with disturbances in glucose regulation, including hyperglycemia and hypoglycemia. These events have occurred most often in patients receiving concomitant oral hypoglycemic agents or insulin. Severe cases of hypoglycemia, including coma and death, have been reported. Diabetic patients should be monitored closely for signs/symptoms of disordered glucose regulation.Discontinue if a hypoglycemic reaction occurs and immediately initiate appropriate therapy.

· Quinolone 類藥品警語：

(1)沒有其他替代治療選擇時，才用於下列適應症：慢性支氣管炎急性惡化、急性非複雜性膀胱炎、非複雜性泌尿道感染、急性鼻竇炎。

(2)過去使用quinolone或fluoroquinolone類曾發生嚴重不良反應，應避免使用，應先確認沒有替代治療選擇並謹慎評估效益/風險。

(3)肌腱炎及肌腱斷裂(好發於阿基里斯腱)，有時為雙側，可能於使用48小時內發生，也可能停藥數月後才發生。老年人、腎功能不良、曾進行器官移植或同時併用皮質類固醇會增加風險，故應避免併用皮質類固醇。

(4)精神相關不良反應，包括中毒性精神病、精神病反應

進展至自殺意念/想法、幻覺或妄想；憂鬱或自殘行為如企圖自殺或完成自殺；焦慮、躁動或緊張；精神混亂、瞻妄、失去方向感或注意力無法集中；失眠或做惡夢；記憶力受損。可能發生在第一次投藥後。倘出現前述不良反應，應停用並開始適當治療。應特別注意治療的精神病或有精神疾病史的病人。
(5)癲癇(痙攣)風險、增加顱內壓(假性腦腫瘤)、頭暈和顫抖有關。如發生應停用並開始適當治療。
(6)血糖異常，曾有嚴重低血糖導致昏迷或死亡通報案例。如發生應停用並立即開始適當的治療。
(7)增加主動脈瘤及主動脈剝離相關風險，尤其老年人。有動脈瘤疾病之家族史，或已有主動脈瘤及/或主動脈剝離，或具有加重主動脈瘤及主動脈剝離之危險時，需謹慎評估其效益及風險與其他治療方式。建議病人如有突發性腹痛、胸或背痛，應立即就醫。

藥名相似: Tab: 250mg(20839); Inj: 200mg/100mL vial(3

外觀相似:

外觀描述: 白色圓扁錠，一面中央有刻痕，及"ST"、"131"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1038747

06.14B Quinolones, oral

21268 **C / Unsafe**

ROZOXIN F.C. TABLETS 100MG 樂作欣 膜衣錠100毫克

(CDC二線TB)Levofloxacin 100mg FC tab

Dosage: 2衛福部提供-CDC二線TB 21268

·Acute exacerbation of chronic bronchitis: PO, 500mg q24h for 7 days
·Chronic bacterial prostatitis: PO, 500mg q24h for 28 days
·Bacterial sinusitis: PO, 750mg q24h for 5 days or 500mg q24h for 10-14 days
·Community acquired pneumonia: PO, 500mg q24h for 7-14 days or 750mg q24h for 5 days
·Infection of skin: complicated, PO, 750mg q24h for 7-14 days; uncomplicated, PO, 500mg q24h for 7-10 days
·Nosocomial pneumonia: PO, 750mg q24h for 7-14 days
·Urinary tract infections: complicated, PO, 250mg q24h for 10 days or 750mg q24h for 5 days; uncomplicated, PO, 250mg q24h for 3 days
·Tuberculosis: PO, 500mg-1000mg qd

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

·Normal renal function dosing of 750mg/day:
Clcr 20-49mL/min: Initial 750mg, then 750mg q48h
Clcr 10-19mL/min: Initial 750mg, then 500mg q48h
·Normal renal function dosing of 500mg/day:
Clcr 20-49mL/min: Initial 500mg, then 250mg q24h
Clcr 10-19mL/min: Initial 500mg, then 250mg q48h
·Normal renal function dosing of 250mg/day:
Clcr 20-49mL/min: No dosage adjustment needed
Clcr 10-19mL/min: Initial 250mg, then 250mg q48h
(No dosage adjustment is required in uncomplicated UTI)

P: Tab: 100mg(21268, 二線TB用藥), 500mg(21270)(27899, 二線TB用藥); Oph Soln: 0.5%, 5mL(29205); Inj: 250mg/50mL Vial(31184)

ADR:

COMMON
Diarrhea, nausea, dizziness, headache, insomnia
SERIOUS
Aortic aneurysm or dissection, cardiac arrest, prolonged QT interval, Torsades de pointes, ventricular tachycardia, erythema multiforme, Stevens-Johnson syndrome, hypoglycemia, aplastic anemia, pancytopenia, thrombocytopenic purpura, hepatitis, liver failure, anaphylactoid reaction, hypersensitivity reaction, exacerbations of myasthenia gravis, rupture of tendon, tendinitis, disorientated, disturbance of attention, Guillain-Barre syndrome, memory impairment, peripheral neuropathy, pseudotumor cerebri, raised intracranial pressure, seizure, retinal detachment, delirium, depression, hallucinations, paranoid disorder, psychotic disorder, suicidal, acute renal failure, unterstitial nephritis

NOTE: 室溫儲存

· It should be taken at least 2 hrs before or after iron salts, antacids and sucralfate administeration
· Fluoroquinolones have been associated with disturbances in glucose regulation, including hyperglycemia and hypoglycemia. These events have occurred most often in patients receiving concomitant oral hypoglycemic agents or insulin. Severe cases of hypoglycemia, including coma and death, have been reported. Diabetic patients should be monitored closely for signs/symptoms of disordered glucose regulation.Discontinue if a hypoglycemic reaction occurs and immediately initiate appropriate therapy.
·Quinolone 類藥品警語：
(1)過去使用quinolone或fluoroquinolone類曾發生嚴重不良反應，應避免使用，應先確認沒有替代治療選擇並謹慎評估效益/風險。
(2)肌腱炎及肌腱斷裂(好發於阿基里斯腱)，有時為雙側，可能於使用48小時內發生，也可能停藥數月後才發生。老年人、腎功能不良、曾進行器官移植或同時併用皮質類固醇會增加風險，故應避免併用皮質類固醇。
(3)精神相關不良反應，包括中毒性精神病、精神病反應進展至自殺意念/想法、幻覺或妄想；憂鬱或自殘行為如企圖自殺或完成自殺；焦慮、躁動或緊張；精神混亂、瞻妄、失去方向感或注意力無法集中；失眠或做惡夢；記憶力受損。可能發生在第一次投藥後。倘出現前述不良反應，應停用並開始適當治療。應特別注意治療的精神病或有精神疾病史的病人。
(4)癲癇(痙攣)風險、增加顱內壓(假性腦腫瘤)、頭暈和顫抖有關。如發生應停用並開始適當治療。
(5)血糖異常，曾有嚴重低血糖導致昏迷或死亡通報案例。如發生應停用並立即開始適當的治療。

(6)增加主動脈瘤及主動脈剝離相關風險，尤其老年人。有動脈瘤疾病之家族史，或已有主動脈瘤及/或主動脈剝離，或具有加重主動脈瘤及主動脈剝離之危險時，需謹慎評估其效益及風險與其他治療方式。建議病人如有突發性腹痛、胸或背痛，應立即就醫。

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，有PM 010字樣

06.14B Quinolones, oral

21269 **C / Unsafe**

Mosflow Film Coated Tablets 400mg "信東"摩斯羅膜衣錠400毫克

Moxifloxacin 400mg FC tab

Dosage: 1常備品 21269

Adult

· Chronic bronchitis, community-acquired pneumonia, sinusitis, skin and skin structure infection, intra-abdominal infection: PO, 400mg qd for 5-21 days; duration of therapy depends on the type of infection

· Tuberculosis: PO, 400mg qd

Pediatric

Safety and efficacy have not been established in patients less than 18 years old

Dosing adjustments in hepatic impairment:

No dosage adjustment needed; Use with caution secondary to the risk of QT prolongation

Dosing adjustments in renal impairment:

No dosage adjustment needed

P:

ADR:

COMMON

Hypokalemia, abdominal pain, constipation, diarrhea, nausea, vomiting, ALT/SGPT level abnormal, dizziness, headache

SERIOUS

Aortic aneurysm or dissection, prolonged QT interval, Torsades de pointes, rash, Stevens-Johnson syndrome, toxic epidermal necrolysis, hyperglycemia, hypoglycemia, Clostridium difficile diarrhea, agranulocytosis, aplastic anemia, hemolytic anemia, pancytopenia, thrombocytopenia, hepatic necrosis, hepatitis, liver failure, anaphylactoid reaction, hypersensitivity reaction, exacerbations of myasthenia gravis, rupture of tendon, tendinitis, disorientated, disturbance of attention, Guillain-Barre syndrome, memory impairment, peripheral neuropathy, pseudotumor cerebri, raised intracranial pressure, seizure, retinal detachment, agitation, feeling nervous, paranoid disorder, suicidal, renal failure, extrinsic allergic alveolitis, serum sickness due to drug

NOTE: 室溫儲存

· Avoid use in patients with known prolongation of the QT interval, uncorrected hypokalemia or patients receiving class IA or III antiarrhythmic agents

· Take at least 4 hr before or 8 hr after magnesium or aluminum antacids, sucralfate, iron or zinc supplements

· Safety and efficacy not established in children or adolescents younger than 18 years of age

· Fluoroquinolones have been associated with disturbances in glucose regulation, including hyperglycemia and hypoglycemia. These events have occurred most often in patients receiving concomitant oral hypoglycemic agents or insulin. Severe cases of hypoglycemia, including coma and death, have been reported. Diabetic patients should be monitored closely for signs/symptoms of disordered glucose regulation.Discontinue if a hypoglycemic reaction occurs and immediately initiate appropriate therapy.

· Quinolone 類藥品警語：

(1)沒有其他替代治療選擇時，才用於下列適應症：慢性支氣管炎急性惡化、急性非複雜性膀胱炎。

(2)過去使用quinolone或fluoroquinolone類曾發生嚴重不良反應，應避免使用，應先確認沒有替代治療選擇並謹慎評估效益/風險。

(3)肌腱炎及肌腱斷裂(好發於阿基里斯腱)，有時為雙側，可能於使用48小時內發生，也可能停藥數月後才發生。老年人、腎功能不良、曾進行器官移植或同時併用皮質類固醇會增加風險，故應避免併用皮質類固醇。

(4)精神相關不良反應，包括中毒性精神病、精神病反應進展至自殺意念/想法、幻覺或妄想；憂鬱或自殘行為如企圖自殺或完成自殺；焦慮、躁動或緊張；精神混亂、瞻妄、失去方向感或注意力無法集中；失眠或做惡夢；記憶力受損。可能發生在第一次投藥後。倘出現前述不良反應，應停用並開始適當治療。應特別注意治療的精神病或有精神疾病史的病人。

(5)癲癇(痙攣)風險、增加顱內壓(假性腦腫瘤)、頭暈和顫抖有關。如發生應停用並開始適當治療。

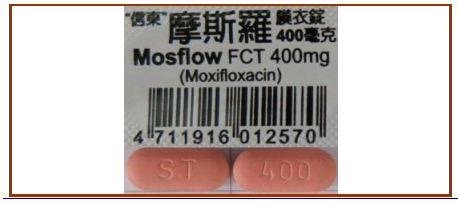
(6)血糖異常，曾有嚴重低血糖導致昏迷或死亡通報案例。如發生應停用並立即開始適當的治療。

(7)增加主動脈瘤及主動脈剝離相關風險，尤其老年人。有動脈瘤疾病之家族史，或已有主動脈瘤及/或主動脈剝離，或具有加重主動脈瘤及主動脈剝離之危險時，需謹慎評估其效益及風險與其他治療方式。建議病人如有突發性腹痛、胸或背痛，應立即就醫。

藥名相似:

外觀相似:

外觀描述: 淺磚紅色長橢圓錠，一面有 ST，另一面有 400 字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1057910

06.14B Quinolones, oral

21270 **C / Unsafe**

Leflodal F.C. Tablets 500 mg 佐淨菌膜衣錠 500 毫克

Levofloxacin 500mg FC tab

Dosage: 1常備品 21270

·Acute exacerbation of chronic bronchitis: PO, 500mg q24h for 7 days
·Chronic bacterial prostatitis: PO, 500mg q24h for 28 days
·Bacterial sinusitis: PO, 750mg q24h for 5 days or 500mg q24h for 10-14 days
·Community acquired pneumonia: PO, 500mg q24h for 7-14 days or 750mg q24h for 5 days
·Infection of skin: complicated, PO, 750mg q24h for 7-14 days; uncomplicated, PO, 500mg q24h for 7-10 days
·Nosocomial pneumonia: PO, 750mg q24h for 7-14 days
·Urinary tract infections: complicated, PO, 250mg q24h for 10 days or 750mg q24h for 5 days; uncomplicated, PO, 250mg q24h for 3 days
·Tuberculosis: PO, 500mg-1000mg qd

(Use may be justified if the benefits outweigh the risks)
·Community acquired pneumonia, acute otitis media: PO,
6 mons-5 yrs: 8-10mg/kg q12h; Max. 750mg/day
5 yrs-16 yrs: 8-10mg/kg qd; Max. 750mg/day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

·Normal renal function dosing of 750mg/day:
Clcr 20-49mL/min: Initial 750mg, then 750mg q48h
Clcr 10-19mL/min: Initial 750mg, then 500mg q48h
·Normal renal function dosing of 500mg/day:
Clcr 20-49mL/min: Initial 500mg, then 250mg q24h
Clcr 10-19mL/min: Initial 500mg, then 250mg q48h
·Normal renal function dosing of 250mg/day:
Clcr 20-49mL/min: No dosage adjustment needed
Clcr 10-19mL/min: Initial 250mg, then 250mg q48h
(No dosage adjustment is required in uncomplicated UTI)

P:

ADR:

COMMON
Diarrhea, nausea, dizziness, headache, insomnia
SERIOUS
Aortic aneurysm or dissection, cardiac arrest, prolonged QT interval, Torsades de pointes, ventricular tachycardia, erythema multiforme, Stevens-Johnson syndrome, hypoglycemia, aplastic anemia, pancytopenia, thrombocytopenic purpura, hepatitis, liver failure, anaphylactoid reaction, hypersensitivity reaction, exacerbations of myasthenia gravis, rupture of tendon, tendinitis, disorientated, disturbance of attention, Guillain-Barre syndrome, memory impairment, peripheral neuropathy, pseudotumor cerebri, raised intracranial pressure, seizure, retinal detachment, delirium, depression, hallucinations, paranoid disorder, psychotic disorder, suicidal, acute renal failure, unterstitial nephritis

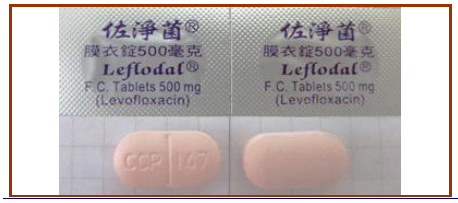
NOTE: 室溫儲存

· It should be taken at least 2 hrs before or after iron salts, antacids and sucralfate administeration
· Fluoroquinolones have been associated with disturbances in glucose regulation, including hyperglycemia and hypoglycemia. These events have occurred most often in patients receiving concomitant oral hypoglycemic agents or insulin. Severe cases of hypoglycemia, including coma and death, have been reported. Diabetic patients should be monitored closely for signs/symptoms of disordered glucose regulation.Discontinue if a hypoglycemic reaction occurs and immediately initiate appropriate therapy.
· Quinolone 類藥品警語：
(1)沒有其他替代治療選擇時，才用於下列適應症：慢性支氣管炎急性惡化、急性非複雜性膀胱炎、非複雜性泌尿道感染、急性鼻竇炎。
(2)過去使用quinolone或fluoroquinolone類曾發生嚴重不良反應，應避免使用，應先確認沒有替代治療選擇並謹慎評估效益/風險。
(3)肌腱炎及肌腱斷裂(好發於阿基里斯腱)，有時為雙側，可能於使用48小時內發生，也可能停藥數月後才發生。老年人、腎功能不良、曾進行器官移植或同時併用皮質類固醇會增加風險，故應避免併用皮質類固醇。
(4)精神相關不良反應，包括中毒性精神病、精神病反應進展至自殺意念/想法、幻覺或妄想；憂鬱或自殘行為如企圖自殺或完成自殺；焦慮、躁動或緊張；精神混亂、瞻妄、失去方向感或注意力無法集中；失眠或做惡夢；記憶力受損。可能發生在第一次投藥後。倘出現前述不良反應，應停用並開始適當治療。應特別注意治療的精神病或有精神疾病史的病人。
(5)癲癇(痙攣)風險、增加顱內壓(假性腦腫瘤)、頭暈和顫抖有關。如發生應停用並開始適當治療。
(6)血糖異常，曾有嚴重低血糖導致昏迷或死亡通報案例。如發生應停用並立即開始適當的治療。
(7)增加主動脈瘤及主動脈剝離相關風險，尤其老年人。有動脈瘤疾病之家族史，或已有主動脈瘤及/或主動脈剝離，或具有加重主動脈瘤及主動脈剝離之危險時，需謹慎評估其效益及風險與其他治療方式。建議病人如有突發性腹痛、胸或背痛，應立即就醫。

藥名相似:

外觀相似:

外觀描述: 淺粉紅色長橢圓扁錠，一面中間有一刻痕，有CCP及147字樣



TFDA許可證
http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049696

06.14B Quinolones, oral

21272 UK / No report(毫

Taigexyn Capsule 250mg (Nemonoxacin) 太捷信膠囊250毫克(奈諾沙星)

Nemonoxacin 250mg cap

Dosage: 1常備品 21272

Adult
· Community-acquired pneumonia: PO, ac, 500mg qd for 7 to 10 days

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA (Not studied)

Dosing adjustments in renal impairment:

Clcr 60-90 mL/min: No dosage adjustment needed
Moderate to severe impairment: Not recommended

P: Cap: 250mg(21272)

ADR:

Nausea, diarrhea, vomiting, abdominal discomfort, neutropenia, dizziness, headache, ALT(SGPT) increased, AST(SGOT) increased, GGT increased, decreased white blood cell count

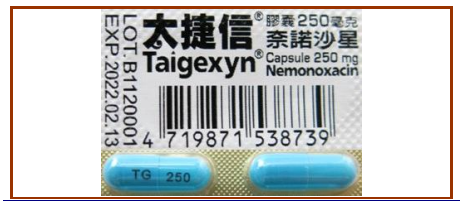
NOTE: 室溫儲存

· Administer on an empty stomach (at least 2h before or 2h after a meal)
· Take this medicine at least 2 hours before antacids, sucralfate, multivitamins or products containing iron or zinc.
· Fluoroquinolones have been associated with disturbances in glucose regulation, including hyperglycemia and hypoglycemia. These events have occurred most often in patients receiving concomitant oral hypoglycemic agents or insulin. Severe cases of hypoglycemia, including coma and death, have been reported. Diabetic patients should be monitored closely for signs/symptoms of disordered glucose regulation.Discontinue if a hypoglycemic reaction occurs and immediately initiate appropriate therapy.
· Quinolone類藥品可能與肢體障礙及潛在不可逆嚴重不良反應之發生相關，包括肌腱炎、肌腱斷裂、周邊神經炎及中樞神經系統作用。
· 過去使用過quinolone或fluoroquinolone類藥品曾發生嚴重不良反應的病人，應避免使用本藥。
· 此藥品為non-fluorinated quinolone，但仍建議對fluoroquinolone類偶有發生之嚴重不良事件：肌腱炎及肌腱斷裂、重症肌無力的惡化、偽膜性腸炎、嚴重過敏反應、光敏反應/ 光毒性、嚴重水皰反應、中樞神經系統作用、周邊神經病變、肝毒性、血糖異常等予以關注，並進行觀察。

藥名相似:

外觀相似:

外觀描述: 淡藍色膠囊，有TG及 250字樣



06.14B Quinolones, oral

27896 **C / Unsafe**

Levofloxacin F.C. Tablet 750mg "P.L." 平福樂欣膜衣錠750毫克

(CDC二線TB)Levofloxacin 750mg tab

Dosage: 2衛福部提供 -CDC二線TB 27896

Adult
·Acute exacerbation of chronic bronchitis: PO, 500mg q24h for 7 days
·Chronic bacterial prostatitis: PO, 500mg q24h for 28 days
·Bacterial sinusitis: PO, 750mg q24h for 5 days or 500mg q24h for 10-14 days
·Community acquired pneumonia: PO, 500mg q24h for 7-14 days or 750mg q24h for 5 days
·Infection of skin: complicated, PO, 750mg q24h for 7-14 days; uncomplicated, PO, 500mg q24h for 7-10 days
·Nosocomial pneumonia: PO, 750mg q24h for 7-14 days
·Urinary tract infections: complicated, PO, 250mg q24h for 10 days or 750mg q24h for 5 days; uncomplicated, PO, 250mg q24h for 3 days
·Tuberculosis: PO, 500mg-1000mg qd

Pediatric: (Use may be justified if the benefits outweigh the risks)
·Community acquired pneumonia, acute otitis media: PO,
6 mons-5 yrs: 8-10mg/kg q12h; Max. 750mg/day
5 yrs-16 yrs: 8-10mg/kg qd; Max. 750mg/day
·Tuberculosis: PO, < 5 yrs: 10mg/kg bid; ≧5 yrs: 1g qd

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

·Normal renal function dosing of 750mg/day:
Clcr 20-49mL/min: Initial 750mg, then 750mg q48h
Clcr 10-19mL/min: Initial 750mg, then 500mg q48h
·Normal renal function dosing of 500mg/day:
Clcr 20-49mL/min: Initial 500mg, then 250mg q24h
Clcr 10-19mL/min: Initial 500mg, then 250mg q48h
·Normal renal function dosing of 250mg/day:
Clcr 20-49mL/min: No dosage adjustment needed
Clcr 10-19mL/min: Initial 250mg, then 250mg q48h
(No dosage adjustment is required in uncomplicated UTI)

P: Pediatric: (Use may be justified if the benefits outweigh the risks)
·Community acquired pneumonia, acute otitis media: PO,
6 mons-5 yrs: 8-10mg/kg q12h; Max. 750mg/day
5 yrs-16 yrs: 8-10mg/kg qd; Max. 750mg/day
·Tuberculosis: PO, < 5 yrs: 10mg/kg bid; ≧5 yrs: 1g qd

ADR:

COMMON
Diarrhea, nausea, dizziness, headache, insomnia
SERIOUS
Aortic aneurysm or dissection, cardiac arrest, prolonged QT interval, Torsades de pointes, ventricular tachycardia, erythema multiforme, Stevens-Johnson syndrome, hypoglycemia, aplastic

anemia, pancytopenia, thrombocytopenic purpura, hepatitis, liver failure, anaphylactoid reaction, hypersensitivity reaction, exacerbations of myasthenia gravis, rupture of tendon, tendinitis, disorientated, disturbance of attention, Guillain-Barre syndrome, memory impairment, peripheral neuropathy, pseudotumor cerebri, raised intracranial pressure, seizure, retinal detachment, delirium, depression, hallucinations, paranoid disorder, psychotic disorder, suicidal, acute renal failure, unterstitial nephritis

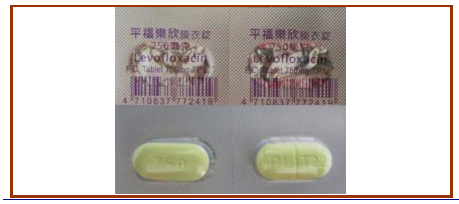
NOTE: 室溫儲存

· It should be taken at least 2 hrs before or after iron salts, antacids and sucralfate administeration
· Fluoroquinolones have been associated with disturbances in glucose regulation, including hyperglycemia and hypoglycemia. These events have occurred most often in patients receiving concomitant oral hypoglycemic agents or insulin. Severe cases of hypoglycemia, including coma and death, have been reported. Diabetic patients should be monitored closely for signs/symptoms of disordered glucose regulation.Discontinue if a hypoglycemic reaction occurs and immediately initiate appropriate therapy.
·Quinolone 類藥品警語：
(1)過去使用quinolone或fluoroquinolone類曾發生嚴重不良反應，應避免使用，應先確認沒有替代治療選擇並謹慎評估效益/風險。
(2)肌腱炎及肌腱斷裂(好發於阿基里斯腱)，有時為雙側，可能於使用48小時內發生，也可能停藥數月後才發生。老年人、腎功能不良、曾進行器官移植或同時併用皮質類固醇會增加風險，故應避免併用皮質類固醇。
(3)精神相關不良反應，包括中毒性精神病、精神病反應進展至自殺意念/想法、幻覺或妄想；憂鬱或自殘行為如企圖自殺或完成自殺；焦慮、躁動或緊張；精神混亂、瞻妄、失去方向感或注意力無法集中；失眠或做惡夢；記憶力受損。可能發生在第一次投藥後。倘出現前述不良反應，應停用並開始適當治療。應特別注意治療的精神病或有精神疾病史的病人。
(4)癲癇(痙攣)風險、增加顱內壓(假性腦腫瘤)、頭暈和顫抖有關。如發生應停用並開始適當治療。
(5)血糖異常，曾有嚴重低血糖導致昏迷或死亡通報案例。如發生應停用並立即開始適當的治療。
(6)增加主動脈瘤及主動脈剝離相關風險，尤其老年人。有動脈瘤疾病之家族史，或已有主動脈瘤及/或主動脈剝離，或具有加重主動脈瘤及主動脈剝離之危險時，需謹慎評估其效益及風險與其他治療方式。建議病人如有突發性腹痛、胸或背痛，應立即就醫。

藥名相似:

外觀相似:

外觀描述: 黃色橢圓形錠，一面有PL T22字樣，另一面有750字樣



06.14B Quinolones, oral

27898 **C / Unsafe**

Floxsafe 400 (Moxifloxacin Tablets 400mg) (CDC二線TB)福樂星膜衣錠400毫克

(CDC二線TB)Moxifloxacin 400mg tab

Dosage: 2衛福部提供-CDC二線TB 27898

Adult
· Chronic bronchitis, community-acquired pneumonia, sinusitis, skin and skin structure infection, intra-abdominal infection: PO, 400mg qd for 5-21 days; duration of therapy depends on the type of infection
· Tuberculosis: PO, 400mg qd

Pediatric
Safety and efficacy have not been established in patients less than 18 years old

Dosing adjustments in hepatic impairment:

No dosage adjustment needed; Use with caution secondary to the risk of QT prolongation

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 400mg(21269)(27898, 二線TB用藥); Inj: 400mg/250mL Bot(31182)

ADR:

COMMON
Hypokalemia, abdominal pain, constipation, diarrhea, nausea, vomiting, ALT/SGPT level abnormal, dizziness, headache
SERIOUS
Aortic aneurysm or dissection, prolonged QT interval, Torsades de pointes, rash, Stevens-Johnson syndrome, toxic epidermal necrolysis, hyperglycemia, hypoglycemia, Clostridium difficile diarrhea, agranulocytosis, aplastic anemia, hemolytic anemia, pancytopenia, thrombocytopenia, hepatic necrosis, hepatitis, liver failure, anaphylactoid reaction, hypersensitivity reaction, exacerbations of myasthenia gravis, rupture of tendon, tendinitis, disorientated, disturbance of attention, Guillain-Barre syndrome, memory impairment, peripheral neuropathy, pseudotumor cerebri, raised intracranial pressure, seizure, retinal detachment, agitation, feeling nervous, paranoid disorder, suicidal, renal failure, extrinsic allergic alveolitis, serum sickness due to drug

NOTE: 室溫儲存

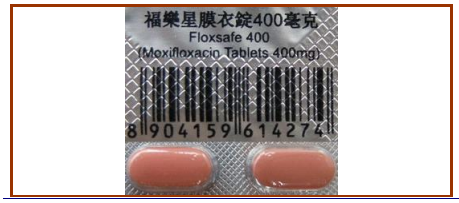
· Avoid use in patients with known prolongation of the QT interval, uncorrected hypokalemia or patients receiving class IA or III antiarrhythmic agents
· Take at least 4 hr before or 8 hr after magnesium or aluminum antacids, sucralfate, iron or zinc supplements
· Safety and efficacy not established in children or adolescents younger than 18 years of age
· Fluoroquinolones have been associated with disturbances in glucose regulation, including hyperglycemia and hypoglycemia. These events have occurred most often in patients receiving concomitant oral hypoglycemic agents or insulin. Severe cases of hypoglycemia, including coma and

death, have been reported. Diabetic patients should be monitored closely for signs/symptoms of disordered glucose regulation.Discontinue if a hypoglycemic reaction occurs and immediately initiate appropriate therapy.
· Quinolone 類藥品警語：
(1)過去使用quinolone或fluoroquinolone類曾發生嚴重不良反應，應避免使用，應先確認沒有替代治療選擇並謹慎評估效益/風險。
(2)肌腱炎及肌腱斷裂(好發於阿基里斯腱)，有時為雙側，可能於使用48小時內發生，也可能停藥數月後才發生。老年人、腎功能不良、曾進行器官移植或同時併用皮質類固醇會增加風險，故應避免併用皮質類固醇。
(3)精神相關不良反應，包括中毒性精神病、精神病反應進展至自殺意念/想法、幻覺或妄想；憂鬱或自殘行為如企圖自殺或完成自殺；焦慮、躁動或緊張；精神混亂、瞻妄、失去方向感或注意力無法集中；失眠或做惡夢；記憶力受損。可能發生在第一次投藥後。倘出現前述不良反應，應停用並開始適當治療。應特別注意治療的精神病或有精神疾病史的病人。
(4)癲癇(痙攣)風險、增加顱內壓(假性腦腫瘤)、頭暈和顫抖有關。如發生應停用並開始適當治療。
(5)血糖異常，曾有嚴重低血糖導致昏迷或死亡通報案例。如發生應停用並立即開始適當的治療。
(6)增加主動脈瘤及主動脈剝離相關風險，尤其老年人。有動脈瘤疾病之家族史，或已有主動脈瘤及/或主動脈剝離，或具有加重主動脈瘤及主動脈剝離之危險時，需謹慎評估其效益及風險與其他治療方式。建議病人如有突發性腹痛、胸或背痛，應立即就醫。

藥名相似:

外觀相似:

外觀描述: 淺磚紅色長橢圓錠



06.14B Quinolones, oral

27899 **C / Unsafe**

Leflodal F.C. Tablets 500 mg 佐淨菌膜衣錠 500 毫克

(CDC二線TB)Levofloxacin 500mg tab

Dosage: 2衛福部提供 -CDC二線TB 27899

Adult
·Acute exacerbation of chronic bronchitis: PO, 500mg q24h for 7 days
·Chronic bacterial prostatitis: PO, 500mg q24h for 28 days
·Bacterial sinusitis: PO, 750mg q24h for 5 days or 500mg q24h for 10-14 days
·Community acquired pneumonia: PO, 500mg q24h for 7-14 days or 750mg q24h for 5 days
·Infection of skin: complicated, PO, 750mg q24h for 7-14 days; uncomplicated, PO, 500mg q24h for 7-10 days
·Nosocomial pneumonia: PO, 750mg q24h for 7-14 days
·Urinary tract infections: complicated, PO, 250mg q24h for 10 days or 750mg q24h for 5 days; uncomplicated, PO, 250mg q24h for 3 days
·Tuberculosis: PO, 500mg-1000mg qd

Pediatric: (Use may be justified if the benefits outweigh the risks)
·Community acquired pneumonia, acute otitis media: PO,
6 mons-5 yrs: 8-10mg/kg q12h; Max. 750mg/day
5 yrs-16 yrs: 8-10mg/kg qd; Max. 750mg/day
·Tuberculosis: PO, < 5 yrs: 10mg/kg bid; ≥5 yrs: 1g qd

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

·Normal renal function dosing of 750mg/day:
Clcr 20-49mL/min: Initial 750mg, then 750mg q48h
Clcr 10-19mL/min: Initial 750mg, then 500mg q48h
·Normal renal function dosing of 500mg/day:
Clcr 20-49mL/min: Initial 500mg, then 250mg q24h
Clcr 10-19mL/min: Initial 500mg, then 250mg q48h
·Normal renal function dosing of 250mg/day:
Clcr 20-49mL/min: No dosage adjustment needed
Clcr 10-19mL/min: Initial 250mg, then 250mg q48h
(No dosage adjustment is required in uncomplicated UTI)

P: Tab: 500mg(21270)(27899, 二線TB用藥),750mg(27896,二線TB用藥); Oph Soln: 0.5%, 5mL(29205); Inj: 250mg/50mL Vial(31184)

ADR:

COMMON
Diarrhea, nausea, dizziness, headache, insomnia
SERIOUS
Aortic aneurysm or dissection, cardiac arrest, prolonged QT interval, Torsades de pointes, ventricular tachycardia, erythema multiforme, Stevens-Johnson syndrome, hypoglycemia, aplastic anemia, pancytopenia, thrombocytopenic purpura, hepatitis, liver failure, anaphylactoid reaction, hypersensitivity reaction, exacerbations of myasthenia gravis, rupture of tendon, tendinitis, disorientated, disturbance of attention, Guillain-Barre syndrome, memory impairment, peripheral neuropathy, pseudotumor cerebri, raised intracranial pressure, seizure, retinal detachment, delirium, depression, hallucinations, paranoid disorder, psychotic disorder, suicidal, acute renal failure, unterstitial nephritis

NOTE: 室溫儲存

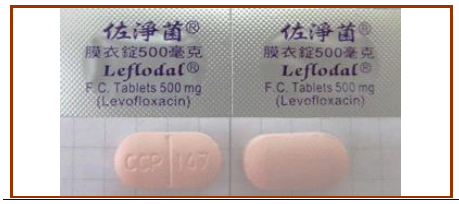
· It should be taken at least 2 hrs before or after iron salts, antacids and sucralfate administeration
· Fluoroquinolones have been associated with disturbances in glucose regulation, including hyperglycemia and hypoglycemia. These events have occurred most often in patients receiving concomitant oral hypoglycemic agents or insulin. Severe cases of hypoglycemia, including coma and death, have been reported. Diabetic patients should be monitored closely for signs/symptoms of disordered glucose regulation.Discontinue if a hypoglycemic reaction occurs and immediately

initiate appropriate therapy.
·Quinolone 類藥品警語：
(1)過去使用quinolone或fluoroquinolone類曾發生嚴重不良反應，應避免使用，應先確認沒有替代治療選擇並謹慎評估效益/風險。
(2)肌腱炎及肌腱斷裂(好發於阿基里斯腱)，有時為雙側，可能於使用48小時內發生，也可能停藥數月後才發生。老年人、腎功能不良、曾進行器官移植或同時併用皮質類固醇會增加風險，故應避免併用皮質類固醇。
(3)精神相關不良反應，包括中毒性精神病、精神病反應進展至自殺意念/想法、幻覺或妄想；憂鬱或自殘行為如企圖自殺或完成自殺；焦慮、躁動或緊張；精神混亂、瞻妄、失去方向感或注意力無法集中；失眠或做惡夢；記憶力受損。可能發生在第一次投藥後。倘出現前述不良反應，應停用並開始適當治療。應特別注意治療的精神病或有精神疾病史的病人。
(4)癲癇(痙攣)風險、增加顱內壓(假性腦腫瘤)、頭暈和顫抖有關。如發生應停用並開始適當治療。
(5)血糖異常，曾有嚴重低血糖導致昏迷或死亡通報案例。如發生應停用並立即開始適當的治療。
(6)增加主動脈瘤及主動脈剝離相關風險，尤其老年人。有動脈瘤疾病之家族史，或已有主動脈瘤及/或主動脈剝離，或具有加重主動脈瘤及主動脈剝離之危險時，需謹慎評估其效益及風險與其他治療方式。建議病人如有突發性腹痛、胸或背痛，應立即就醫。

藥名相似:

外觀相似:

外觀描述: 膚色長橢圓形錠,有CCP及147字樣



06.14B Quinolones, oral

27972 **C / Unsafe**

Levonolon F.C. Tablets 500 mg 樂富妥膜衣錠 500 毫克

(CDC漢生病)Levofloxacin 500mg tab

Dosage: 2衛福部提供 27972

Adult
·Acute exacerbation of chronic bronchitis: PO, 500mg q24h for 7 days
·Chronic bacterial prostatitis: PO, 500mg q24h for 28 days
·Bacterial sinusitis: PO, 750mg q24h for 5 days or 500mg q24h for 10-14 days
·Community acquired pneumonia: PO, 500mg q24h for 7-14 days or 750mg q24h for 5 days
·Infection of skin: complicated, PO, 750mg q24h for 7-14 days; uncomplicated, PO, 500mg q24h for 7-10 days
·Nosocomial pneumonia: PO, 750mg q24h for 7-14 days
·Urinary tract infections: complicated, PO, 250mg q24h for 10 days or 750mg q24h for 5 days; uncomplicated, PO, 250mg q24h for 3 days
·Tuberculosis: PO, 500mg-1000mg qd
·Hansen's disease: PO, <50kg: 500mg, ≧50kg: 750mg qd

Pediatric: (Use may be justified if the benefits outweigh the risks)
·Community acquired pneumonia, acute otitis media: PO,
6 mons-5 yrs: 8-10mg/kg q12h; Max. 750mg/day
5 yrs-16 yrs: 8-10mg/kg qd; Max. 750mg/day
·Hansen's disease: PO, <50kg: 500mg, ≧50kg: 750mg qd

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

·Normal renal function dosing of 750mg/day:
Clcr 20-49mL/min: Initial 750mg, then 750mg q48h
Clcr 10-19mL/min: Initial 750mg, then 500mg q48h
·Normal renal function dosing of 500mg/day:
Clcr 20-49mL/min: Initial 500mg, then 250mg q24h
Clcr 10-19mL/min: Initial 500mg, then 250mg q48h
·Normal renal function dosing of 250mg/day:
Clcr 20-49mL/min: No dosage adjustment needed
Clcr 10-19mL/min: Initial 250mg, then 250mg q48h
(No dosage adjustment is required in uncomplicated
UTI)

P:

ADR:

COMMON
Diarrhea, nausea, dizziness, headache, insomnia
SERIOUS
Aortic aneurysm or dissection, cardiac arrest, prolonged QT interval, Torsades de pointes, ventricular tachycardia, erythema multiforme, Stevens-Johnson syndrome, hypoglycemia, aplastic anemia, pancytopenia, thrombocytopenic purpura, hepatitis, liver failure, anaphylactoid reaction, hypersensitivity reaction, exacerbations of myasthenia gravis, rupture of tendon, tendinitis, disorientated, disturbance of attention, Guillain-Barre syndrome, memory impairment, peripheral neuropathy, pseudotumor cerebri, raised intracranial pressure, seizure, retinal detachment, delirium, depression, hallucinations, paranoid disorder, psychotic disorder, suicidal, acute renal failure, unterstitial nephritis

NOTE:

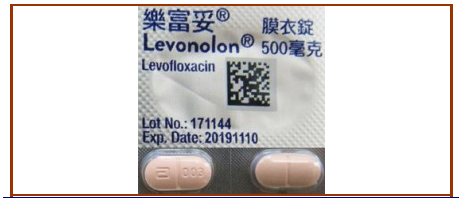
· It should be taken at least 2 hrs before or after iron salts, antacids and sucralfate administeration
· Fluoroquinolones have been associated with disturbances in glucose regulation, including hyperglycemia and hypoglycemia. These events have occurred most often in patients receiving concomitant oral hypoglycemic agents or insulin. Severe cases of hypoglycemia, including coma and death, have been reported. Diabetic patients should be monitored closely for signs/symptoms of disordered glucose regulation.Discontinue if a hypoglycemic reaction occurs and immediately initiate appropriate therapy.
·Quinolone 類藥品警語：
(1)過去使用quinolone或fluoroquinolone類曾發生嚴重不良反應，應避免使用，應先確認沒有替代治療選擇並謹慎評估效益/風險。

(2)肌腱炎及肌腱斷裂(好發於阿基里斯腱)，有時為雙側，可能於使用48小時內發生，也可能停藥數月後才發生。老年人、腎功能不良、曾進行器官移植或同時併用皮質類固醇會增加風險，故應避免併用皮質類固醇。
(3)精神相關不良反應，包括中毒性精神病、精神病反應進展至自殺意念/想法、幻覺或妄想；憂鬱或自殘行為如企圖自殺或完成自殺；焦慮、躁動或緊張；精神混亂、瞻妄、失去方向感或注意力無法集中；失眠或做惡夢；記憶力受損。可能發生在第一次投藥後。倘出現前述不良反應，應停用並開始適當治療。應特別注意治療的精神病或有精神疾病史的病人。
(4)癲癇(痙攣)風險、增加顱內壓(假性腦腫瘤)、頭暈和顫抖有關。如發生應停用並開始適當治療。
(5)血糖異常，曾有嚴重低血糖導致昏迷或死亡通報案例。如發生應停用並立即開始適當的治療。
(6)增加主動脈瘤及主動脈剝離相關風險，尤其老年人。有動脈瘤疾病之家族史，或已有主動脈瘤及/或主動脈剝離，或具有加重主動脈瘤及主動脈剝離之危險時，需謹慎評估其效益及風險與其他治療方式。建議病人如有突發性腹痛、胸或背痛，應立即就醫。

藥名相似:

外觀相似:

外觀描述: 膚色長橢圓形錠,有003字樣



06.14B Quinolones, oral

27973 C / Unsafe

Floxsafe 400 (Moxifloxacin Tablets 400mg) 福樂星膜衣錠400毫克

(CDC漢生病)Moxifloxacin 400mg tab

Dosage: 2衛福部提供 27973

Adult
· Chronic bronchitis, community-acquired pneumonia, sinusitis, skin and skin structure infection, intra-abdominal infection: PO, 400mg qd for 5-21 days; duration of therapy depends on the type of infection
· Tuberculosis: PO, 400mg qd
· Hansen's disease: PO, 400mg qd

Pediatric
Safety and efficacy have not been established in patients less than 18 years old

Dosing adjustments in hepatic impairment:

No dosage adjustment needed; Use with caution secondary to the risk of QT prolongation

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 400mg(21269)(27898, 二線TB用藥)(27973, 二線漢生病); Inj: 400mg/250mL Bot(31182)

ADR:

COMMON
Hypokalemia, abdominal pain, constipation, diarrhea, nausea, vomiting, ALT/SGPT level abnormal, dizziness, headache
SERIOUS
Aortic aneurysm or dissection, prolonged QT interval, Torsades de pointes, rash, Stevens-Johnson syndrome, toxic epidermal necrolysis, hyperglycemia, hypoglycemia, Clostridium difficile diarrhea, agranulocytosis, aplastic anemia, hemolytic anemia, pancytopenia, thrombocytopenia, hepatic necrosis, hepatitis, liver failure, anaphylactoid reaction, hypersensitivity reaction, exacerbations of myasthenia gravis, rupture of tendon, tendinitis, disorientated, disturbance of attention, Guillain-Barre syndrome, memory impairment, peripheral neuropathy, pseudotumor cerebri, raised intracranial pressure, seizure, retinal detachment, agitation, feeling nervous, paranoid disorder, suicidal, renal failure, extrinsic allergic alveolitis, serum sickness due to drug

NOTE: 室溫儲存

· Avoid use in patients with known prolongation of the QT interval, uncorrected hypokalemia or patients receiving class IA or III antiarrhythmic agents
· Take at least 4 hr before or 8 hr after magnesium or aluminum antacids, sucralfate, iron or zinc supplements
· Safety and efficacy not established in children or adolescents younger than 18 years of age
· Fluoroquinolones have been associated with disturbances in glucose regulation, including hyperglycemia and hypoglycemia. These events have occurred most often in patients receiving concomitant oral hypoglycemic agents or insulin. Severe cases of hypoglycemia, including coma and death, have been reported. Diabetic patients should be monitored closely for signs/symptoms of disordered glucose regulation.Discontinue if a hypoglycemic reaction occurs and immediately initiate appropriate therapy.
· Quinolone 類藥品警語：
(1)過去使用quinolone或fluoroquinolone類曾發生嚴重不良反應，應避免使用，應先確認沒有替代治療選擇並謹慎評估效益/風險。
(2)肌腱炎及肌腱斷裂(好發於阿基里斯腱)，有時為雙側，可能於使用48小時內發生，也可能停藥數月後才發生。老年人、腎功能不良、曾進行器官移植或同時併用皮質類固醇會增加風險，故應避免併用皮質類固醇。
(3)精神相關不良反應，包括中毒性精神病、精神病反應進展至自殺意念/想法、幻覺或妄想；憂鬱或自殘行為如企圖自殺或完成自殺；焦慮、躁動或緊張；精神混亂、瞻妄、失去方向感或注意力無法集中；失眠或做惡夢；記憶力受損。可能發生在第一次投藥後。倘出現前述不良反應，應停用並開始適當治療。應特別注意治療的精神病或有精神疾病史的病人。
(4)癲癇(痙攣)風險、增加顱內壓(假性腦腫瘤)、頭暈和顫抖有關。如發生應停用並開始適當治療。
(5)血糖異常，曾有嚴重低血糖導致昏迷或死亡通報案例。如發生應停用並立即開始適當的治療。
(6)增加主動脈瘤及主動脈剝離相關風險，尤其老年人。有動脈瘤疾病之家族史，或已有主動脈瘤及/或主動脈剝離，或具有加重主動脈瘤及主動脈剝離之危險時，需謹慎評估其效益及風險與其他治療方式。建議病人如有突發性腹痛、胸或背痛，應立即就醫。

藥名相似:

外觀相似:

外觀描述: 淺磚紅色長橢圓錠，有BAYER及M400字樣

06.16 Sulfonamides

21200 D / Infant risk is

MORCASIN TABLETS "SINPHAR" 孟克杏錠

Sulfamethoxazole 400mg & Trimethoprim 80mg (Co-trimoxazole) tab

Dosage: 1常備品 21200

Adult: (Doses based on TMP component)
· Traveler's diarrhea: PO, 160mg q12h for 5 days
· Acute exacerbations of chronic bronchitis: PO, 160mg q12h for 14 days
· Chancroid: PO, 160mg q12h for 7 days
· UTI, enteritis & acute otitis media: PO, 160mg q12h for 10-14 days (5 days for enteritis)
· Pneumocystis jiroveci pneumonia: PO, 15-20mg/kg/day in 3-4 div doses for 14-21 days

Pediatric: (Doses based on TMP component)
· Otitis media: PO, 8mg/kg/day div. q12h for 10 days
· Pneumocystis jiroveci pneumonia, prophylaxis: PO, 150mg/m2/day in 2 div. doses 3 times/wk on consecutive days; alternative regimens, 150mg/m2 once daily 3 times/ wk on consecutive days or 150mg/m2/day in 2 div. doses every day or 3 times/wk on alternate days
· Pneumocystis jiroveci pneumonia, treatment: PO, 15-20mg/kg/day div. q6-8h for 14-21 days
· Toxoplasmic encephalitis, prophylaxis: PO, 150mg/m2/day in 2 div. doses
· Urinary tract infections: PO, 8mg/kg/day div. q12h for 10 days

Dosing adjustments in hepatic impairment:

Use with caution.

Dosing adjustments in renal impairment:

Clcr>30mL/min: The standard dose
Clcr 15-30mL/min: Half the standard dose
Clcr<15mL/min: Not recommended

P:

ADR:

COMMON
Anorexia, nausea, vomiting, rash, urticaria
SERIOUS
Severe allergic reactions (eg. Stevens-Johnson syndrome, toxic epidermal necrolysis), fulminant hepatic necrosis, aplastic anemia, agranulocytosis, other blood dyscrasias

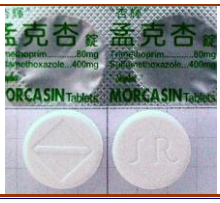
NOTE: 室溫儲存

· Patients should be instructed to maintain an adequate fluid intake in order to prevent crystalluria and stone formation.
· Not recommended for use with infants <2 mon (PCP prophylaxis can begin at 1 month of age)

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有菱形刻痕，另一面有SR字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1024964

06.16 Sulfonamides

21202 B / Unsafe

SALAZINE ENTERIC COATED TABLETS 500MG (SULFASALAZINE) "S.T." "信東" 撒樂腸溶錠５００公絲

Sulfasalazine 500mg EC tab

Dosage: 1常備品 21202

Adult
· Rheumatoid arthritis: PO, initially, 0.5-1g/day; increase weekly to MD 2g/day in 2 div doses; Max. 3g/day (if response to 2g/day is inadequate after 12 wks of treatment)
· Ulcerative colitis: PO, initially, 1g 3-4 times/day, MD 2g/day in div doses; may initiate therapy with 0.5-1g/day

Pediatric
· Juvenile rheumatoid arthritis(≧6 yrs): PO, 30-50mg/kg/day in 2 div doses; Max. 2g/day
· Ulcerative colitis(≧2 yrs): PO, initially, 40-60mg/kg/day in 3-6 div doses; MD. 20-30mg/kg/day in 4 div. doses; Max. 2g/day

Dosing adjustments in hepatic impairment:

Not recommended

Dosing adjustments in renal impairment:

Clcr 10-30mL/min: Administer q12h
Clcr <10mL/min: Administer qd

P:

ADR:

COMMON
Rash, loss of appetite, nausea, vomiting, headache, reversible oligozoospermia
SERIOUS
Leukopenia, macrocytic anemia, macrocytosis, neutropenia, hepatotoxicity, systemic lupus erythematosus (rare), nephrotoxicity, pulmonary infiltrate

NOTE: 室溫儲存

· Swallow whole. Do not break, crush or chew
· May cause yellow-orange discoloration of urine and skin
· Take after meals or with food

藥名相似:

外觀相似:

外觀描述: 黃橘色橢圓扁錠，一面有"ST"及另一面有"344"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043929

06.16 Sulfonamides

27519 C /

Exdapsone Tablets 100 mg 達普頌錠劑 100 毫克

Dapsone 100mg tab

Dosage: 1常備品 27519

Adult
·Dermatitis herpetiformis: PO, initial 50mg/day, MD 50-300mg qd
·Leprosy: PO, 100mg qd in combination with one or more anti-leprosy drugs (rifampin, clofazimine or ethionamide) for 3-10 years
·Prevention of pneumocystis jiroveci (formerly pneumocystis carinii) pneumonia: PO, 100mg qd or 50mg bid
·Treatment of pneumocystis jiroveci (formerly pneumocystis carinii) pneumonia: PO,100mg qd in conjunction with trimethoprim (5mg/kg tid) for 21 days

Pediatric
·Leprosy: PO, 1-2mg/kg/day in combination with other anti-leprosy medications, Max. 100mg/day
·Prevention of pneumocystis jiroveci (formerly pneumocystis carinii) pneumonia: (≧1 mon) PO, 2mg/kg/day, Max. 100mg/day; or 4mg/kg once a week, Max. 200mg/dose

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 100mg(27519)

ADR:

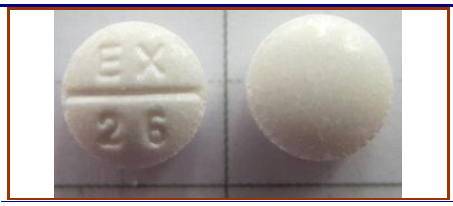
SERIOUS
Erythema multiforme, erythema nodosum, inflammation of skin and/or subcutaneous tissue, toxic epidermal necrolysis, toxic erythema, abdominal pain, pancreatitis, acquired Heinz body anemia (associated with G6PD deficiency, methemoglobin reductase deficiency or hemoglobin M), agranulocytosis, aplastic anemia, disorder of hematopoietic structure, glucose-6-phosphate dehydrogenase deficiency anemia, Heinz bodies, hemolysis, methemoglobin reductase deficiency, cholestatic jaundice syndrome (rare), toxic hepatitis, peripheral neuropathy (rare), suicide intent (rare)

NOTE: 儲存25℃以下

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，有EX及26字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1050876

06.16 Sulfonamides

27962 C /

多菌MDT-Combi-MB (Hansen's disease) 多菌型漢生病用藥

多菌MDT-Combi-MB (Dapsone, Clofazimine, Rifampin)

Dosage: 2衛福部提供 27962

Adult
·Multibacillary (MB) leprosy: PO, rifampicin 600mg, clofazimine 300mg and dapsone 100mg on day 1; dapsone 100mg and clofazimine 50mg on day2-27 of each 28-day cycle. A full course of treatment is 48 weeks

Pediatric
·Multibacillary(MB) leprosy: PO,
10-14 yrs: rifampicin 450mg and clofazimine 150mg q4w, then dapsone 50mg and clofazimine 50mg qod
>15 yrs: Same as adult

Dosing adjustments in hepatic impairment:

Rifampicin/Clofazimine
Severe hepatic impairment: Dose adjustments may be required
Dapsone
NDA

Dosing adjustments in renal impairment:

Clofazimine
No dosage adjustment needed
Dapsone
Dosage adjustment is needed

P: Blister pack: MDT-Combi-MB(27962), MDT-Combi-PB(27963)

ADR:

Rifampicin
Sweat/saliva/urine/tear discoloration, heartburn, loss of appetite, nausea, increased liver function test, influenza-like illness, thrombocytopenia (high-dose), hepatotoxicity
Clofazimine
Drug-induced pigmentation, dry skin, pruritus, rash, drug-induced gastrointestinal disturbance, nausea, vomiting, conjunctival pigmentation, corneal pigmentation, abnormal color of body fluids, bowel obstruction, gastrointestinal hemorrhage, crystalline deposits of clofazimine, splenic infarction, vision disturbances, hyperglycemia
Dapsone
Erythema multiforme, erythema nodosum, inflammation of skin and/or subcutaneous tissue, toxic epidermal necrolysis, toxic erythema, abdominal pain, pancreatitis, G6PD deficiency anemia, agranulocytosis, aplastic anemia, disease of hematopoietic system, methemoglobinemia, cholestatic jaundice syndrome, toxic hepatitis, peripheral neuropathy

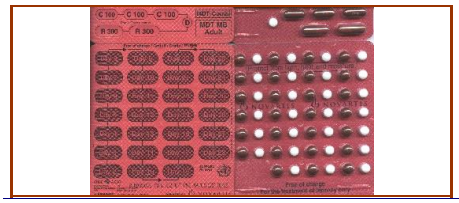
NOTE: 室溫儲存

·MDT-Combi-MB pack contains: 2 brownish-red capsules of 300mg rifampicin (Rimactane*), 3 brown rod-capsules of 100mg clofazimine (Lamprene*), 27 brown ball-capsules of 50mg clofazimine (Lamprene*), 28 white tablets of 100mg dapsone
·限診治漢生病之醫師(吳育弘、林揚志、蕭百芬及孫培倫醫師)處方

藥名相似:

外觀相似:

外觀描述: 棕色/紅色膠囊；褐色長膠囊；褐色球狀膠囊；白色圓型錠



06.16 Sulfonamides

27963 C /

少菌MDT-Combi-PB (Hansen's disease) 少菌型漢生病用藥

少菌MDT-Combi-PB (Dapsone, Rifampin)

Dosage: 2衛福部提供 27963

Adult
·Paucibacillary (PB) leprosy: PO, rifampicin 600mg every 4 weeks plus dapsone 100mg daily. A full course of treatment is 24 weeks

Pediatric
·Paucibacillary leprosy:
10-14 yrs: rifampicin 450mg every 4 weeks plus dapsone 50mg daily
>15 yrs: Same as adult

Dosing adjustments in hepatic impairment:

Rifampicin
Severe hepatic impairment: Dose adjustments may be required
Dapsone
NDA

Dosing adjustments in renal impairment:

Dapsone
Dosage adjustment is needed

P: Blister pack: MDT-Combi-MB(27962), MDT-Combi-PB(27963)

ADR:

Rifampicin
Sweat/saliva/urine/tear discoloration, heartburn, loss of appetite, nausea, increased liver function test, influenza-like illness, thrombocytopenia (high-dose), hepatotoxicity
Dapsone
Erythema multiforme, erythema nodosum, inflammation of skin and/or subcutaneous tissue, toxic epidermal necrolysis, toxic erythema, abdominal pain, pancreatitis, G6PD deficiency anemia, agranulocytosis, aplastic anemia, disease of hematopoietic system, methemoglobinemia, cholestatic jaundice syndrome, toxic hepatitis, peripheral neuropathy

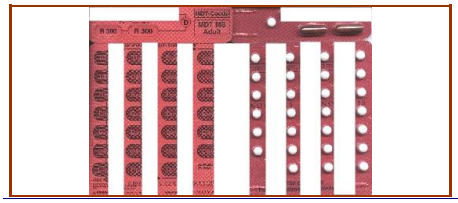
NOTE: 室溫儲存

·MDT-Combi-PB pack contains: 2 brownish-red capsules of 300mg rifampicin (Rimactane*), 28 white tablets of 100mg dapsone
·調配MDT-Combi-PB pack 可取MDT-Combi-MB pack 剪去clofazimine (3 brown rod-capsules and 27 brown ball-capsules)
·限診治漢生病之醫師(吳育弘、林揚志、蕭百芬及孫培倫醫師)處方

藥名相似:

外觀相似:

外觀描述: 2顆棕色/紅色膠囊；28顆白色圓型錠



06.16 Sulfonamides

28477 D / Infant risk is

SULFACOTRIM SUSPENSION "CENTER" 沙法克寧懸液劑〝晟德〞

Sulfamethoxazole 40mg/mL & Trimethoprim 8mg/mL(Co-trimoxazole) susp. 60mL/bot

Dosage: 1常備品 28477

Adult: (Doses based on TMP component)
· Traveler's diarrhea: PO, 160mg q12h for 5 days
· Acute exacerbations of chronic bronchitis: PO, 160mg q12h for 14 days
· Chancroid: PO, 160mg q12h for 7 days
· UTI, enteritis: PO, 160mg q12h for 10-14 days (5 days for enteritis)
· Pneumocystis jiroveci pneumonia: PO, 15-20mg/kg/day in 3-4 div doses for 14-21 days

Pediatric: (Doses based on TMP component)
· Otitis media: PO, 8mg/kg/day q12h for 10 days
· Pneumocystis jiroveci pneumonia, prophylaxis: PO,150 mg/m2/day in 2 div. doses 3 times/wk on consecutive days;alternative regimens, 150mg/m2/day 3 times/wk on consecutive days or 150mg/m2/day in 2 div. doses or 3 times/wk on alternate days
· Pneumocystis jiroveci pneumonia, treatment: PO, 15-20mg/kg/day div. q6-8h for 14-21 days
· Toxoplasmic encephalitis, prophylaxis: PO, 150mg/m2/day in 2 div. doses
· Urinary tract infections: PO, 8mg/kg/day div. q12h for 10 days

Dosing adjustments in hepatic impairment:

Use with caution.

Dosing adjustments in renal impairment:

Clcr>30mL/min: The standard dose
Clcr 15-30mL/min: Half the standard dose
Clcr<15mL/min: Not recommended

P: Tab: 400mg/80mg(21200); Syr: 2.4g/0.48g/60mL(28477); Inj: 400mg/80mg/5mL Amp(31164)

ADR:

COMMON
Anorexia, nausea, vomiting, rash, urticaria
SERIOUS
Severe allergic reactions (eg. Stevens-Johnson syndrome, toxic epidermal necrolysis), fulminant hepatic necrosis, aplastic anemia, agranulocytosis, other blood dyscrasias

NOTE: 室溫儲存

· 《Contraindications》History of sulfonamide- or trimethoprim-induced immune thrombocytopenia; Hypersensitivity to sulfonamides or trimethoprim; Infants younger than 2 months of age; Marked hepatic damage; Megaloblastic anemia due to folate deficiency; Severe renal insufficiency, when renal function cannot be monitored ;
· 《仿單禁忌》1.對於有過敏性反應，孕婦支氣管喘息·肝腎功能不良及有血性惡病質之病患需留意使用。2.接受本季治療時須經常做血球計數，若有異狀不能繼續使用。3.剛出生嬰孩禁止服用。4.老年病患不能以利尿劑Thiazides與本劑一起服用。
· Patients should be instructed to maintain an adequate fluid intake in order to prevent crystalluria and stone formation.
· Not recommended for use with infants <2 mon (PCP prophylaxis can begin at 1 month of age)

藥名相似:

外觀相似:

外觀描述: 60mL白色半透明塑膠瓶，微黃色懸浮液體

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044321

06.16 Sulfonamides

31164 **D / Infant risk is**

SEVATRIM INJECTION 雪白淨注射液

Sulfamethoxazole 400mg & Trimethoprim 80mg (Co-trimoxazole) 5mL amp

Dosage: 1常備品 31164

Adult: (Doses based on TMP component)
· Minor infections: IV infusion, 8–10mg/kg/day in 2-4 doses
· Severe infections and Pneumocystis jiroveci pneumonia: IV infusion, 20mg/kg/day div. q6-8h

Pediatric: (Doses based on TMP component)
· Minor infection, shigellosis: IV infusion, 8–10mg/kg/day in 2-4 doses
· Pneumocystis jiroveci pneumonia, treatment: IV infusion, 15-20mg/kg/day div. q6-8h for 14-21 days

Dosing adjustments in hepatic impairment:

Use with caution.

Dosing adjustments in renal impairment:

Clcr>30mL/min: The standard dose
Clcr 15-30mL/min: Half the standard dose
Clcr<15mL/min: Not recommended

P: Tab: 400mg/80mg(21200); Syr: 2.4g/0.48g/60mL(28477); Inj: 400mg/80mg/5mL Amp(31164)

ADR:

COMMON
Anorexia, nausea, vomiting, rash, urticaria
SERIOUS
Severe allergic reactions (eg. Stevens-Johnson syndrome, toxic epidermal necrolysis), fulminant hepatic necrosis, aplastic anemia, agranulocytosis, other blood dyscrasias

NOTE: 室溫儲存

· Not recommended for use with infants <2 mon.

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液，棕色玻璃安瓿，頸部有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1012528

06.18 Urinary Anti-infectives

21045 **B / Unsafe**

MONUROL 3G, GRANULES "贊邦" 梅樂黴素顆粒劑

Fosfomycin granules 3g/pack

Dosage: 1常備品 21045

· This medicine should not be used in patient more than 75 years of age.(仿單)
· Uncomplicated urinary tract infections: PO, ac, 3g as a single dose.

· This medicine should not be used in children less than 12 years of age.(仿單)
· Uncomplicated urinary tract infections: PO, ac, 2g as a single dose(Martindale)

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

· Dosage adjustment required
· Clcr < 10 mL/min Not recommended.

P: Granules: 3g/pk(21045)

ADR:

COMMON
Diarrhea, Nausea, Backache, Headache, Dysmenorrhea, Pharyngitis, Rhinitis, Pain.
SERIOUS
Aplastic anemia, Cholestatic jaundice syndrome, Hepatic necrosis, Toxic megacolon, Angioedema.

NOTE: 室溫保存25℃以下

· It should be given on an empty stomach.
· It must be dissolved in 50-75ml of water and take immediately.
· 本品賦形劑不含阿斯巴甜。

06.00 抗感染劑ANTI-INFECTIVE AGENTS

藥名相似:

外觀相似:

外觀描述: 暗紅色底紙盒白字有黃綠色區塊；紙袋單包裝暗紅色底/白字"Monurol"字樣有黃綠色區塊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023974

08.02A Nitrogen Mustards

21601 D / Unsafe

Chloraminophene Capsules 2 mg --

■■Chlorambucil 2mg cap

Dosage: 1常備品 21601

Adult

· Leukemia, chronic lymphocytic: PO, initiallly 0.1-0.2mg/kg/day for 3-6 wk; MD 0.03-0.1mg/kg/day

· Leukemia, chronic lymphocytic: intermittent, biweekly, or once-monthly pulse course, PO, single dose of 0.4mg/kg, increase dose by 0.1mg/kg to produce mild hematologic toxicity, until control of lymphocytosis or toxicity

· Leukemia, chronic lymphocytic: high dose therapy, PO, 30mg/m(2) once q2w has been used

· Lymphomas, malignant: PO, initially 0.1-0.2mg/kg/day for 3-6 wk;MD 0.03-0.1mg/kg/day

· Lymphomas, malignant: (non-Hodgkin's lymphoma) high dose therapy, PO 30mg/m(2) q2w has been used

Pediatric

· Not FDA approved for use in children

· Leukemia, chronic lymphocytic: PO, 0.1-0.2mg/kg/day or 4.5mg/m(2)/day as single dose or in divided daily doses

· Lymphomas, malignant: PO, 0.1-0.2mg/kg/day or 4.5mg/m(2)/day as single dose or in divided daily doses

· Nephrotic syndrome: PO, 0.1 to 0.2mg/kg/day, in a single dose, for 8-12 weeks

Dosing adjustments in hepatic impairment:

consider a dose reduction.

Dosing adjustments in renal impairment:

Clcr 10-50 ml/min: 75% of dose
Clcr <10 ml/min: 50% of dose
CAPD: 50% of dos

P: Tab: 2mg(21601)

ADR:

COMMON
Anemia, Thrombocytopenia.
SERIOUS
Cutaneous hypersensitivity, Toxic epidermal necrolysis, Acute leukemia, Leukopenia, Myelosuppression, Neutropenia, Pancytopenia, Hepatotoxicity, Hypersensitivity reaction, Seizure, Hallucinations, Sterility Reversible or permanent Infertility, Interstitial pneumonia, Pulmonary fibrosis, Secondary malignant neoplastic disease, Tumor lysis syndrome.

NOTE: 室溫儲存

Use with precaution in following condition:
1.Children with nephrotic syndrome, increased seizure risk
2.Concurrent use of other potentially epileptogenic drugs
3.Do not administer full dosage within 4 weeks of completion of full course of radiation therapy or chemotherapy, risk of bone marrow damage
4.History of seizure disorder or head trauma
5.Patients receiving high pulse doses of chlorambucil; increased seizure risk
6.Use proper procedures for handling and disposal of chemotherapy
7.可能進行自體幹細胞移植的病人不宜長時間接受本藥治療。
8.服藥期間可能造成免疫不全，不建議注射活性減毒疫苗。

藥名相似:

外觀相似:

外觀描述: 白色膠囊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023974

08.02A Nitrogen Mustards

21602 D / Unsafe

ENDOXAN SUGAR-COATED TABLETS 癌德星錠

■■Cyclophosphamide 50mg tab

Dosage: 1常備品 21602

Adult

· For treatment of (breast cancer, leukemias, lymphoma, multiple myeloma, mycosis fungoides, neuroblastoma, ovarian cancer, retinoblastoma): PO, 1-5mg/kg daily

Pediatric

· For treatment of (breast cancer, leukemias, lymphoma, multiple myeloma, mycosis fungoides, neuroblastoma, ovarian cancer, retinoblastoma): PO, 1-5mg/kg daily

· Minimal change nephrotic syndrome: PO, 2-3mg/kg daily for 60-90 days

Dosing adjustments in hepatic impairment:

Bilirubin 3.1-5 mg/dL or transaminases >3 times ULN :
75% of the normal dose
Bilirubin >5 mg/dL : avoid use

Dosing adjustments in renal impairment:

1.GFR>50mL/min: No dosage reduction is required
2.GFR 10-50mL/min: Receive 75% of the normal
3.GFR<10mL/min: Receive 50% of the normal dose

P:

ADR:

COMMON
Alopecia, amenorrhea, leukopenia, N/V
SERIOUS
Cardiomyopathies, hemorrhagic cystitis infections, interstitial pneumonitis, oligospermia,azoospermia, Stevens-Johnson syndrome, toxic epidermal necrolysis

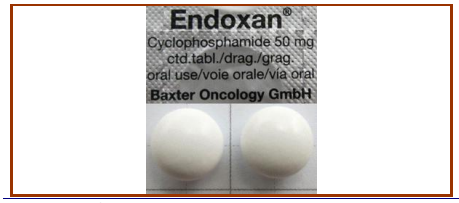
NOTE: 室溫儲存

1.Forced fluid intake helps prevent hemorrhagic cystitis
2.When cyclophosphamide is used in combined cytotoxic regimens, dose reduction of cyclophosphamide as well as other drugs may be necessary

藥名相似: Tab: 50mg(21602); Inj: 200mg p/v(31206)

外觀相似:

外觀描述: 白色圓形糖衣錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2012601

08.02A Nitrogen Mustards

21605 demonstrated / Infant risk can

ALKERAN MELPHALAN TABLETS 2MG 威克瘤錠

■■Melphalan 2mg tab

Dosage: 1常備品 21605

Adult

· Epithelial ovarian cancer: PO, 0.2mg/kg qd for 5 days; repeat q4-5wk depending on hematologic tolerance

· Multiple myeloma: PO, 6mg/day for 2-3 wk, then 4 wk off, then when blood cell/platelet counts are rising, 2mg/day; other regimens include 0.25mg/kg/day for 4 consecutive days (0.2mg/kg/day for 5 days) in combination with prednisone- total dose of 1mg/kg/course repeated every 4-6 weeks if granulocyte/platelet counts have returned to normal; 10mg/day for 7-10 days with a maintenance dose of 2 mg/day; 0.15mg/kg/day for 7 days with a maintenance dose of 0.05mg/kg/day or less

· Multiple myeloma, palliative treatment (combination therapy): PO, melphalan 10mg/m(2) with PO prednisone 60mg/m(2) days 1-4 repeat cycle every 42 days

Pediatric

Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment is needed

Dosing adjustments in renal impairment:

50% dose reduction is recommended if the blood urea nitrogen is greater than 30 mg/dL or the serum creatinine is greater than 1.5 mg/dL

P: Tab: 2mg(21605); Inj: 50mg(37870, 急用藥)

ADR:

COMMON

Stomatitis.

SERIOUS

Cardiac arrest, Acute myeloid leukemia, Aplastic bone marrow, Bone marrow depression, Hemolytic anemia, Leukemia, Acute granulocytic or myelomonocytic, Myeloproliferative disorder, Hepatitis, Anaphylaxis, Acute renal failure, Interstitial pneumonia, Pulmonary fibrosis, Secondary malignant neoplastic disease.

NOTE: 冰箱保存

·《Contraindications》Hypersensitivity to melphalan; Prior resistance to melphalan；

·致癌性-白血病: 長期合併治療與放射性治療的老年人，應權衡引發白血病(AML及MSD)的風險和可能的治療效益；併用thalidomide或lenalidomide及prednisone時，有報告會提高白血病誘發風險；第二原發性惡性腫瘤: 與烷化劑的使用有關。特別是合併lenalidomide及prednisone或thalidomide及prednisone治療的新診斷多發性骨髓瘤老年人。

·避孕-合併lenalidomide及 prednisone，或合併thalidomide及prednisone(或dexamethasone)治療者其發生靜脈栓塞的風險較高，故不建議使用合併型口服避孕藥，應改採其他有效避孕方法。停用合併型口服避孕藥後，靜脈栓塞風險仍持續4-6週；建議男性治療期間及治療後6個月，暫停生育計畫。接受本藥治療可能導致不可逆不孕症，在開始治療前宜先諮詢精子保存。

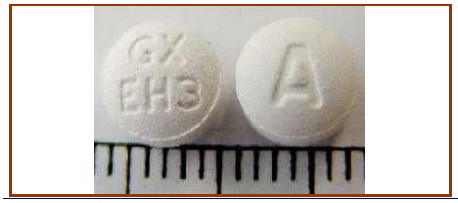
·栓塞問題-至少前5個月應同時給予栓塞預防治療，尤其已知有栓塞危險因子者。一但發生栓塞，應立即停止治療，並開始抗凝血治療。當抗凝血治療達穩定，栓塞也控制，效益風險評估後，可再次以原劑量治療。期間病人需持續接受抗凝血治療。

·交互作用：增列曾有報告，兒科病人採用busulfan-melphalan療程時，melphalan與前一劑口服bulsulfan間隔不到24小時可能影響毒性的發生。

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，有GX EH3及A字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2009145

08.02A Nitrogen Mustards

31206 D / Infant risk has

Endoxan Injection 癌得星注射劑

■■Cyclophosphamide inj 200mg pow in vial

Dosage: 1常備品 31206

Adult

· For treatment of (breast cancer, leukemia, lymphoma, multiple myeloma, mycosis fungoides, neuroblastoma, ovarian cancer, retinoblastoma): IV, 40-50mg/kg in divided doses over 2-5 days or 10-15mg/kg every 7-10 days or 3-5mg/kg twice weekly

· Lupus nephritis: IV, 1g/m2/month; typically combined with a corticosteroid

Pediatric

· For treatment of (breast cancer, leukemia, lymphoma, multiple myeloma, mycosis fungoides, neuroblastoma, ovarian cancer, retinoblastoma): the same as for adult

· Lupus nephritis: IV, 500-750mg/m2/month, titrate to 1g/m2/month

Dosing adjustments in hepatic impairment:

Bilirubin 3.1-5 mg/dL or transaminases >3 times ULN :

75% of the normal dose

Bilirubin >5 mg/dL : avoid use

Dosing adjustments in renal impairment:

1.GFR>50mL/min: No dosage reduction is required

2.GFR 10-50mL/min: Receive 75% of the normal dose

3.GFR<10mL/min: Receive 50% of the normal dose

P: Tab: 50mg(21602); Inj: 200mg p/v(31206)

ADR:

COMMON
Alopecia, Disorder of skin pigmentation, Nail damage, Rash, Abdominal discomfort, Diarrhea, Loss of appetite, Nausea and vomiting, Leukopenia, Neutropenia, Amenorrhea.
SERIOUS
Cardiac tamponade, Cardiotoxicity, Congestive heart failure, Pericardial effusion, Erythema multiforme, Malignant tumor of dermis, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Acute myeloid leukemia, Chronic myeloid leukemia, Malignant tumor of lymphoid hemopoietic and related tissue, Myelodysplastic syndrome, Angiosarcoma of liver, Anaphylaxis, Acquired contracture of bladder neck, Bladder cancer, Fibrosis of urinary bladder, Hemorrhagic cystitis, Pyelitis, Renal hematuria, Secondary malignant neoplasm of renal pelvis, Azoospermia, Oligozoospermia, Interstitial pneumonia, Pulmonary fibrosis, Infectious disease.

NOTE: 室溫儲存

1.Need to shake vigorously to dissolve (10ml NS to 200mg)
2.Use forced hydration to induce polyuria to avoid hemorrhagic cystitis
3. Prophylactic treatment of cystitis with Mesna may help prevent or limit the urinary toxic effects of Cyclophosphamide overdose.
4.There are no known antidote, Cyclophosphamide and its metabolites can be hemodialyzed; therefore, rapid hemodialysis should be used when treating any suicidal or accidental overdose or poisoning.
5. May cause bone marrow suppression, which can cause white blood cell loss, neutropenia, thrombocytopenia (related to a higher risk of bleeding events) and anemia.
6. May cause significant suppression of the immune response, severe immunosuppression has led to serious or fatal infections, including pneumonia and other bacterial, fungal, viral, protozoal and parasitic infections, and has been reported to have sepsis and septic shock. Latent infections can be reactivated; various bacterial, fungal, viral, protozoal and parasitic infections have been reported to reactivate.

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021304

08.02A Nitrogen Mustards

31228 D / Unsafe

HOLOXAN (2GM) "愛斯達 "好克癌注射劑 2 公克

■■Ifosfamide 2g pow in vial

Dosage: 1常備品 31228

Adult
· Testicular neoplasms: IV, 1.2g/m2/day for 5 days repeat every 3 weeks
· Malignant neoplasms (I.e., sarcomas, small cell lung cancer, cervical cancer, ovarian cancer, uterine cancer): IV, 1.2-2.5g/m2/day for 3-5 days, with cycles of therapy repeated as necessary depending on the patient's response

Pediatric
· Safety and effectiveness in children have not been established
· Solid tumors: IV, 1.6-1.8g/m(2) daily for 5 days has been used

Dosing adjustments in hepatic impairment:

AST>300 or bilirubin>3.0 mg/dL, decrease Ifosfamide dose by 75%.

Dosing adjustments in renal impairment:

1.GFR>50mL/min: No dosage adjustment needed.
2.GFR 10-50mL/min: No dosage adjustment needed.
3.GFR<10mL/min: 75% dose for normal renal function

P: Inj: 2g Vial(31228)

ADR:

COMMON
Alopecia, N/V
SERIOUS
Central nervous system toxicities, metabolic acidosis, renal toxicity, myelosuppression, urotoxicity

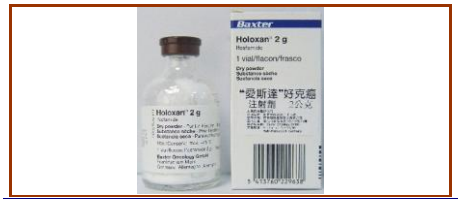
NOTE: 室溫儲存

1. Administer hydration (minimum 2 L/day) plus mesna to limit urotoxicity; recommended IV mesna dosing is 20% of ifosfamide dosage (w/w) at the time of the ifosfamide infusion, 4 and 8 hrs after every ifosfamide dose
2.Reconstitute with SWFI/BWFI to a concentration of 50 mg/ml; dilute further to 0.6-20 mg/mL in D5W, NS, LR, SWFI
3.IV infusion over at least 30 minutes

藥名相似:

外觀相似:

外觀描述:



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2018479

08.02A Nitrogen Mustards

37507 D / Unsafe

Innomustine Injection 普癌汰 乾粉靜脈注射劑

■■Bendamustine HCl 100mg pow in vial

Dosage: 1常備品 37507

Adult
·Chronic lymphoid leukemia: IV infusion over 30mins, 100mg/m(2) on days 1 and 2; repeat q4wks up to 6 cycles

·Rituximab-refractory, indolent Non-Hodgkin's lymphoma: IV infusion over 60mins, 120mg/m(2) on days 1 and 2; repeat q3wks up to 8 cycles

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Mild to moderate hepatic impairment (serum bilirubin<3mg/dL): No dosage adjustment needed
Severe hepatic impairment (serum bilirubin>3mg/dL): NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 100mg (37507)(37771, 捐贈用藥)

ADR:

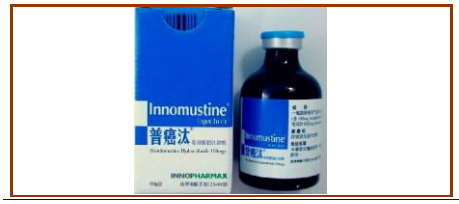
COMMON
Rash, weight loss, constipation, diarrhea, loss of appetite, nausea, stomatitis, vomiting, headache, cough, dyspnea, dehydration, fatigue, fever
SERIOUS
Hypertensive crisis, dermatologic toxicity, Stevens-Johnson syndrome, toxic epidermal necrolysis, hyperuricemia, acute myeloid leukemia, anemia, febrile neutropenia, leukopenia, lymphocytopenia, myelodysplastic syndrome, myeloproliferative disorder, myelosuppression (grade 3 and 4), neutropenia, thrombocytopenia, anaphylaxis, hypersensitivity reaction, infectious disease, sepsis, septic shock, renal failure, squamous cell carcinoma of bronchus, myelodysplastic syndrome, tumor lysis syndrome

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色凍晶乾粉、『藍』蓋棕色玻璃小瓶



08.02A Nitrogen Mustards

37870 D /

MELPHATHER* 50 (Melphalan for injection BP 50mg) -

■■急用Melphalan 50mg inj pow in vial with solvent 10mL vial

Dosage: 2急用藥 37870

Adult
· Multiple myeloma, palliative treatment (patients for whom oral therapy is not appropriate): IV infusion, 16mg/m2(over 15-20 minutes) at 2 wk intervals for 4 doses; then after adequate recovery from toxicity at 4 wk intervals
· Hodgkin's lymphoma
1.Mini-BEAM regimen: IV infusion, day 1 BCNU 60mg/m2; days 2–5 etoposide 75mg/m2; cytarabine 100mg/m2 q12h; day 6 melphalan 30mg/m2 .
2.Dexa-BEAM regimen: IV, day 1-10 dexamethasone 8mg q8h; day 2 BCNU 60mg/m2; day 3 melphalan 20mg/m2; day 4-7 etoposide 250 mg/m2/day; cytarabine 100mg/m2 q12h.
· Ovarian carcinoma: 0.2mg/kg/day for 5 days, repeat every 4-5 wks.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

No dose adjustment needed

Dosing adjustments in renal impairment:

BUN > 30 mg/dL or Scr > 1.5 mg/dL: Reduce dose by 50%

P: Tab: 2mg(21605); Inj: 50mg(37870, 急用藥)

ADR:

COMMON
Alopecia, stomatitis
SERIOUS
Abnormal liver function tests, jaundice, hepatitis, hypersensitivity reactions/anaphylaxis, hemolytic anemia, myelosuppression, pulmonary infiltrates/fibrosis, secondary malignancies, sterility, vasculitis

NOTE: 室溫儲存

· Diluted solutions are unstable. Administration should be completed within 60 minutes of reconstitution.

藥名相似:

外觀相似:

外觀描述: 注射乾粉，紅色蓋玻璃小瓶，另附有白色蓋玻璃小瓶裝稀釋液

08.02B Nitrosoureas

37867 D /

Gliadel Wafer 格立得植入劑

■■急用Carmustine 7.7mg in polifeprosan 20 implant

Dosage: 2急用藥 37867

Adult:
· Glioblastoma multiforme of brain (in patients with recurrent glioblastoma multiforme for whom surgical resection is indicated), adjunct: Implantation, 8 wafers placed in resection cavity if size and shape of cavity permits; if cavity size and shape cannot accommodate 8 wafers, place maximum number of wafers as allowed

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Wafer: 8 wafers/SH (37867, 急用);
Inj: 100mg vial (31203, 專案藥)

ADR:

Convulsions, aphasia, brain edema, intracranial hypertension, confusion, hemiplegia, drowsiness, headache, surgical site healing abnormalities, fever, urinary tract infection, infection including abscess or meningitis, pain, rash, stupor, nausea or vomiting

NOTE: -20℃

· Unopened foil pouches may be kept at room temperature for a maximum of 6 hours.
· The wafers may be broken in half, but wafers broken in more than 2 pieces should be discarded in a biohazard container.
· Avoid communication between the surgical resection cavity and the ventricular system.

藥名相似:

外觀相似:

外觀描述:

08.02C Alkyl Sulfonates

31259 **D / Infant risk can**

BUSULFEX (R) INJECTION 補束剋 注射劑

■■Busulfan inj 60mg/10mL vial

Dosage: 1常備品 31259

ADULT
Chronic myeloid leukemia - Hemopoietic stem cell transplant : IV infusion over 2h, 0.8 mg/kg q6h for 4 consecutive days (16 total doses) starting on bone marrow transplant day -7, in combination with cyclophosphamide 60 mg/kg IV as a 1-hour infusion on bone marrow transplant day -3, 6 hours after the final dose of busulfan and again on bone marrow/progenitor cell transplant day -2; administer hematopoietic progenitor cells on day 0.

Pediatric
<12kg:Chronic myeloid leukemia - Hemopoietic stem cell transplant : IV infusion over 2h, 1.1 mg/kg q6h for 4 consecutive days (16 total doses).
>12kg:Chronic myeloid leukemia - Hemopoietic stem cell transplant : IV infusion over 2h, 0.8 mg/kg q6h for 4 consecutive days (16 total doses).

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment is needed.

P:

ADR:

COMMON
Hyperglycemia, hypokalemia, hypomagnesemia, abdominal pain, diarrhea, loss of appetite, nausea, stomatitis, vomiting, headache, insomnia, anxiety, fever.
SERIOUS
Cardiac tamponade, anemia, aplastic anemia, granulocytopenic disorder, leukemia, myelosuppression, neutropenia, pancytopenia, thrombocytopenia, veno-occlusive disease of the liver, graft versus host disease, seizure, ovarian failure, pneumonia, pulmonary fibrosis, pulmonary hemorrhage.

NOTE:

·《Contraindications》Hypersensitivity to busulfan or any component of the product ;
1.Premedication: Anticonvulsants 12 hours prior to busulfan to 24 hours after last dose of busulfan.
2.Premedication: Administer antiemetics prior to the first dose of busulfan and continue on a fixed schedule through busulfan administration.

藥名相似:

外觀相似:

外觀描述: 10mL透明注射液，『紫』蓋玻璃小瓶，白底 紫/黑 字標籤

08.02E Other alkylating Agents

21630 **D / Unsafe**

Tamos Capsules 100 mg 特莫斯膠囊 100 毫克

■■Temozolomide 100mg cap

Dosage: 1常備品 21630

Adult
· Anaplastic astrocytoma, malignant glioma: PO, 150-200mg/m(2) qd X 5 days; cycle every 28 days
· Glioblastoma multiforme(newly diagnosed) concomitantly with radiotherapy and then as maintenance: initial dose, concomitant with focal radiotherapy: 75 mg/m(2) once daily for 42 days; maintenance dose, cycle 1 (4 weeks after completion of initial therapy): 150 mg/m(2) once daily for 5 days, repeat every 28 days.cycle 2-6: 200 mg/m(2) once daily for 5 days, repeat every 28 days.

Pediatric
· Safety and effectiveness have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: 100mg(27509 急用; 21630), 20mg(27507 急用)

ADR:

NOTE: 室溫儲存

1.Take on an empty stomach or at bedtime to decrease nausea; do not open or chew capsules;

adjust dose based on platelet/neutrophil counts
2.Antiemetics may be administered

藥名相似:

外觀相似:

外觀描述: 粉紅色/白色膠囊，有LP及206字樣

08.02E Other alkylating Agents

21631 /

Tamos Capsules 20mg 特莫斯膠囊20毫克

■■Temozolomide 20mg cap

Dosage: 1常備品 21631

Adult
· Anaplastic astrocytoma, malignant glioma: PO, 150-200mg/m(2) qd X 5 days; cycle every 28 days
· Glioblastoma multiforme(newly diagnosed) concomitantly with radiotherapy and then as maintenance: initial dose, concomitant with focal radiotherapy: 75 mg/m(2) once daily for 42 days; maintenance dose, cycle 1 (4 weeks after completion of initial therapy): 150 mg/m(2) once daily for 5 days, repeat every 28 days.cycle 2-6: 200 mg/m(2) once daily for 5 days, repeat every 28 days.

Pediatric
· Safety and effectiveness have not been established

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Cap: 100mg(27509 急用; 21630), 20mg(27507 急用, 21631捐贈)

ADR:

NOTE: 室溫儲存

1.Take on an empty stomach or at bedtime to decrease nausea; do not open or chew capsules; adjust dose based on platelet/neutrophil counts
2.Antiemetics may be administered

藥名相似:

外觀相似:

外觀描述: 黃色/白色膠囊，有LP及605字樣

08.02E Other alkylating Agents

31218 D / Unsafe

DBL DACARBAZINE FOR INJECTION 200MG 達卡巴仁注射劑200毫克

■■Dacarbazine inj 200mg pow in vial

Dosage: 1常備品 31218

Adult
· Melanoma, malignant: IV, 2-4.5mg/kg/day for 10 days; may repeat every 4wks
· Melanoma, malignant: IV, 250mg/m(2) for 5 days; may repeat every 3wks
· Hodgkin's disease: IV, 150mg/m(2)/day for 5 days in combination with other effective drugs; may repeat every 4wks
· Hodgkin's disease: IV, 375mg/m(2) on day 1 in combination with other effective drugs; repeat every 15 days

Pediatric
· Not approved by FDA

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 46-60 ml/min : 80%
Clcr 31-45 ml/min : 75%
Clcr <30 ml/min : 70%

P: Inj: 200mg Vial(31218)

ADR:

COMMON
Alopecia, anorexia, N/V, flu-like symptoms, headache, polyneuropathy, hypotension
SERIOUS
Anaphylaxis, cerebral hemorrhage, hepatotoxicity, hepatic necrosis, hepatic vein thrombosis, myelosuppression, photosensitivity, seizures

NOTE: 儲存2-8℃避光

1.Infuse IV in 500mL D5W or NS over 15 min
2.Maximum concentration 25 mg/ml

藥名相似:

外觀相似:

外觀描述: 淺黃色注射粉，黑色塑膠蓋褐色玻璃小瓶，白底紫色字標簽有淺黃色區塊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022131

08.04B Anthracyclines and related substances

31222 D / Unsafe

MITOXANTRONE INJECTION 2MG/ML "SYNMOSA" "健喬"雙羥恩昆注射液 2 毫克/毫升

■■Mitoxantrone HCl 20mg/10mL vial

Dosage: 1常備品 31222

Adult
· Leukemia, acute nonlymphocytic: IV, induction, 12mg/m(2) daily on days 1-3, in combination with cytarabine 100mg/m(2) daily as continuous IV infusion on days 1-7
· Leukemia, acute nonlymphocytic: IV, re-induction, 12mg/m(2) daily for 2 days in combination with cytarabine 100mg/m(2) daily as continuous IV infusion on days 1-5
· Leukemia, acute nonlymphocytic: consolidation,

12mg/m(2) IV daily on days 1 and 2, in combination with cytarabine 100mg/m(2) daily as continuous IV infusion on days 1-5
· Multiple sclerosis: IV, 12mg/m(2) every 3 months; should not ordinarily be administered to patients who have received a cumulative dose of 140mg/m(2) or greater
· Prostate cancer: IV, 12-14mg/m(2) every 21 days, in combination with corticosteroids

Pediatric
· The safety and efficacy of mitoxantrone in pediatric patients have not been established
· Solid tumor configuration: 5 to 8 mg/m(2)/week IV; alternative dosing regimen 18 to 20 mg/m(2) IV every 3 to 4 week

Dosing adjustments in hepatic impairment:

· Dosage adjustment may be necessary.
· MS patients with hepatic impairment should not receive mitoxantrone.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Inj: 20mg/10mL Vial(31222)

ADR:

COMMON
Alopecia, diarrhea, nausea, vomiting, headache, menstrual disorders, mucositis
urinary tract infection, abnormal liver function tests
SERIOUS
Cardiac toxicity, hepatotoxicity, myelosuppression (frequent), secondary leukemia and myelodysplasia

NOTE: 冰箱冷藏，不可冷凍

1.Dilute to at least 50 mL (NS or D5W)
2.For intravenous administration only; do not give intra-arterial, SC, IM or intrathecal
3.Irritant, stop administration if extravasation occurs infuse over 5-15 min
4.Limit lifetime cumulative dose to 140-160mg/m(2) to decrease cardiac toxicity

藥名相似:

外觀相似:

外觀描述: 藍色澄清注射液、『綠』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1033445

08.04B Anthracyclines and related substances

31224 **D / Unsafe**

EPICIN INJCETION 益彼欣注射液

■■Epirubicin HCl 10mg/5mL vial

Dosage: 1常備品 31224

Adult
· Breast cancer, adjuvant therapy: IV, 100mg/m(2) on day 1 repeated every 21 days for 6 cycles in combination with cyclophosphamide and 5-fluorouracil
· Cancers, others: IV, usual dose range 60-120mg/m(2) every 21-28 days in combination with other agents; specific dosing and frequency is protocol dependent

Pediatric: NDA

Dosing adjustments in hepatic impairment:

Bilirubin 1.2 -3mg/dL or the AST is 2 to 4 times the upper limit of normal: 1/2 of the recommended starting dosage
Bilirubin >3mg/dL or the AST is greater than 4 times the upper limit of normal: 1/4 of the recommended starting dosage

Dosing adjustments in renal impairment:

Scr >5 mg/dL: lower dose should be considered

P: Inj: 10mg/5mL Vial(31224), 50mg/25mL Vial(31225)

ADR:

COMMON
Alopecia, rash, skin changes, radiation-recall reactions, amenorrhea, hot flashes, fever, infection, lethargy, N/V, diarrhea, mucositis
SERIOUS
AML (acute myelogenous leukemia), secondary, anaphylaxis, hypersensitivity, ECG abnormalities, myocardial toxicity (possibly fatal CHF), local tissue necrosis (secondary to extravasation), myelosuppression (possibly severe), tumor-lysis syndrome, hyperuricemia

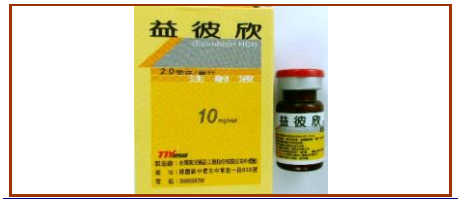
NOTE: 冰箱冷藏，不可冷凍。

1.Risk of CHF increases rapidly above total cumulative doses of 900mg/m(2); prior anthracycline exposure should be considered in total dose exposure
2.Vesicant, caution to extravasation, IV only
3.Patients receiving 120mg/m(2) regimens should be administered prophylactic antibiotics with trimethoprim-sulfamethoxazole or a fluoroquinolone

藥名相似:

外觀相似:

外觀描述: 5mL橘紅色注射液，『紅』蓋棕色玻璃小瓶



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1047003

08.04B Anthracyclines and related substances

31225 **D / Unsafe**

EPICIN INJCETION 益彼欣注射液

■■Epirubicin HCl 50mg/25mL vial

Dosage: 1常備品 31225

Adult
· Breast cancer, adjuvant therapy: IV, 100mg/m(2) on day 1 repeated every 21 days for 6 cycles in combination with cyclophosphamide and 5-fluorouracil
· Cancers, others: IV, usual dose range 60-120mg/m(2) every 21-28 days in combination with other agents; specific dosing and frequency is

protocol dependent

Pediatric: NDA

Dosing adjustments in hepatic impairment:

Bilirubin 1.2 -3mg/dL or the AST is 2 to 4 times the upper limit of normal: 1/2 of the recommended starting dosage
Bilirubin >3mg/dL or the AST is greater than 4 times the upper limit of normal: 1/4 of the recommended starting dosage

Dosing adjustments in renal impairment:

Scr >5 mg/dL: lower dose should be considered

P: Inj: 10mg/5mL Vial(31224), 50mg/25mL Vial(31225)

ADR:

COMMON
Alopecia, rash, skin changes, radiation-recall reactions, amenorrhea, hot flashes, fever, infection, lethargy, N/V, diarrhea, mucositis
SERIOUS
AML (acute myelogenous leukemia), secondary, anaphylaxis, hypersensitivity, ECG abnormalities, myocardial toxicity (possibly fatal CHF), local tissue necrosis (secondary to extravasation), myelosuppression (possibly severe), tumor-lysis syndrome, hyperuricemia

NOTE: 冰箱冷藏，不可冷凍。

1.Risk of CHF increases rapidly above total cumulative doses of 900mg/m(2); prior anthracycline exposure should be considered in total dose exposure
2.Vesicant, caution to extravasation, IV only
3.Patients receiving 120mg/m(2) regimens should be administered prophylactic antibiotics with trimethoprim-sulfamethoxazole or a fluoroquinolone

藥名相似:

外觀相似: 50MG

外觀描述: 25mL橘紅色注射液，『紅』蓋棕色玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1047003

08.04B Anthracyclines and related substances

31232 **UK / Unsafe**

LIPO-DOX LIPOSOME INJECTION 2MG/ML(DOXORUBICIN HYDROCHLORIDE) 力得微脂體注射劑2毫克/毫升（鹽酸杜薩魯比辛）

■■Doxorubicin HCl liposome 20mg/10mL vial

Dosage: 1常備品 31232

Adult
· AIDS-related Kaposi's sarcoma: IV, 20mg/m(2) over 30 min q3w
· Ovarian cancer: IV, 50mg/m(2) over 1 hour q4w
· Multiple myeloma: 30 mg/m(2) q3w in combination with bortezomib
· Breast cancer, advanced/metastatic: 50 mg/m(2) q4w

Pediatric: NDA

Dosing adjustments in hepatic impairment:

Serum bilirubin 1.2-3mg/dL: Give 1/2 the normal dose
Serum bilirubin>3mg/dL: Give 1/4 the normal dose

Dosing adjustments in renal impairment:

NDA

P: Inj: 20mg/10mL(31232); Inj: doxorubicin 10mg with 5ml SWI(31247)

ADR:

COMMON
Asthenia, abdominal pain, constipation, diarrhea, N/V, alopecia
SERIOUS
Myelosuppression, alkaline phosphatase increase (AIDS-Kaposi's patients), cardiomyopathy, infusion reactions, palmar-plantar erythrodysesthesia, rash, stomatitis

NOTE: 冰箱冷藏，不可冷凍

1.The dose of DOXORUBICIN HYDROCHLORIDE LIPOSOME is different than that of conventional DOXORUBICIN and the two formulations are not interchangeable

藥名相似:

外觀相似:

外觀描述: 10mL紅色注射液、『白』蓋玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1041037

08.04B Anthracyclines and related substances

31276 **D / Unsafe**

ADRIAMYCIN* INJ. 2MG/ML 艾黴素注射液

■■Doxorubicin HCl 10mg/5mL vial (Adriamycin)

Dosage: 1常備品 31276

Adult
·Treatment of carcinomas of breast, lung, bladder, thyroid, and ovarian; bone and sof-tissue sarcomas; leukemias:
Single agent: IV, 60-75mg/m(2) every 21 days
In combination with other chemotherapy agents: IV, 40-60mg/m(2) every 21 to 28 days

Pediatric
Same as for adults

Dosing adjustments in hepatic impairment:

Plasma bilirubin (mg/dL) 1.2 to 3.0 : 50% dose
Plasma bilirubin (mg/dL) > 3.0 :25% dose

Dosing adjustments in renal impairment:

Dosage adjustment is not necessary.

P: Inj: 10mg with 5ml SWI(31247), 10mg/5mL(31276); Inj: Doxorubicin, liposome 20mg/10mL Vial(31232)

ADR:

NOTE: 室溫儲存

1.Vesicant; avoid extravasation
2.Limit lifetime cumulative doses of doxorubicin to 450-550mg/m(2) to decrease cardiac toxicity; total dose should take into account previous tx with other anthracyclines/potentially cardiotoxic agents
3.The dose of liposomal doxorubicin is different than that of conventional doxorubicin and the two formulations are not interchangeable

藥名相似:

外觀相似:

外觀描述: 紅色注射藥劑，『紅』色蓋透明玻璃小瓶，黃底黑/紅字標籤

08.04B Anthracyclines and related substances

31277 **D / Unsafe**

ZAVEDOS* 1MG/ML INJECTION VIAL 艾達黴素靜脈注射劑 1 毫克 / 毫升

■■Idarubicin HCl inj 5mg/5mL vial

Dosage: 1常備品 31277

Adult
· Leukemia, acute myeloid (induction): IV, 12mg/m(2) qd for 3 days in combination with cytarabine
· Leukemia, acute myeloid (consolidation): IV, 10-12mg/m(2) qd for 2 days

Pediatric
· Safety and effectiveness in children have not been established
· Leukemia, acute non-lymphocytic/lymphocytic: IV, 8-10mg/m(2) daily for 3 days has been used

Dosing adjustments in hepatic impairment:

1.Serum bilirubin concentrations of 2.6-5mg/dL: Received idarubicin with a 50% reduction in dose
2.Serum bilirubin concentration exceeding 5mg/dL: Idarubicin should not be given

Dosing adjustments in renal impairment:

Clcr 10-50 ml/min : 75% of dose
Clcr <10 ml/min : 50% of dose
HD/CAPD : supplemental dose not neede

P: Inj: 5mg Vial(31226), 5mg/5mL Vial(31277)

ADR:

COMMON
Alopecia, Rash, Urticaria, Diarrhea, severe, Grade 4 Diarrhea, Nausea and vomiting, Stomach cramps, Headache.
SERIOUS
Cardiac dysrhythmia, Chest pain, Congestive heart failure, Myocardial infarction, Inflammatory disease of mucous membrane, Myelosuppression (frequent), Hepatotoxicity, Nephrotoxicity, Infectious disease.

NOTE: 室溫儲存

1.Administer IV over 10-15 min into freely running D5W or NS IV infusion
2.Vesicant: severe local tissue necrosis can occur with extravasation
3.Limit lifetime cumulative doses of anthracyclines (idarubicin <150 mg/m(2)) to decrease cardiac toxicity
· 停用其他具心臟毒性之藥物治療後，再接受anthracycline類藥物治療的病人，發生心臟毒性風險可能會升高。尤其半衰期長的藥物，如trastuzumab可能持續在血液中循環達7個月，故停後7個月內應儘可能避免使用anthracycline類藥物，若在期間內使用，建議應謹慎監測心臟功能。
· 原患有心臟病或因其它疾病有特定臨床表徵(貧血、骨髓抑制、感染、白血病心包膜炎及/或心肌炎)的病人，發生此類心肌毒性風險可能較高。
· anthracycline引發的心肌病變通常會伴隨持續性的QRS波電壓降低、心室收縮時間間隔(PEP/LET)超出正常限值增加以及相較於治療前基準值的左心室射出分率(left ventricular ejection fraction, LVEF)下降。在開始治療前，應先使用心電圖(ECG)和多時閘門心室造影(multiple gated acquisition, MUGA)或心臟超音波(ECHO)評估心臟功能(LVEF評估)。應重複進行MUGA或ECHO以評估LVEF，尤其是使用較高累積劑量時。追蹤過程中，用於評估的技術應保持一致。即早在臨床上診斷出藥物所引發的心肌損傷對藥理治療發揮作用至關重要。

藥名相似:

外觀相似:

外觀描述: 橘紅色注射液，『紫』蓋透明玻璃小瓶，白底黑/桃紅字標籤

08.04C Other cytotoxic antibiotics

31202 **D / Unsafe**

BLEOCIN* FOR INJECTION 15MG 撲類惡

■■Bleomycin HCl inj 15mg pow in vial

Dosage: 1常備品 31202

Adult
· Lymphoma, Hodgkin's: IV, IM, SC, 10-20units/m(2) (0.25-0.5units/kg) once or twice weekly; MD, following a 50% response, use a maintenance dose of 1 unit once daily or 5 units once weekly
· Lymphoma, non-Hodgkin's, testicular carcinoma, squamous cell carcinoma: IV, IM, SC,10-20units/m(2) (0.25-0.5units/kg) once or twice weekly
· Malignant pleural effusions: Intrapleura injection, 60units single bolus dose dissolved in 50-100 mL NS

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 40-50 mL/min: 70%
Clcr 30-40 mL/min: 60%
Clcr 20-30 mL/min: 55%
Clcr 10-20 mL/min: 45%
Clcr 5-10 mL/min: 40%

P: Inj: 5mg Vial(31201), Inj: 15mg Vial(31202)

ADR:

COMMON
Alopecia, chills, dermal reactions (erythema, rash, striae, vesiculation, hyperpigmentation, skin tenderness), fever, mental confusion, nausea/vomiting, stomatitis
SERIOUS
Hepatic toxicity, hypotension, myelosuppression, pneumonitis, pulmonary fibrosis(in elderly population and total dose > 400 units, renal toxicity, vascular toxicity (rare; eg, MI, CVA, Raynaud's), wheezing

NOTE: 儲存2-8℃

1. IV dose in 50mL NS administered over 10-15 min
2. Test dose of 2 units prior to full dose suggested in lymphoma patients as a caution for anaphylactoid reactions
3. 1 unit = 1 mg

藥名相似:

外觀相似:

外觀描述: 透明玻璃瓶，白色乾粉，藍綠色蓋

08.04C Other cytotoxic antibiotics

31274 **demonstrated / Infant risk can**

VESIMYCIN 10 (MITOMYCIN FOR INJECTION USP 10MG) 10MG/VIAL -

■■專案癌MITOMYCIN 10MG (針劑)

Dosage: 1常備品 31274

Adult
· Carcinoma of bladder: Intravesically, 20-40 mg QW in 20-100 mL of NS or in 20-40 mL of water (off-label dosage)
· Gastric or Pancreatic cancer, disseminated adenocarcinoma, in combination with other agents: IV, 20 mg/m(2)/dose Q6-8wks

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

· CrCl <10 mL/minute: Reduce dose to 75% of usual dose
· Scr >1.7 mg/dL: Do not administer

P: P inj: 2mg(31214), 10mg(31233, 31274)

ADR:

COMMON
Loss of appetite, nausea and vomiting, blebitis, cataract, disorder of cornea, endophthalmitis, hyphema, hypotony of eye, leaking filtering bleb, retinal hemorrhage , thrombosis of retinal vein, fever
SERIOUS
Cellulitis, disseminated intravascular coagulation, myelosuppression, hemolytic uremic syndrome

NOTE: 室溫儲存

1. Administer as IV infusion in 50 Ml NS over 15mins
2. Doses in excess of 20 mg/m(2) have not been shown to be more efficacious, only increased risk for toxicity
3. No dosages should be repeated unless leukocyte count has returned to 4000/m(3) and platelet count to 100,000/m(3)
4.Vesicant: avoid extravasation

藥名相似:

外觀相似:

外觀描述: 注射乾粉，透明『綠』色蓋褐色玻璃小瓶，白底黑字標籤有紫色區塊

08.06A Vinca alkaloids and analogues

21599 **D /**

NAVELBINE 20MG, SOFT CAPSULE 溫諾平20毫克軟膠囊

■■Vinorelbine 20mg soft cap

Dosage: 1常備品 21599

Adult
· Non-small cell lung cancer, metastatic breast cancer: PO, 60mg/m2 once weekly during the first 3 doses, the dose starting with the 4th administration can be increased to 80mg/m2/wk unless the neutrophil count is below 500/mm3 or more than once between 500 and 1000/mm3. Max. 160mg/wk. With any dose of 80mg/m2, if the neutrophil count is below 500/mm3 or more than once between 500 and 1000/mm3, the administration should be postponed until the count returns to normal, and the dose should be reduced from 80 to 60mg/m2/wk.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

·mild hepatic impairment (total bilirubin < 1.5 times of upper limit of normal[ULN] and 1.5-2.5 times of ALAT and/or ASAT ULN): 60 mg/m2 weekly.
·moderate hepatic impairment (total bilirubin greater than 1.5-3 times ULN: 50mg/m2 weekly.
·severe hepatic impairment: no command.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Soft cap: 20mg(21599); Inj: 10mg/1mL Vial(31211)

ADR:

COMMON

·Dermatologic: Alopecia (grades 1 and 2, up to 35%; grades 3 and 4, 4% to 12%), Injection site reaction
·Gastrointestinal: Diarrhea, Nausea, Vomiting
·Neurologic: Asthenia, Neuromyopathy
SERIOUS
·Cardiovascular: Non-ST segment elevation myocardial infarction, acute
·Gastrointestinal: Bowel obstruction, Constipation, Pancreatitis, Paralytic ileus, Perforation of intestine
·Hematologic: Granulocytopenic disorder (Severe), Significantly greater in combination with cisplatin, Myelosuppression, Significantly greater in combination with cisplatin
·Hepatic: AST/SGOT level raised (frequent)
·Respiratory: Acute respiratory distress syndrome, Bronchospasm, Interstitial lung disease
·Other: Sepsis

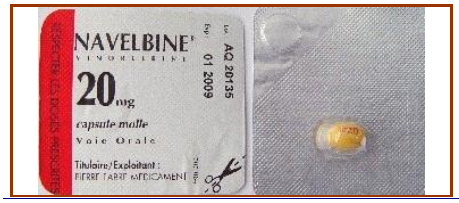
NOTE: 冰箱保存

1. Capsule must be swallowed whole during a meal
2. The liquid content in the capsule has irritant properties, in case of contact, immediately wash with water or NS
3. If vomiting occurs in the hours following ingestion of the drug, never repeat the dose
4.The bioavailability of oral form at dose of 60 and 80mg/m2 is comparable to that of doses of 25 and 30mg/m2 of IV form
5.有缺血性心臟病或體能欠佳者，建議使用本藥前須特別注意。

藥名相似:

外觀相似:

外觀描述: 每片一顆，淺棕色軟膠囊，有"N20"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024269

08.06A Vinca alkaloids and analogues

31211 **D / Unknown(有**

VINELBINE* INJECTION 維諾拜注射液

■■Vinorelbine inj 10mg/1mL vial

Dosage: 1常備品 31211

Adult
· Breast cancer: IV, 30mg/m(2)/week over 6-10 min
· Lung cancer, non-small cell: IV, 25-30mg/m(2)/week over 6-10 min single use or with cisplatin

Pediatric: NDA

Dosing adjustments in hepatic impairment:

Total bilirubin 2.1-3mg/dL: 50% of starting dose
Total bilirubin greater than 3mg/dL: 25% of starting dose

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Inj: 10mg/mL Vial(31211)

ADR:

COMMON
Alopecia, asthenia, diarrhea, nausea, vomiting, injection site reactions, neuromyopathy
SERIOUS
Acute respiratory distress syndrome, acute shortness of breath, bronchospasm, interstitial pulmonary changes, myelosuppression, severe granulocytopenia (significantly greater in combination with cisplatin), pancreatitis, constipation, paralytic ileus, intestinal obstruction, necrosis and/or perforation, sepsis, serum glutamic-oxaloacetic transaminase (SGOT) elevation (frequent)

NOTE: 冰箱冷藏，不可冷凍。

1. Vesicant: avoid extravasation
2. IV use only; fatal if given intrathecally
3.Vinorelbine should be used with caution in patients with a history of coronary heart disease
4.交互作用：
(1)"常見的交互作用"-不建議併用活性減毒疫苗；-與phenytoin併用時，腸胃對phenytoin的吸收降低，可能引起癲癇發作的危險性。或者，phenytoin導致肝代謝增加，造成細胞毒性藥物失去藥效。
(2)"長春花屬植物鹼/本藥特有的交互作用"-不建議併用Itraconazole，由於降低肝代謝而增加神經毒性。

藥名相似:

外觀相似:

外觀描述: 1mL注射液，『紫』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025489

08.06A Vinca alkaloids and analogues

31216 **D / Infant risk can**

VINCRISTINE SULPHATE INJECTION 1MG/1ML "DBL" 文克斯汀注射液 1 公絲/1 公撮

■■Vincristine sulfate inj 1mg/1mL vial

Dosage: 1常備品 31216

Adult
· Acute leukemia: 1.4mg/m(2)/wk (Max. 2mg)
· Lymphoma-Hodgkin's, non-Hodgkin's: 1.4mg/m(2)/wk (Max. 2mg)
· Rhabdomyosarcoma: 1.4mg/m(2)/wk (Max. 2mg)
(Dose limit depends on patient, physician, protocol, and institution)

Pediatric
· Over 10kg: IV, 1.5-2mg/m(2) once weekly, varies per protocol
· 10kg or less: IV, 0.05mg/kg once weekly, varies per protocol

Dosing adjustments in hepatic impairment:

A. The manufacturer recommends a 50% reduction in dose of vincristine if the direct serum bilirubin value is above 3mg/dL
B. Administer 100% of the dose if the patient's current bilirubin level is 1.5mg/dL and SGOT is less than 60 IU. Administer 50% of the dose if bilirubin is 1.5 to 3mg/dL or SGOT is 60 to 180 IU. Do not give vincristine if bilirubin is greater than 3.1mg/dL or

SGOT is greater than 180 IU

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Inj: 1mg/1mL Vial(31216)

ADR:

COMMON
Alopecia, Constipation, Nausea and vomiting.
SERIOUS
Syndrome of inappropriate antidiuretic hormone secretion, Cranial nerve disorder, Neurotoxicity, Paralysis, Seizure, Vocal cord palsy, Functional visual loss, Ototoxicity, Death, Intrathecal administration.

NOTE: 冰箱冷藏2-8℃，不可冷凍。

1.IV only, intrathecal is fatal
2.Vesicant-avoid extravasation
3.外滲可能造成嚴重局部反應，導致疼痛和蜂窩性組織炎。
4.本藥具免疫抑制效用，感染病人投與前應考量相關風險與效益。對帶狀?疹、既有或新近感染水痘(包括新近暴露)者慎用，因有引發嚴重全身性疾病的風險。
5.對接受本藥治療的病人進行疫苗接種應極度慎用。與病人有密切接觸者，特別是家人，應延後接受口服小兒麻痺疫苗接種。
6.與其他耳毒性藥品併用需極度謹慎，如含鉑抗癌藥品。

藥名相似:

外觀相似:

外觀描述: 透明溶液、『紅』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022047

08.06A Vinca alkaloids and analogues

31217 **D / Infant risk can**

VINBLASTINE SULFATE INJECTION 1MG/ML "DBL" 敏伯斯登注射液 1 公絲 / 1 公撮

■■Vinblastine sulfate 10mg/10mL vial

Dosage: 1常備品 31217

Adult
Initial, 0.1mg/kg/wk (3.7mg/m2/ wk) raised by increment of 0.05mg/kg/wk (1.8-1.9mg/m2/wk) until WBC falls to 3000/mm3 or a decrease in tumor size occurs or a Max. dose of 0.5mg/kg (18.5mg/m2) is reached;
MD, dosage with increment smaller than the final initial dose every 7-14days or 10mg 1-2 times a month

Pediatric
2.5mg/m2 infused over 1 min every wk; dose may be increased up to 12.5mg/m2 if tolerance

Dosing adjustments in hepatic impairment:

A 50% reduction in vinblastine sulfate dose is recommended for patients with a direct serum bilirubin exceeding 3 mg/dL

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Inj: 10mg/10mL Vial(31217)

ADR:

COMMON
Hypertension, Alopecia, Constipation, Bone pain, Jaw pain, Malaise.
SERIOUS
Leukopenia, Thrombocytopenia, Cerebrovascular accident, Neurotoxicity, Acute respiratory distress syndrome, Death, Intrathecal administration.

NOTE: 冰箱儲存

1.Administer no more frequently than once weekly
2.Fatal if given intrathecally. For intravenous use only. "
3.Vesicant-avoid extravasation
4.Do not inject into extremity in which circulation is impaired or potentially impaired by conditions such as compressing or invading neoplasm, phlebitis or varicosity
˙分泌於乳汁中少有資訊，有鑑於對嬰兒的風險，投與本劑期間不建議哺乳。(仿單)
˙接受此藥治療的病人應避免接種活性疫苗或減毒活疫苗。(仿單)

藥名相似:

外觀相似:

外觀描述: 10mL注射液，『褐』色膠蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021880

08.06B Podophyllotoxin Derivatives

21615 **D / Unsafe**

VEPESID CAPSULES 50MG 滅必治軟膠囊 5 0 公絲

■■Etoposide (VP-16) 50mg soft cap

Dosage: 1常備品 21615

Adult
· Small cell lung cancer: PO, twice the IV dose rounded to the nearest 50mg given once daily if total dose <400mg or in divided doses if >400mg
· Malignant neoplasms: PO, 100-200mg/m(2)/day, day 1 to 5 or 200mg/m(2)/day ,day 1, 3 ,5 ; every 3-4weeks

Pediatric
· Safety and effectiveness have not been established

Dosing adjustments in hepatic impairment:

Bilirubin< 1.5mg/dL& AST< 60 units: Normal dose
Bilirubin 1.5 - 3.0mg/dL or AST 60-180 units: 50% dose
Bilirubin> 3.1mg/dL or AST>180 units: Should be omitted

Dosing adjustments in renal impairment:

GFR 10-50mL/min: 75% of dose
GFR <10mL/min: 50% of dose

P: Cap: 50mg(21615); Inj: 100mg/5mL Vial(31223)

ADR:

COMMON
Alopecia, anorexia, diarrhea, mucositis, nausea, vomiting, asthenia, malaise, chills, fever
SERIOUS
Acute leukemia, allergic reactions, hepatotoxicity, myelosuppression (frequent; dose-limiting), Stevens-Johnson syndrome, toxic epidermal necrolysis

NOTE: 室溫儲存

1. Low serum albumin may increase risk of etoposide toxicity
2. Myelosuppression is the dose-limiting toxicity - monitor blood counts

藥名相似: Cap: 50mg(21615); Inj: 100mg/5mL Vial(3122

外觀相似:

外觀描述: 粉紅色長橢圓軟膠囊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2020882

08.06B Podophyllotoxin Derivatives

31223 **D / Unsafe**

FYTOSID FOR IV INJECTION 癌妥滅靜脈注射液 100毫克

■■Etoposide(VP-16) 100mg/5mL vial

Dosage: 1常備品 31223

Adult
· Lung cancer, small cell: IV, range, 35mg/m(2)/day for 4 days, to 50mg/m(2)/day for 5 days; in combination with other approved chemotherapeutic agents; repeat at 3-4 wk intervals
· Testicular cancer: IV, range, 50-100mg/m(2)/day days 1-5, to 100mg/m(2)/day on days 1, 3, 5; in combination with other approved chemotherapeutic agents; repeat at 3-4 wk intervals

Pediatric
· Etoposide 100mg/m(2) for 5 days (in combination with ifosfamide) was used in refractory childhood acute leukemia

Dosing adjustments in hepatic impairment:

Bilirubin< 1.5mg/dL & AST< 60 Units: Normal dose
Bilirubin 1.5-3.0mg/dL or AST 60-180 Units: 50% dose
Bilirubin> 3.1mg/dL or AST>180 Units: Should be omitted

Dosing adjustments in renal impairment:

GFR 10-50mL/min: 75% of dose
GFR <10mL/min: 50% of dose

P: Cap: 50mg(21615); Inj: 100mg/5mL Vial(31223)

ADR:

COMMON
Alopecia, anorexia, diarrhea, mucositis, nausea, vomiting, asthenia, malaise, chills, fever
SERIOUS
Anaphylactic reaction (higher risk in children at high doses), acute leukemia, allergic reaction, hepatic toxicity, myelosuppression (frequent; dose-limiting), Stevens-Johnson syndrome, toxic epidermal necrolysis

NOTE: 室溫儲存

1.Must be diluted to a final concentration of 0.2-0.4mg/ml
2.Do not administer undiluted, monitor closely for ppt
3.Administered slowly to avoid hypotension

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液『黃色』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024638

08.06C Taxanes

31235 **D / Infant risk can**

■■Tynen Injection 鈦能注射劑

■■Docetaxel inj 20mg/1mL vial

Dosage: 1常備品 31235

Adult
· Breast cancer: IV, 60-100mg/m(2) q3w
· Lung cancer, non-small cell: IV, 75mg/m(2) over 1 hour q3w
· Prostate cancer: IV, 75mg/m(2) over 1 hour q3w
· Gastric adenocarcinoma: IV, 75 mg/m2 every 3 weeks (in combination with cisplatin and fluorouracil)
· Head and neck cancer: I.V.: 75 mg/m2 every 3 weeks (in combination with cisplatin and fluorouracil) for 3 or 4 cycles, followed by radiation therapy

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Docetaxel should not be administered to patients having any of the following altered laboratory values:
- Serum bilirubin greater than the upper limit of normal
- Transaminase (SGOT, SGPT) levels greater than 1.5 times the upper limit of normal in conjunction with alkaline phosphatase levels greater than 2.5 times the upper the limit of normal

Dosing adjustments in renal impairment:

NDA

P: Inj: 20mg/1mL (31235), 80mg/4mL (31236)

ADR:

COMMON
Body fluid retention, Vasodilatation, Alopecia, Disorder of skin and/or subcutaneous tissue, Nail changes, Pruritus, Rash, Diarrhea, Inflammatory disease of mucous membrane, Nausea, Stomatitis, Vomiting, All Grades Anemia, All Grades Leukopenia, All Grades Neutropenia, Asthenia,

Neuropathy, Amenorrhea, Fever of unknown origin.
SERIOUS
acute Generalized exanthematous pustulosis, , Stevens-Johnson syndrome, Toxic epidermal necrolysis, Colitis, Grade 3 or 4 Anemia, Febrile neutropenia, Grade 3 or 4 Leukopenia, Grade 3 or 4 Neutropenia, Thrombocytopenia, Liver function tests abnormal, Anaphylaxis, Secondary malignant neoplastic disease, Renal failure, Pulmonary embolism, Infectious disease.

NOTE: 冰箱冷藏2-8℃，不可冷凍

1.Dilute to a final concentration of 0.3-0.74 mg/mL
2.Premedicate with a steroid, H1, and a H2-blocker
3.Vesicant
4.賦形劑中含96%乙醇(酒精)，肝臟損傷病人使用治療應考量。
5.嗜中性白血球低下者，有發生胃腸道併發症的風險且發病的第一天就可能會導致死亡。應於早期嚴密監測胃腸道毒性。
6.對paclitaxel產生過敏反應者，很可能也對本藥過敏，對於本藥治療初期進行監測。
7.年齡≥60歲者併用capecitabine治療，相關第3和4級不良反應會增加，且因嚴重不良反應導致早期停藥情況會增加。

藥名相似:

外觀相似:

外觀描述: 淺黃色透明色注射液，紅蓋透明玻璃小瓶，『綠』色標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1057240

08.06C Taxanes

31236 **D / Infant risk can**

▪▪Tynen Injection 鈦能注射劑

▪▪Docetaxel inj 80mg/4mL vial

Dosage: 1常備品 31236

Adult
· Breast cancer: IV, 60-100mg/m(2) q3w
· Lung cancer, non-small cell: IV, 75mg/m(2) over 1 hour q3w
· Prostate cancer: IV, 75mg/m(2) over 1 hour q3w
· Gastric adenocarcinoma: IV, 75 mg/m2 every 3 weeks (in combination with cisplatin and fluorouracil)
· Head and neck cancer: I.V.: 75 mg/m2 every 3 weeks (in combination with cisplatin and fluorouracil) for 3 or 4 cycles, followed by radiation therapy

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Docetaxel should not be administered to patients having any of the following altered laboratory values:
- Serum bilirubin greater than the upper limit of normal
- Transaminase (SGOT, SGPT) levels greater than 1.5 times the upper limit of normal in conjunction with alkaline phosphatase levels greater than 2.5 times the upper the limit of normal

Dosing adjustments in renal impairment:

NDA

P: Inj: 20mg/1mL Vial(31235), 80mg/4mL Vial(31236)

ADR:

COMMON
Body fluid retention, Vasodilatation, Alopecia, Disorder of skin and/or subcutaneous tissue, Nail changes, Pruritus, Rash, Diarrhea, Inflammatory disease of mucous membrane, Nausea, Stomatitis, Vomiting, All Grades Anemia, All Grades Leukopenia, All Grades Neutropenia, Asthenia, Neuropathy, Amenorrhea, Fever of unknown origin.
SERIOUS
Acute Generalized exanthematous pustulosis, , Stevens-Johnson syndrome, Toxic epidermal necrolysis, Colitis, Grade 3 or 4 Anemia, Febrile neutropenia, Grade 3 or 4 Leukopenia, Grade 3 or 4 Neutropenia, Thrombocytopenia, Liver function tests abnormal, Anaphylaxis, Secondary malignant neoplastic disease, Renal failure, Pulmonary embolism, Infectious disease.

NOTE: 冰箱冷藏2-8℃，不可冷凍

1.Dilute to a final concentration of 0.3-1.2mg/mL
2.Premedicate with a steroid, H1, and a H2-blocker
3.Vesicant
4.賦形劑中含96%乙醇(酒精)，肝臟損傷病人使用治療應考量。
5.嗜中性白血球低下者，有發生胃腸道併發症的風險且發病的第一天就可能會導致死亡。應於早期嚴密監測胃腸道毒性。
6.對paclitaxel產生過敏反應者，很可能也對本藥過敏，對於本藥治療初期進行監測。
7.年齡≥60歲者併用capecitabine治療，相關第3和4級不良反應會增加，且因嚴重不良反應導致早期停藥情況會增加。

藥名相似:

外觀相似:

外觀描述: 淺黃色透明色注射液，紅蓋透明玻璃小瓶，『紫』色標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1057240

08.06C Taxanes

31262 **D / Unsafe**

PHYXOL INJECTION 6MG/ML "SINPHAR" "杏輝" 輝克癒蘇注射劑 6 毫克/毫升

▪▪Paclitaxel inj 30mg/5mL vial

Dosage: 1常備品 31262

Adult
· Advanced ovarian cancer: IV, 135-175mg/m(2) over 3 to 24 hrs q3 weeks
· Metastatic breast cancer: IV, 175mg/m(2) over 3 hrs q3 weeks

· Non-small cell lung cancer: IV, 135mg/m(2) over 24 hrs q3 weeks
· AIDS-related Kaposi's sarcoma: IV, 135mg/m(2) over 3 hrs q3 weeks OR 100mg/m(2) over 3 hrs q2 weeks

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Transaminase Levels	Bilirubin Levels	Recommended Paclitaxel Dose
24 HOUR INFUSION		
< 2X ULN	AND <= 1.5 mg/dL	135mg/m(2)
2-<10X ULN	AND <= 1.5 mg/dL	100mg/m(2)
< 10X ULN	AND 1.6- 7.5 mg/dL	50 mg/m(2)
>=10X ULN	OR >7.5 mg/dL	Avoid use
3 HOUR INFUSION		
< 10X ULN	AND <= 1.25 X ULN	175mg/m(2)
< 10X ULN	AND 1.26-2X ULN	135mg/m(2)
< 10X ULN	AND 2.01-5X ULN	90 mg/m(2)
>= 10X ULN	OR >5X ULN	Avoid use

ULN= upper limit of normal; m(2)= square meter

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Inj: 60mg/10mL Vial(31254),30mg/5mL Vial(31262)(31240,自費)

ADR:

NOTE: 室溫儲存

1.Dilute to a final concentration of 0.3-1.2 mg/mL; administer through 0.22 micron filter and polyethylene-lined sets
2.Premedicate with a steroid, H1, and a H2-blocker

藥名相似:

外觀相似:

外觀描述: 5mL注射液，『藍』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044466

08.06C Taxanes

31278 **D / Unsafe**

ABRAXANE* for Injectable Suspension 亞伯杉注射劑

■■急用Nab-paclitaxel inj 100mg vial

Dosage: 2急用藥 31278

Adult
· Metastatic pancreatic cancer in combination with gemcitabine: IV over 30 to 40 min, 125 mg/m(2) on days 1, 8, and 15 of each 28-day cycle; followed immediately by gemcitabine 1000 mg/m(2) ; continued until disease progression or unacceptable toxicity.
· Metastatic breast cancer: IV over 30min, 260mg/m(2) q3weeks.
· Metastatic non-small cell lung cancer in combination with carboplatin: IV over 30min, 100 mg/m(2) on days 1, 8, and 15 of each 21-day cycle; carboplatin dosed to an AUC 6 mg x min/mL on day 1 only of each 21-day cycle beginning immediately after completion of paclitaxel; continue until disease progression or unacceptable toxicity.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

·Hepatic impairment with bilirubin levels> 5xULN or AST>10xULN: Use not recommended regardless of indication.
·(Adenoma of pancreas) hepatic impairment:
--Mild (bilirubin< or equal to 1.5xULN and AST <10xULN): No dose adjustment required
--Moderate or severe (bilirubin >1.5 up to 5 xULN and AST <10xULN): Use not recommended.
·(Non-small cell lung cancer) hepatic impairment:
--Moderate to severe (bilirubin >1.5 up to 5xULN and AST<10xULN): Decrease initial dose to 80mg/m(2); may increase subsequent doses to 100 mg/m(2) if 2 cycles at the reduced dose are tolerated.
·(Breast cancer) hepatic impairment:
--Moderate to severe (bilirubin>1.5 up to 5xULN and AST <10xULN): Decrease initial dose to 200 mg/m(2); may increase subsequent doses to 260 mg/m(2) if 2 cycles at the reduced dose are tolerated.

Dosing adjustments in renal impairment:

Clcr 30-90 mL/min: No dose adjustment required.
CrCl <30 mL/min: Use has not been studied

P: Inj: 100mg/20mLvial(31278)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 『藍』蓋透明玻璃小瓶

08.06C Taxanes

31287 **D / Infant risk can**

Taxotere 20mg/ml Concentrate for solution for infusion 剋癌易20毫克/毫升單支注射液

■■Docetaxel inj 20mg/1mL vial

Dosage: 1常備品 31287

Adult
· Breast cancer: IV, 60-100mg/m(2) q3w
· Lung cancer, non-small cell: IV, 75mg/m(2) over 1 hour q3w
· Prostate cancer: IV, 75mg/m(2) over 1 hour q3w
· Gastric adenocarcinoma: IV, 75 mg/m2 every 3 weeks (in combination with cisplatin and fluorouracil)
· Head and neck cancer: I.V.: 75 mg/m2 every 3 weeks (in combination with cisplatin and fluorouracil) for 3 or 4 cycles, followed by radiation therapy

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Docetaxel should not be administered to patients having any of the following altered laboratory values:
- Serum bilirubin greater than the upper limit of normal
- Transaminase (SGOT, SGPT) levels greater than 1.5 times the upper limit of normal in conjunction with alkaline phosphatase levels greater than 2.5 times the upper the limit of normal

Dosing adjustments in renal impairment:

NDA

P: Inj: 20mg/1mL (31235), 80mg/4mL (31236)

ADR:

COMMON
Body fluid retention, Vasodilatation, Alopecia, Disorder of skin and/or subcutaneous tissue, Nail changes, Pruritus, Rash, Diarrhea, Inflammatory disease of mucous membrane, Nausea, Stomatitis, Vomiting, All Grades Anemia, All Grades Leukopenia, All Grades Neutropenia, Asthenia, Neuropathy, Amenorrhea, Fever of unknown origin.
SERIOUS
acute Generalized exanthematous pustulosis, , Stevens-Johnson syndrome, Toxic epidermal necrolysis, Colitis, Grade 3 or 4 Anemia, Febrile neutropenia, Grade 3 or 4 Leukopenia, Grade 3 or 4 Neutropenia, Thrombocytopenia, Liver function tests abnormal, Anaphylaxis, Secondary malignant neoplastic disease, Renal failure, Pulmonary embolism, Infectious disease.

NOTE: 2-25度

1.Dilute to a final concentration of 0.3-0.74 mg/mL
2.Premedicate with a steroid, H1, and a H2-blocker
3.Vesicant
4.賦形劑中含96%乙醇(酒精)，肝臟損傷病人使用治療應考量。
5.嗜中性白血球低下者，有發生胃腸道併發症的風險且發病的第一天就可能會導致死亡。應於早期嚴密監測胃腸道毒性。
6.對paclitaxel產生過敏反應者，很可能也對本藥過敏，對於本藥治療初期進行監測。
7.年齡≥60歲者併用capecitabine治療，相關第3和4級不良反應會增加，且因嚴重不良反應導致早期停藥情況會增加。

藥名相似:

外觀相似:

外觀描述: 淺黃色透明色注射液，『綠』蓋透明玻璃小瓶

08.06C Taxanes

31288 **D / Infant risk can**

Taxotere 20mg/ml Concentrate for solution for infusion 剋癌易20毫克/毫升單支注射液

■■Docetaxel 80mg/4mL vial

Dosage: 1常備品 31288

Adult
· Breast cancer: IV, 60-100mg/m(2) q3w
· Lung cancer, non-small cell: IV, 75mg/m(2) over 1 hour q3w
· Prostate cancer: IV, 75mg/m(2) over 1 hour q3w
· Gastric adenocarcinoma: IV, 75 mg/m2 every 3 weeks (in combination with cisplatin and fluorouracil)
· Head and neck cancer: I.V.: 75 mg/m2 every 3 weeks (in combination with cisplatin and fluorouracil) for 3 or 4 cycles, followed by radiation therapy

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Docetaxel should not be administered to patients having any of the following altered laboratory values:
- Serum bilirubin greater than the upper limit of normal
- Transaminase (SGOT, SGPT) levels greater than 1.5 times the upper limit of normal in conjunction with alkaline phosphatase levels greater than 2.5 times the upper the limit of normal

Dosing adjustments in renal impairment:

NDA

P: Inj: 20mg/1mL Vial(31235), 80mg/4mL Vial(31236)

ADR:

COMMON
Body fluid retention, Vasodilatation, Alopecia, Disorder of skin and/or subcutaneous tissue, Nail changes, Pruritus, Rash, Diarrhea, Inflammatory

disease of mucous membrane, Nausea, Stomatitis, Vomiting, All Grades Anemia, All Grades Leukopenia, All Grades Neutropenia, Asthenia, Neuropathy, Amenorrhea, Fever of unknown origin.
SERIOUS
Aacute Generalized exanthematous pustulosis, , Stevens-Johnson syndrome, Toxic epidermal necrolysis, Colitis, Grade 3 or 4 Anemia, Febrile neutropenia, Grade 3 or 4 Leukopenia, Grade 3 or 4 Neutropenia, Thrombocytopenia, Liver function tests abnormal, Anaphylaxis, Secondary malignant neoplastic disease, Renal failure, Pulmonary embolism, Infectious disease.

NOTE: 2-25度

1.Dilute to a final concentration of 0.3-1.2mg/mL
2.Premedicate with a steroid, H1, and a H2-blocker
3.Vesicant
4.賦形劑中含96%乙醇(酒精)，肝臟損傷病人使用治療應考量。
5.嗜中性白血球低下者，有發生胃腸道併發症的風險且發病的第一天就可能會導致死亡。應於早期嚴密監測胃腸道毒性。
6.對paclitaxel產生過敏反應者，很可能也對本藥過敏，對於本藥治療初期進行監測。
7.年齡≥60歲者併用capecitabine治療，相關第3和4級不良反應會增加，且因嚴重不良反應導致早期停藥情況會增加。

藥名相似:

外觀相似:

外觀描述: 淺黃色透明色注射液，『紅』蓋透明玻璃小瓶

08.08A Folic acid analogues

21607 X / Unsafe

METHOTREXATE SODIUM TABLETS 2.5MG 滅殺除癌錠 2．5 毫克

■■Methotrexate sodium 2.5mg tab

Dosage: 1常備品 21607

Adult
· Trophoblastic neoplasm: PO, 15-30mg/day for 5 days; repeat in one or more weeks for 3-5 courses
· Leukemia (maintenance): PO, 30mg/m(2)/week administered in 2 divided doses
· Lymphoma: PO, 10-25mg/day for 4-8day with 7-10 days rest intervals
· Psoriasis: PO, 2.5-5mg q12h for 3 doses each wk up to 25-30mg/wk; weekly single dose, 10-25mg/dose once weekly
· Rheumatoid arthitis: PO, 2.5mg q12h for 3 doses each week or 7.5mg once/wk, should not exceed 20mg/wk

Pediatric
· Juvenile rheumatoid arthritis: PO, 10mg/m(2) once weekly
· Leukemia-acute lymphoblastic (maintenance): PO, 20mg/m(2) weekly
· Lymphoma-non-Hodgkin's: PO, 10mg/m(2) once weekly

Dosing adjustments in hepatic impairment:

Bilirubin< 3mg/dL & AST< 180 Units: Normal dose
Bilirubin 3.1-5.0mg/dL or AST>180 Units: 75% of the normal dose
Bilirubin> 5.0mg/dL: Should be omitted

Dosing adjustments in renal impairment:

GFR>50mL/min: No dosage adjustment
GFR 10-50mL/min: 50% of the normal dose
GFR<10mL/min: Should be avoided

P:

ADR:

COMMON
Alopecia, photosensitivity, rash, anorexia, diarrhea, N/V, stomatitis
SERIOUS
Arachnoiditis (with intrathecal administration) cirrhosis, elevated liver function test, hepatic fibrosis atrophy, necrosis, gastrointestinal bleeding, mucositis, ulceration, hyperuricemia, nephropathy, renal failure
interstitial pneumonitis, myelosuppression

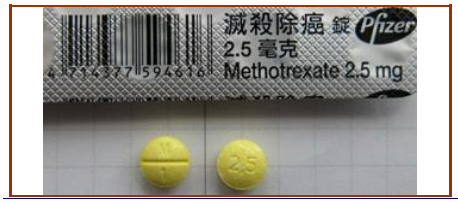
NOTE: 室溫儲存

1.Oral, given 1-2hrs before or 2-3hrs after meals
2.Leucovorin may be employed as antidote
3.Alcohol increases risk of hepatotoxicity

藥名相似:

外觀相似:

外觀描述: 黃色圓扁錠,有M 1及2.5字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022726

08.08A Folic acid analogues

31213 X / Unsafe

METHOTREXATE INJECTION "DBL" 盈壽求得注射液

■■Methotrexate (MTX)inj 50mg/2mL vial

Dosage: 1常備品 31213

Adult
· Trophoblastic neoplasm: IV, IM, 15-30mg/day for 5days; repeat in one or more weeks for 3-5 courses
· Acute lymphoid leukemia (maintenance): IM, 30mg/m(2)/week administered in 2 divided doses; 2.5mg/kg IV every 14 days has also been used
· Psoriasis: IM, IV, 10-25mg/dose once weekly
· Breast cancer: IV, 40mg/m(2) as adjuvant in combination with other antineoplastic agents (eg cyclophosphamide, fluorouracil, vincristine, prednisone) on days 1 and 8 every 28 days; or on day 1 of a 21 days cycle
· Head and neck cancer: IV, doses vary widely from 15-30mg/day to 12-15g/m(2)/dose IV over 4 hours
· Osteosarcoma: IV, initial 12g/m(2), if a peak serum methotrexate concentration of 1,000 micromolar is not obtained the dose can be

increased to 15g/m(2); use in combination with other chemotherapy agents, Clcr must >60 ml/min before beginning therapy

Pediatric
· Leukemia, acute lymphoblastic (induction): IV, 3.3mg/m(2)/day in combination with corticosteroid therapy for 4-6 weeks
· Leukemia, acute lymphoblastic (maintenance): IM, 30mg/m(2)/week administered in 2 divided doses; 2.5mg/kg IV every 14 days has also been used
· Leukemia, meningeal: IT, 6mg if less than 1yr old; 8mg if 1yr old; 10mg if 2yr old; 12mg for 3yrs and older

Dosing adjustments in hepatic impairment:

Bilirubin< 3mg/dL & AST< 180 Units: Normal dose
Bilirubin 3.1-5.0mg/dL or AST>180 Units: 75% of the normal dose
Bilirubin> 5.0mg/dL: Should be omitted

Dosing adjustments in renal impairment:

GFR 10-50mL/min: 50% of the normal dose
GFR<10mL/min: Should be avoided

P: Tab: 2.5mg(21607); Inj: 1g/40mL Vial(31221); Inj: 50mg/2mL Vial(31213)

ADR:

COMMON
·Dermatologic: Alopecia (0.5% to 3%), Photosensitivity, Rash
·Gastrointestinal: Diarrhea (1% to 3%), Nausea and vomiting (greater than 10%)
·Hematologic: Leukopenia (1% to 3%), Thrombocytopenia (3% to 10%)
·Neurologic: Dizziness (1% to 3%)
SERIOUS
Cardiovascular: Pericardial effusion, Thromboembolic disorder
·Dermatologic: Toxic epidermal necrolysis
·Gastrointestinal: Gastrointestinal hemorrhage, Stomatitis (2% to 10%)
·Hematologic: Aplastic anemia, Malignant lymphoma, Myelosuppression, Pancytopenia (1% to 3%)
·Hepatic: Cirrhosis of liver (0.1%), Hepatic fibrosis (7%), Hepatitis, Hepatotoxicity, Liver failure
·Neurologic: Encephalopathy, Neurotoxicity, Seizure
·Renal: Nephrotoxicity
·Respiratory: Interstitial pneumonia (Infrequent (0.1%-1.2%) .)
·Other: Infectious disease, Tumor lysis syndrome

NOTE: 儲存25℃以下

1. High-dose methotrexate therapy will generally require the use of leukovorin rescue
2.慢性毒性可能致命；一般發生於長期使用（一般兩年或以上）後，以及總累積劑量至少1.5 克後。[HOSPIRA廠仿單版本：HSP Australia 20140909-2]
3.一般而言，疑似發生藥物過量時，
(1)使用 calcium folinate 劑量相等於或高於 methotrexate 施用劑量，且儘速給予，可於第一小時內使用，隨後使用將大幅降低療效。在12 小時內IV 輸注最高為calcium folinate 75 mg ，隨後每 6 小時 IM 12 mg，共給予 4 個劑量。當 methotrexate 平均劑量會引起不良反應時，可每 6 小時 IM calcium folinate 6~12 mg，共給予 4 個劑量。
(2)合併補充水分，並以 sodium bicarbonate 使尿液鹼性化，以避免此藥或其代謝物沉澱於腎小管中。應建議接受 methotrexate 治療的病患補充液體。[HOSPIRA廠仿單版本：HSP Australia 20140909-2]
4.仿單警語：[HOSPIRA廠仿單版本：HSP Australia 20140909-2]
·使用 methotrexate 曾被通報死亡病例。用於治療牛皮癬與類風濕性關節炎時，methotrexate 僅限使用於對其他治療形式反應不佳之重度、難治、致使失能疾病，並且僅可使用於依據切片及 / 或經由諮詢後確診者。
·高劑量或長期使用時具肝毒性，務必在展開治療前確定肝功能，並於治療期間進行定期監測。使用於肝臟損傷或肝功能不全時應格外謹慎。應避免併用可能具有肝毒性的其他藥物與飲酒。
·治療期間與停止治療後至少 3 個月內任一方伴侶便應避免懷孕。
·高劑量併用非類固醇消炎藥（NSAID）時曾通報發生嚴重不良事件，包括骨髓抑制、再生不良性貧血、胃腸道毒性與死亡。
·併用放療可能會增加軟組織壞死與骨壞死的風險。

藥名相似:

外觀相似:

外觀描述: 2mL黃色注射液，『藍』蓋玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021696

08.08A Folic acid analogues

31267 **X / Unsafe**

Methotrexat "Ebewe" "益伯偉" 每索特靜脈注射液１００毫克/毫升

■■Methotrexate(MTX) inj 500mg/5mL vial

Dosage: 1常備品 31267

Adult
· Trophoblastic neoplasm: IV, IM, 15-30mg/day for 5days; repeat in one or more weeks for 3-5 courses
· Acute lymphoid leukemia (maintenance): IM, 30mg/m(2)/week administered in 2 divided doses; 2.5mg/kg IV every 14 days has also been used
· Psoriasis: IM, IV, 10-25mg/dose once weekly
· Breast cancer: IV, 40mg/m(2) as adjuvant in combination with other antineoplastic agents (eg cyclophosphamide, fluorouracil, vincristine, prednisone) on days 1 and 8 every 28 days; or on day 1 of a 21 days cycle
· Head and neck cancer: IV, doses vary widely from 15-30mg/day to 12-15g/m(2)/dose IV over 4 hours
· Osteosarcoma: IV, initial 12g/m(2), if a peak serum methotrexate concentration of 1,000 micromolar is not obtained the dose can be increased to 15g/m(2); use in combination with other chemotherapy agents, Clcr must >60 ml/min before beginning therapy

Pediatric
· Leukemia, acute lymphoblastic (induction): IV, 3.3mg/m(2)/day in combination with corticosteroid therapy for 4-6 weeks
· Leukemia, acute lymphoblastic (maintenance): IM, 30mg/m(2)/week administered in 2 divided doses; 2.5mg/kg IV every 14 days has also been used

· Leukemia, meningeal: IT, 6mg if less than 1yr old; 8mg if 1yr old; 10mg if 2yr old; 12mg for 3yrs and older

Dosing adjustments in hepatic impairment:

Bilirubin< 3mg/dL & AST< 180 Units: Normal dose
Bilirubin 3.1-5.0mg/dL or AST>180 Units: 75% of the normal dose
Bilirubin> 5.0mg/dL: Should be omitted

Dosing adjustments in renal impairment:

GFR 10-50mL/min: 50% of the normal dose
GFR<10mL/min: Should be avoided

P: Tab: 2.5mg(21607); Inj:1g/10mL Vial(31220); Inj:1g/40mL Vial(31221); Inj: 50mg/2mL Vial(31213)

ADR:

COMMON
·Dermatologic: Alopecia (0.5% to 3%), Photosensitivity, Rash
·Gastrointestinal: Diarrhea (1% to 3%), Nausea and vomiting (greater than 10%)
·Hematologic: Leukopenia (1% to 3%), Thrombocytopenia (3% to 10%)
·Neurologic: Dizziness (1% to 3%)
SERIOUS
Cardiovascular: Pericardial effusion, Thromboembolic disorder
·Dermatologic: Toxic epidermal necrolysis
·Gastrointestinal: Gastrointestinal hemorrhage, Stomatitis (2% to 10%)
·Hematologic: Aplastic anemia, Malignant lymphoma, Myelosuppression, Pancytopenia (1% to 3%)
·Hepatic: Cirrhosis of liver (0.1%), Hepatic fibrosis (7%), Hepatitis, Hepatotoxicity, Liver failure
·Neurologic: Encephalopathy, Neurotoxicity, Seizure
·Renal: Nephrotoxicity
·Respiratory: Interstitial pneumonia (Infrequent (0.1%-1.2%) .)
·Other: Infectious disease, Tumor lysis syndrome

NOTE: 避光儲存25℃以下

·《Contraindications》Breastfeeding; Known hypersensitivity to methotrexate or history of severe hypersensitivity reactions, including anaphylaxis; Male patient, sexually active; avoid impregnating woman during and for a minimum of 3 months after therapy; Patients with psoriasis or rheumatoid arthritis with alcoholism, alcoholic liver disease, or other chronic liver disease; Patients with psoriasis or rheumatoid arthritis who have preexisting blood dyscrasias (such as bone marrow hypoplasia, leukopenia, thrombocytopenia, or significant anemia); Patients with psoriasis or rheumatoid arthritis with overt or laboratory evidence of immunodeficiency syndromes; Pregnant women with psoriasis or rheumatoid arthritis(ie, non-neoplastic diseases) ;
·High-dose methotrexate therapy will generally require the use of leukovorin rescue
·慢性毒性可能致命；一般發生於長期使用 (一般兩年或以上) 後，以及總累積劑量至少1.5 克後。[HOSPIRA廠仿單版本：HSP Australia 20140909-2]
·一般而言，疑似發生藥物過量時，
(1)使用 calcium folinate 劑量相等於或高於 methotrexate 施用劑量，且儘速給予，可於第一小時內使用，隨後使用將大幅降低療效。在12 小時內IV 輸注最高為calcium folinate 75 mg ，隨後每 6 小時 IM 12 mg，共給予 4 個劑量。當 methotrexate 平均劑量會引起不良反應時，可每 6 小時 IM calcium folinate 6~12 mg，共給予 4 個劑量。
(2)合併補充水分，並以 sodium bicarbonate 使尿液鹼性化，以避免此藥或其代謝物沉澱於腎小管中。應建議接受 methotrexate 治療的病患補充液體。[HOSPIRA廠仿單版本：HSP Australia 20140909-2]

藥名相似:

外觀相似:

外觀描述: 5mL黃色注射液，透明玻璃瓶，橘蓋

08.08A Folic acid analogues

37623 **D / Caution**

FOLOTYN (pralatrexate injection) Solution for intravenous injection 服瘤停注射劑

■■急用Pralatrexate inj 20mg/1mL vial

Dosage: 2急用藥 37623

Adult:
· Relapsed or refractory peripheral Tcell lymphoma (PTCL): Slow IV (over 3-5 min), 30 mg/m(2) qw for 6 wks in 7-wk cycles, via a side port of a free flowing NS line

Pediatric
· Safety and efficacy not established in pediatric patients

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

eGFR ≧30 mL/min/1.73 m(2): No dosage adjustment needed
eGFR 15-30 mL/min/1.73 m(2): Initial, 15 mg/m(2). Recovery from toxicity, reinitiate therapy at 10 mg/m(2) for mucositis grade 2 recurrence or any grade 3 event; for platelets less than 50,000/mcL for 2 weeks; for recurrence or 2 weeks of absolute neutrophil count (ANC) 500 to 1000/mcL with fever or ANC less than 500/mcL; for any other grade 3 toxicity. Otherwise, if continuing therapy, may continue at prior dose.
ESRD, including dialysis: Avoid use

P: P Inj: 20mg/1mL Vial(37623)

ADR:

COMMON
Edema, constipation, inflammatory disease of mucous membrane, nausea, anemia, neutropenia, thrombocytopenia, cough, fatigue
SERIOUS
Severe disorder of skin, peeling of skin, skin ulcer, toxic epidermal necrolysis, inflammatory disease of mucous membrane (grade 3/4), anemia, febrile neutropenia, neutropenia (grade 3/4), pancytopenia, thrombocytopenia (grade 3/4),

sepsis, dyspnea, dehydration, fever

NOTE: 冰箱冷藏，不可冷凍

NOTE

· All patients should receive vitamin supplementation with folic acid 1 mg to 1.25 mg orally daily (10 days prior to treatment, during, and for 30 days after treatment); and vitamin B12 1000 mcg IM (no more than 10 wks prior to treatment and then every 8 to 10 wks thereafter)

藥名相似:

外觀相似:

外觀描述:

08.08A Folic acid analogues

37711 **D / Caution**

FOLOTYN (pralatrexate injection) Solution for intravenous injection 服瘤停注射劑

■■捐贈急用Pralatrexate 20mg/1mL vial

Dosage: 2急用藥 37711

Adult:

· Relapsed or refractory peripheral Tcell lymphoma (PTCL): Slow IV (over 3-5 min), 30 mg/m(2) qw for 6 wks in 7-wk cycles, via a side port of a free flowing NS line

Pediatric

· Safety and efficacy not established in pediatric patients

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

eGFR ≧30 mL/min/1.73 m(2): : No dosage adjustment needed
eGFR 15-30 mL/min/1.73 m(2): Initial, 15 mg/m(2)
ESRD, including dialysis: Avoid use

P: P Inj: 20mg/1mL Vial(37623)

ADR:

COMMON
Edema, constipation, inflammatory disease of mucous membrane, nausea, anemia, neutropenia, thrombocytopenia, cough, fatigue
SERIOUS
Severe disorder of skin, peeling of skin, skin ulcer, toxic epidermal necrolysis, inflammatory disease of mucous membrane (grade 3/4), anemia, febrile neutropenia, neutropenia (grade 3/4), pancytopenia, thrombocytopenia (grade 3/4), sepsis, dyspnea, dehydration, fever

NOTE: 冰箱冷藏，不可冷凍。

NOTE

· All patients should receive vitamin supplementation with folic acid 1 mg to 1.25 mg orally daily (10 days prior to treatment, during, and for 30 days after treatment); and vitamin B12 1000 mcg IM (no more than 10 wks prior to treatment and then every 8 to 10 wks thereafter)

藥名相似:

外觀相似:

外觀描述:

08.08A Folic acid analogues

37733 **D / Unsafe**

Alimta for Injection 100mg 愛寧達注射劑 100 毫克

■■Pemetrexed 100mg pow in vial

Dosage: 1常備品 37733

Adult

· Malignant mesothelioma of pleura, for patients who are not candidates for surgical resection: IV, 500mg/m2 on day 1, followed 30 mins later by cisplatin 75mg/m2 infused IV over 2 hrs; repeat cycle every 21 days

· Non-small cell lung cancer, patients with locally advanced or metastatic disease after prior chemotherapy: IV, 500mg/m2 on day 1 of each 21-day cycle

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr<45mL/min: Should be avoided

P: Inj: 500mg Vial(37866), 100mg Vial(37733)

ADR:

COMMON
Itching, peeling of skin, constipation, diarrhea, loss of appetite, nausea, pharyngitis, stomatitis, vomiting, anemia, leukopenia, neutropenia, thrombocytopenia, fatigue
SERIOUS
Radiation recall syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis, anemia (grade3/4), febrile neutropenia, leukopenia (grade3/4), neutropenia (grade3/4), thrombocytopenia (grade3/4), sensory neuropathy (grade3/4), renal failure, acute lung injury, interstitial pneumonia

NOTE: 室溫儲存

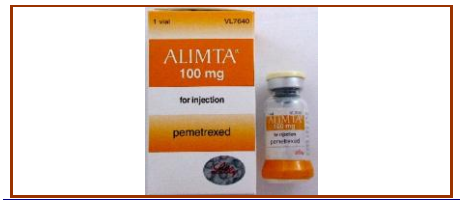
· Administer intravenously over 10 minutes.
· Patients receiving aspirin or other NSAIDs should interrupt dosing for at least 5 days prior, the day of, and 2 days after pemetrexed therapy; if concomitant therapy is necessary, close monitoring for myelosuppression, GI and renal toxicities are recommended.
· All patients should receive premedication/vitamine: dexamethasone 4 mg

orally twice daily for 3 days (before, during, after); folic acid or multivitamine with folic acid 350-1000 mcg orally daily; vitamine B12 1000 mcg IM every 3 cycles

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『米白』蓋透明玻璃小瓶



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024874

08.08A Folic acid analogues

37866 D /

ALIMTA (PEMETREXED FOR INJECTION) 500MG 愛寧達注射劑

■■Pemetrexed 500mg pow in vial

Dosage: 1常備品 37866

Adult

· Malignant mesothelioma of pleura, for patients who are not candidates for surgical resection: IV, 500mg/m2 on day 1, followed 30 mins later by cisplatin 75mg/m2 infused IV over 2 hrs; repeat cycle every 21 days

· Advanced or metastatic non-small cell lung cancer: IV, 500mg/m2 on day 1 of each 21-day cycle

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr<45mL/min: Should be avoided

P: nj: 500mg Vial(37866), 100mg Vial(37733)

ADR:

COMMON

Itching, peeling of skin, constipation, diarrhea, loss of appetite, nausea, pharyngitis, stomatitis, vomiting, anemia, leukopenia, neutropenia, thrombocytopenia, fatigue

SERIOUS

Radiation recall syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis, anemia (grade3/4), febrile neutropenia, leukopenia (grade3/4), neutropenia (grade3/4), thrombocytopenia (grade3/4), sensory neuropathy (grade3/4), renal failure, acute lung injury, interstitial pneumonia

NOTE: 室溫儲存

· Administer intravenously over 10 minutes.

· Patients receiving aspirin or other NSAIDs should interrupt dosing for at least 5 days prior, the day of, and 2 days after pemetrexed therapy; if concomitant therapy is necessary, close monitoring for myelosuppression, GI and renal toxicities are recommended.

· All patients should receive premedication/vitamine: dexamethasone 4 mg orally twice daily for 3 days (before, during, after); folic acid or multivitamine with folic acid 350-1000 mcg orally daily; vitamine B12 1000 mcg IM every 3 cycles

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『米白』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024084

08.08B Purine Analogues

37822 D /

FLUDARA LYOPHILIZED IV INJECTION 福達樂靜脈凍晶注射劑

■■急用Fludarabine 50mg pow in vial

Dosage: 2急用藥 37822

Adult

· Chronic lymphocytic leukemia: IV over 30 min, 25mg/m(2) daily for 5 days, repeat every 28 days

· Acute myeloid leukemia: 25 mg/m(2)/day IV days 1-5 has been used in combination with cytarabine and granulocyte colony stimulating factor (FLAG regimen)

Pediatric

· Acute myeloid leukemia: 25 mg/m(2)/day IV days 2-6 has been used in combination with cytarabine and granulocyte colony stimulating factor (FLAG regimen)

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr<30mL/min: Use not recommended
Clcr 30-70mL/min: dose should be reduced by 20%

P: Inj: 50mg Vial(37822)

ADR:

COMMON

Anorexia, nausea, vomiting, fatigue, weakness, chills, malaise

SERIOUS

Aplasia (rare), autoimmune hemolytic, anemia, edema, fever, infection myelosuppression, neurotoxicity, pneumonia, transfusion-associated graft-versus-host disease (rare)

NOTE: 室溫保存

Predisposition to increased toxicity with advanced age, renal insufficiency, bone marrow impairment

藥名相似:

外觀相似:

外觀描述: 白色乾粉，綠蓋玻璃小瓶

08.08B Purine Analogues

37970 D / Unsafe

Evoltra concentrate for solution for infusion 宜保安濃縮輸注液1毫克/毫升

■■急用Clofarabine 20mg/20mL vial

Dosage: 2急用藥 37970

Adult(≦ 21yrs)
·Relapsed or refractory acute lymphoid leukemia: IV infusion over 2 hours, 52mg/m(2) qd for 5 days; repeat every 2 to 6 weeks.

Pediatric (≧1yr)
·Relapsed or refractory acute lymphoid leukemia: Same as adult

Dosing adjustments in hepatic impairment:

Mild to moderate renal impairmant: Use with caution
Severe renal impairment: Use is contraindicated

Dosing adjustments in renal impairment:

Mild to moderate hepatic impairmant: Use with caution
Severe hepatic impairment: Use is contraindicated

P: Inj: 20mg/20mL Vial(37970)(37972, 捐贈用藥)

ADR:

COMMON
Hypotension, tachycardia, erythema, flushing, petechiae, pruritus, rash, abdominal pain, diarrhea, loss of appetite, nausea, upper abdominal pain, vomiting, anemia, lymphocytopenia (grade 3 or higher), thrombocytopenia, ALT/SGPT level raised, AST/SGOT level raised, serum bilirubin raised, infection of bladder catheter, pain in limb, headache, anxiety, serum creatinine raised, epistaxis, pleural effusion, fatigue, rigor
SERIOUS
Stevens-Johnson syndrome, toxic epidermal necrolysis, anemia (grade 3 or higher), febrile neutropenia, leukopenia (grade 3 or higher), neutropenia (grade 3 or higher), pancytopenia, thrombocytopenia (grade 3 or higher), veno-occlusive disease of the liver, infectious disease, sepsis, septic shock, cerebrovascular accident, acute renal failure (grade3/4), capillary leak syndrome, systemic inflammatory response syndrome, tumor lysis syndrome

NOTE: 室溫儲存

·Each vial contains 3.08mmol(70.77mg) of sodium.
·A longer infusion time should be considered in children weighing < 20kg to reduce anxiety and irritability and to avoid high clofarabine concentrations.
·Hydration should be maintained during treatment to minimise the risk of tumour lysis syndrome and other adverse effects.
·Avoid concomitant use nephrotoxic drugs or hepatotoxic drugs during the 5 days of administration.

藥名相似:

外觀相似:

外觀描述: 20mL注射液，藍蓋玻璃小瓶

08.08C Pyrimidine Analogues

21610 demonstrated / Infant risk has

UFUR CAPSULE 友復 膠囊

■■Tegafur 100mg, Uracil 224mg cap

Dosage: 1常備品 21610

Adult
PO, based on tegafur, 300-350mg/m2/day div. into 2-3 doses

Pediatric
NDA

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: Tegafur 100mg & Uracil 224mg (1:4)(21610)

ADR:

Leukopenia, thrombocytopenia, myelosuppression, hypotension with flushing, dizziness, speech difficulties, confusion, ataxia, visual changes, headache, sedation, lethargy, N/V, stomatitis, diarrhea, abnormal liver function tests, metallic taste, chronic active hepatitis

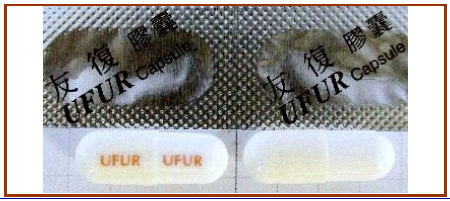
NOTE: 室溫儲存

1.CNS toxicity of TEGAFUR has been associated with plasma concentrations exceeding 50 mcg/mL
2. Pregnancy risk categories of Uracil:【D】

藥名相似:

外觀相似: 外盒：Folina* 15mg Tab (25203)

外觀描述: 白色膠囊，有UFUR字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043698

08.08C Pyrimidine Analogues

21613 D /

XELODA TABLETS 500MG 截瘤達錠 5 0 0 毫克

■■Capecitabine 500mg tab

Dosage: 1常備品 21613

Adult
· Metastatic breast cancer, colorectal cancer: PO, 2500mg/m2/day in 2 div. doses for 2wk followed by 1-wk rest as 3-wk cycles
· Gastric cancer: 2500 mg/m(2)/day in 2 div. doses for 14 days plus cisplatin 60 mg/m(2) on D1, repeated every 3 weeks

Pediatric
Safety and effectiveness have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 51-80mL/min: No dosage adjustment needed
Clcr 30-50mL/min: 75% of the capecitabine starting dose.
Clcr<30mL/min: Capecitabine should not be administered to patients

P: Tab: 500mg(21613)

ADR:

COMMON
Abdominal pain, anorexia, constipation, N/V, stomatitis, dermatitis, fatigue
SERIOUS
Anemia, neutropenia, thrombocytopenia, diarrhea, hand-foot syndrome, hyperbilirubinemia, myocardial infarction

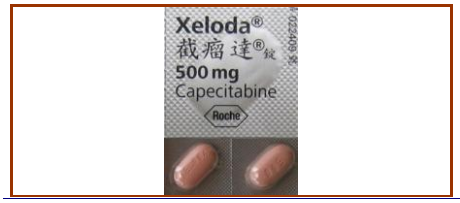
NOTE: 室溫儲存

1.Give dose within 30 minutes after a meal (morning and evening)
2. Prophylaxis for toxicities should be implemented when possible
3. Doses missed during treatment cycles should NOT be replaced

藥名相似: Tab: 500mg(21613)

外觀相似: CellCept* 250mg Cap(27210)

外觀描述: 粉紅色長橢圓錠，有500及XELODA字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022409

08.08C Pyrimidine Analogues

27573 UK /

TS-1 CAPSULES 25MG 愛斯萬膠囊25毫克

■■Tegafur 25mg, Gimeracil 7.25mg, Oteracil potassium 24.5mg cap

Dosage: 1常備品 27573

Adult
· Gastric cancer, colorectal cancer, head and neck cancer, non-small cell lung cancer, inoperable or recurrent breast cancer: PO, based on tegafur according to body surface area. BSA <1.25m(2), 40mg bid; BSA 1.25-1.5m(2), 50mg bid; BSA >1.5m(2), 60mg bid for 28 days, followed by a 14-day rest

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: TS-1 25mg(27573)(27585,捐贈用藥);TS-1 20mg(27574)(27586,捐贈用藥)

ADR:

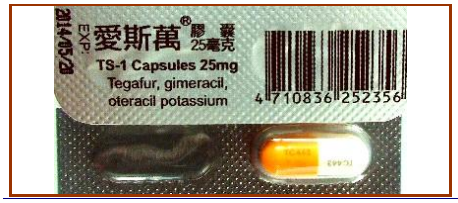
NOTE: 室溫儲存

· A minimum drug rest period of 7 days must be provided
· A minimum washout period of 7 days must be provided when other fluoropyrimidine-group agents are used after withdrawal of TS-1

藥名相似:

外觀相似:

外觀描述: 白/橘色膠囊，有TC443字樣



08.08C Pyrimidine Analogues

27574 UK /

TS-1 CAPSULES 20MG 愛斯萬膠囊20毫克

■■Tegafur 20mg, Gimeracil 5.8mg, Oteracil potassium 19.6mg cap

Dosage: 1常備品 27574

Adult
· Gastric cancer, colorectal cancer, head and neck cancer, non-small cell lung cancer, inoperable or recurrent breast cancer: PO, based on tegafur according to body surface area. BSA <1.25m(2), 40mg bid; BSA 1.25-1.5m(2), 50mg bid; BSA >1.5m(2), 60mg bid for 28 days, followed by a 14-day rest

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: TS-1 25mg(27573)(27585,捐贈用藥);TS-1 20mg(27574)(27586,捐贈用藥)

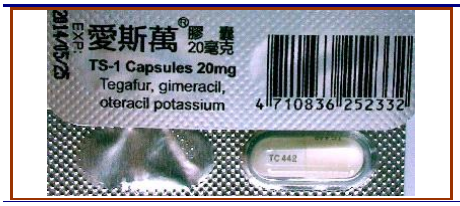
ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色膠囊，有TC442字樣



08.08C Pyrimidine Analogues

27610 ɔt be ruled out / Infant risk can

LONSURF* Film-Coated Tablets 15 mg 朗斯弗膜衣錠15毫克

■■急用Trifluridine 15mg & Tipiracil hydrochloride 7.065mg tab

Dosage: 2急用藥 27610

Adult
Recommended dose based on trifluridine
· Metastatic colorectal cancer: PO, 35 mg/m2 BID within 1 hour of completion of morning and evening meals on days 1-5 and days 8-12 of each 28-day cycle; round dose to nearest 5 mg.Max.80mg/dose(based on trifluridine component).

Pedatric
Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Mild impairment: No adjustment needed to starting dose.
Baseline moderate or severe impairment: Do not initiate therapy.

Dosing adjustments in renal impairment:

Mild to moderate (CrCl 30 to 89 mL/min): No initial dose adjustment necessary; dose adjustment for increased toxicity may be necessary with moderate renal impairment.
Severe impairment or ESRD: Use has not been studied.

P: P Tab: 15mg(27610); 20mg(27611)

ADR:

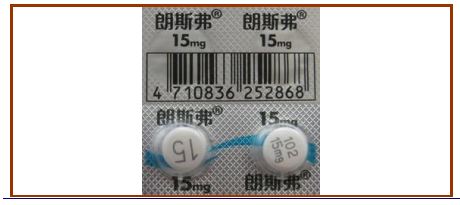
Common
·Abdominal pain, decrease in appetite, diarrhea, nausea, vomiting, fever.
Serious
·Anemia, febrile neutropenia, myelosuppression, neutropenia, thrombocytopenia.

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色雙凸圓形膜衣錠，一面印有15，另一面印有102及15mg的灰色字樣



08.08C Pyrimidine Analogues

27611 ɔt be ruled out / Infant risk can

LONSURF* Film-Coated Tablets 20 mg 朗斯弗膜衣錠20毫克

■■急用Trifluridine 20mg & Tipiracil hydrochloride 9.42mg tab

Dosage: 2急用藥 27611

Adult
Recommended dose based on trifluridine
· Metastatic colorectal cancer: PO, 35 mg/m2 BID within 1 hour of completion of morning and evening meals on days 1-5 and days 8-12 of each 28-day cycle; round dose to nearest 5 mg.Max.80mg/dose(based on trifluridine component) .

Pedatric
Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Mild impairment: No adjustment needed to starting dose.
Baseline moderate or severe impairment: Do not initiate therapy.

Dosing adjustments in renal impairment:

Mild to moderate (CrCl 30 to 89 mL/min): No initial dose adjustment necessary; dose adjustment for increased toxicity may be necessary with moderate renal impairment.
Severe impairment or ESRD: Use has not been studied.

P: P Tab: 15mg(27610); 20mg(27611)

ADR:

Common
·Abdominal pain, decrease in appetite, diarrhea, nausea, vomiting, fever.
Serious
·Anemia, febrile neutropenia, myelosuppression, neutropenia, thrombocytopenia.

NOTE: 室溫儲存

·Prior to initiation, the following criteria must be met: Absolute neutrophil count 1,500/mm(3) or greater or febrile neutropenia resolved, platelet count 75,000/mm(3) or greater, and Grade 3 or 4 nonhematological reactions resolved to Grade 0 or 1

藥名相似:

外觀相似:

外觀描述: 淺紅色雙凸圓形膜衣錠，一面印有20，另一面印有102及20mg的灰色字樣

08.08C Pyrimidine Analogues

31227 D / Unsafe

CYTOSAR FREEZE-DRIED POWDER FOR INJECTION 500MG 賽德薩注射劑500毫克

■■Cytarabine inj 500mg pow in vial

Dosage: 1常備品 31227

Adult
· Acute non-lymphocytic leukemia : Induction, 100-200 mg/m(2) continuous infusion for 7 days
· High dose therapies: 1-3 g/m(2) every 12 hours

Pediatric
Same as adult

Dosing adjustments in hepatic impairment:

Dose should be reduced

Dosing adjustments in renal impairment:

Srcr<1.5mg/dL: 2 or 3g/m(2)
Srcr 1.5-1.9mg/dL or increase from baseline by 0.5 to
1.2mg/dL: 1g/m(2)
Srcr >2.0mg/dL or a change in Scr greater than 1.2mg/dL: 0.1g/m(2)/day

P: Inj:500mg Vial(31227)

ADR:

COMMON
Thrombophlebitis, Rash, Anal inflammation, Diarrhea, Loss of appetite, Nausea, Stomatitis, Ulcer of anus, Ulcer of mouth, Vomiting, Decreased liver function, Fever
SERIOUS
Pericarditis, Sinus bradycardia, Hyperuricemia, Clostridium difficile colitis, Anemia, Decreased reticulocyte count, Hemorrhage, Leukopenia, Megaloblastic anemia, Myelosuppression, Thrombocytopenia, Anaphylaxis, Posterior reversible encephalopathy syndrome, Kidney disease, Pulmonary toxicity, Infectious disease, Sepsis.

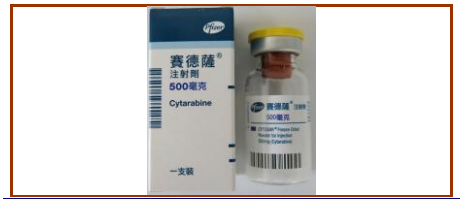
NOTE: 室溫儲存25°C以下

·《Contraindications》Hypersensitivity to cytarabine ;
·Do not use diluents containing benzyl alcohol; preservative-free normal saline is commonly used
˙接受此藥治療的病人，應定期接受骨髓活性、肝、腎功能等檢查，定期監測血中尿酸濃度。
˙接受此藥治療的病人應避免接種活性疫苗或減毒活疫苗。可給與非活性或不活化疫苗；然而對此疫苗的免疫反應可能減弱

藥名相似:

外觀相似:

外觀描述: 白色乾粉，『黃』蓋透明玻璃小瓶



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2001879

08.08C Pyrimidine Analogues

31237 D / Infant risk can

Gemcitabine Sandoz 40mg/ml Concentrate for Solution for Infusion 健仕平"山德士"40毫克/毫升注射劑

■■Gemcitabine inj 200mg/5mL vial

Dosage: 1常備品 31237

Adult
· Pancreatic cancer: IV, initial cycle, 1000mg/m(2) weekly x 7 followed by 1 wk rest; subsequent cycles: 1000mg/m(2) weekly x 3 then 1 wk rest
· Non-small cell lung cancer: 1000mg/m(2) on D1, 8, & 15 every 28 days or 1250mg/m(2) on D1 & 8 every 21 days
· Metastatic breast cancer: 1250 mg/m(2) on D1 and 8 every 21 days, with paclitaxel 175 mg/m(2) before gemcitabine on day 1 of each 21-day cycle
· Ovarian cancer: 1000 mg/m(2) D1 and D8, repeat every 21 days in combination with carboplatin
· Bladder cancer: 1000 mg/m(2)/week for 3 weeks, repeat every 4 weeks

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 200mg/5mL vial(31237), 1000mg/25mL vial(31256)

ADR:

COMMON
Peripheral edema, Alopecia, Rash, Constipation, Diarrhea, Nausea and vomiting, Stomatitis, All Grades Anemia, All Grades Neutropenia, All Grades Thrombocytopenia, Infectious disease, Paresthesia, Peripheral motor neuropathy, Sensory neuropathy, Serum creatinine raised, Dyspnea, Fatigue, Fever.
SERIOUS
Capillary leak syndrome, Bullous eruption, Injection site extravasation, Radiation recall syndrome, Grade 3 or 4 Anemia, Febrile neutropenia, Hemorrhage, Grade 3 or 4 Neutropenia, Grade 3 or 4 Thrombocytopenia, Thrombotic microangiopathy, Hepatotoxicity, Liver failure, Anaphylactoid reaction, Sepsis, Posterior reversible encephalopathy syndrome, Hemolytic uremic syndrome, Renal failure, Acute respiratory distress syndrome, Bronchospasm, Interstitial pneumonia, Pulmonary edema, Pulmonary fibrosis, Respiratory failure, Toxicity due to radiotherapy.

NOTE: 冰箱冷藏，不可冷凍。

1.It shoud be monitored prior to each dose with a complete blood count (CBC)
2.Prolongation of the infusion time beyond 60min & more frequent than weekly dosing have been shown to increase toxicity.

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液，『綠』蓋透明玻璃小瓶，白底深藍字標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025899

08.08C Pyrimidine Analogues

31256 D / Infant risk can

Gemcitabine Sandoz 40mg/ml Concentrate for Solution for Infusion 健仕平"山德士"40毫克/毫升注射劑

■■Gemcitabine inj 1000mg/25mL vial

Dosage: 1常備品 31256

Adult

· Pancreatic cancer: IV, initial cycle, 1000mg/m(2) weekly x 7 followed by 1 wk rest; subsequent cycles: 1000mg/m(2) weekly x 3 then 1 wk rest

· Non-small cell lung cancer 4-wk schedule: IV, 1000mg/m(2) days 1, 8, & 15 every 28 days

· Non-small cell lung cancer 3-wk schedule: IV, 1250mg/m(2) days 1 & 8 every 21 days

· Metastatic breast cancer 1250 mg/m(2) IV over 30 min on days 1 and 8 of each 21-day cycle, with paclitaxel 175 mg/m(2) given as a 3-hour infusion before gemcitabine on day 1 of each 21-day cycle

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 200mg/5mL vial(31237), 1000mg/25mL vial(31256)

ADR:

COMMON

Peripheral edema, Alopecia, Rash, Constipation, Diarrhea, Nausea and vomiting, Stomatitis, All Grades Anemia, All Grades Neutropenia, All Grades Thrombocytopenia, Infectious disease, Paresthesia, Peripheral motor neuropathy, Sensory neuropathy, Serum creatinine raised, Dyspnea, Fatigue, Fever.

SERIOUS

Capillary leak syndrome, Bullous eruption, Injection site extravasation, Radiation recall syndrome, Grade 3 or 4 Anemia, Febrile neutropenia, Hemorrhage, Grade 3 or 4 Neutropenia, Grade 3 or 4 Thrombocytopenia, Thrombotic microangiopathy, Hepatotoxicity, Liver failure, Anaphylactoid reaction, Sepsis, Posterior reversible encephalopathy syndrome, Hemolytic uremic syndrome, Renal failure, Acute respiratory distress syndrome, Bronchospasm, Interstitial pneumonia, Pulmonary edema, Pulmonary fibrosis, Respiratory failure, Toxicity due to radiotherapy.

NOTE: 冰箱冷藏，不可冷凍。

1.It shoud be monitored prior to each dose with a complete blood count (CBC)

2.Prolongation of the infusion time beyond 60min & more frequent than weekly dosing have been shown to increase toxicity.

藥名相似:

外觀相似:

外觀描述: 25mL透明注射液，『綠』蓋透明玻璃小瓶，白底深藍字標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025899

08.08C Pyrimidine Analogues

31264 X / Unsafe

5-Fu* Injection 50mg/ml 好復注射液50毫克/毫升

■■Fluorouracil (5-FU) inj 1g/20mL vial

Dosage: 1常備品 31264

Adult

IV, initial 400-500mg/m2/day (12mg/kg/day) for 4-5days, MD 200-250mg/m2/day qod for 4 days; repeated in 4 weeks; Max. 800mg/day

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Bilirubin>5mg/dL: Should be omitted

Dosing adjustments in renal impairment:

NDA

P: Inj: 1g/20mL Vial(31264)

ADR:

COMMON

Alopecia, hand-foot syndrome, photosensitivity, anorexia, N/V, diarrhea, esophagopharyngitis, stomatitis headache

SERIOUS

Acute cerebellar syndrome, nystagmus, gastrointestinal ulceration, bleeding, lacrimal duct stenosis, lacrimation, visual changes, photophobia, myelosuppression, myocardial ischemia, angina

NOTE: 室溫儲存

Administer IV in 50 mL of D5W over 15 minutes

藥名相似:

外觀相似:

外觀描述: 20mL透明注射液、『綠』蓋玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=51058033

08.08C Pyrimidine Analogues

37974 D /

Vidaza Powder for Suspension for Injection "德國"委丹扎注射劑

■■急用Azacitidine 100mg pow in vial

Dosage: 2急用藥 37974

Adult

·Myelodysplastic syndrome: SC, IV, 75mg/m2/day for 7 days repeated every 4 weeks. Dose may be increased to 100mg/m2/day if no beneficial effect is seen after 2 cycles and no toxicity other than

nausea and vomiting has occurred. Treatment is recommended for at least 4 cycles

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

If unexplained elevations of BUN or Scr occur, delay next cycle until values return to normal or baseline and dose should be reduced by 50% on the next course

P: Inj: 100mg Vial (37839)(37948,捐贈)(37905,Germany)

ADR:

COMMON
Peripheral edema, erythema, erythema at injection site, petechiae, constipation, diarrhea, loss of appetite, nausea, vomiting, ecchymosis, progressive hepatic coma, arthralgia, dizziness, lethargy, pain in limb, rigor, somnolence, cough, dyspnea, pharyngitis, fatigue, fever
SERIOUS
Febrile neutropenia, myelosuppression, thrombocytopenia, leukopenia, neutropenia, renal failure, renal tubular acidosis

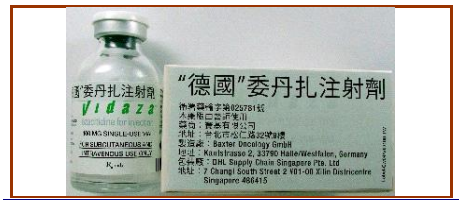
NOTE: 室溫儲存

·Doses greater than 4mL(1 vial) should be divided equally into 2 syringes and injected into 2 separate sites
·Dose should be decreased or delayed based on hematology response
·If serum bicarbonate levels< 20mEq/L(unexplained decrease), the dosage should be reduced by 50% on the next course

藥名相似:

外觀相似:

外觀描述: 白色乾粉，白蓋玻璃小瓶



08.10A Progestogens

25660 **X / Unsafe**

MEGEJOHN TABLETS 160MG 美雅祥錠160毫克

■■Megestrol acetate 160mg tab

Dosage: 1常備品 25660

Adult
· Anorexia, cachexia or unexplained weight loss in patients with AIDS: PO, initial 800mg/day, MD 400-800mg/day
· Breast cancer: PO, 40mg qid
· Endometrial carcinoma: PO, 40-320mg/day in divided doses

Pediatric
safety and effectiveness have not established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 160mg(25660); Susp: 40mg/mL, 240mL/BT(28544)

ADR:

COMMON
Dyspepsia, nausea, vomiting, hot flashes, sweating, hypertension, impotence, insomnia, mood changes, weight gain
SERIOUS
Adrenal insufficiency, thrombophlebitis, pulmonary embolism

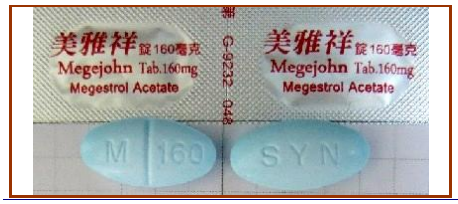
NOTE:

At least 2 months of continuous treatment is considered an adequate period for determining the efficacy of megestrol acetate when used for breast or endometrial cancer

藥名相似:

外觀相似:

外觀描述: 淺藍色橢圓形錠，一面中間有一刻痕及M 160字樣，另一面有SYN字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=148182

08.10A Progestogens

25662 **X / Infant risk is**

MEPRO TABLETS 500MG 美普羅錠500毫克

■■Medroxyprogesterone acetate 500mg tab

Dosage: 1常備品 25662

Adult
· Endometrial and renal carcinoma: PO, 100-500mg/day
· Breast cancinoma: PO, 400mg-1.5g/day
· Prostatic carcinoma: PO, 100-500mg/day

Pediatric
Safety and efficacy not established in children

Dosing adjustments in hepatic impairment:

Dosage adjustment required.
Contraindicated with severe impairment

Dosing adjustments in renal impairment:

NDA

P: Tab: 500mg(25662), 5mg(25675); Divina(25672); Premelle(25666)

ADR:

COMMON
Amenorrhea, breakthrough bleeding, change in menstrual flow, spotting asthenia, dizziness, headache, nervousness, breast tenderness, galactorrhea, change in weight, edema, depression, abdominal pain or discomfort, nausea, insomnia, somnolence

SERIOUS
Cholestatic jaundice, deep vein thrombosis, pulmonary embolism, thrombophlebitis

NOTE: 室溫儲存

withdrawal bleeding usually occurs within 3-7 days after discontinuing medroxyprogesterone acetate therapy.

藥名相似:

外觀相似:

外觀描述: 白色長橢圓扁錠，一面"SYN"，另一面中間有刻痕及"M" "500"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1047788

08.10A Progestogens

28555 X /

MEGAXIA* ES Oral Suspension 125mg/mL 美適亞高濃度微粒懸液劑125毫克/毫升

■■Megestrol acetate susp 125mg/mL, 35mL/bot

Dosage: 1常備品 28555

Adult
· Anorexia, cachexia or unexplained weight loss in patients with AIDS: PO, initial 2.5mL/day, MD 2.5-5mL/day

Pediatric
safety and effectiveness have not established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 160mg(25660); Susp: 125mg/mL,35mL/BT(28555)

ADR:

COMMON
Hypertension, sweating symptom, hot flash, weight gain, dyspepsia, nausea, vomiting, insomnia, mood swings, impotence
SERIOUS
Thrombophlebitis, adrenal insufficiency, pulmonary embolism

NOTE: 室溫儲存

· 《Contraindications》History of hypersensitivity to megestrol acetate or any component of the formulation; Known or suspected pregnancy ; Shake suspension container well before using
· 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 紙盒白/藍底紅字

08.10B Gonadotropin-Releasing Hormone (GnRH) Analogues

35306 X / Unknown(有

LUPRO* Injection 5mg/ml 恩必來注射液 5 毫克/毫升

■■Leuprolide acetate inj 14mg/2.8mL vial

Dosage: 1常備品 35306

Adult
· Prostatic carcinoma: SC, 1mg daily
· Folliculogenesis for in vitro fertilization and embryo transfer (IVF-ET): SC, 1mg daily from mild-luteal phase to the next of ovulation day

Pediatric
· Central precocious puberty: SC, 50mcg/kg/day, if total down-regulation is not achieved titrate upward by 10mcg/kg/day.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 14mg/2.8mL Vial(35306), 3.75mg/2mL Vial(35309)

ADR:

COMMON
Edema, Acne, Injection site pain, Injection site reaction, Rash, Flushing, Vasomotor ; uterine fibroids, Increased testosterone level, transient, Serum triglycerides raised, Weight increase, Constipation, Nausea and vomiting, Anemia, Arthralgia, Arthropathy, Decreased bone mineral density, Myalgia, Asthenia, Dizziness, Headache, Insomnia, Lethargy, Depression, Mood swings, Dysuria, Atrophy of testis, Vaginitis, Cough, Constipation, Malaise and fatigue

SERIOUS
Heart failure, Myocardial infarction, Prolonged QT interval, Pituitary apoplexy, Injury of liver, Anaphylactoid reaction, Fracture of vertebral column, Fracture of vertebral column, Seizure,Suicidal thoughts, Pulmonary embolism

NOTE: 冰箱冷藏，不可冷凍。

藥名相似:

外觀相似:

外觀描述: 2.8mL透明注射液『綠』蓋透明玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049838

08.10B Gonadotropin-Releasing Hormone (GnRH) Analogues

35309 X / Unknown(有

Leuplin Depot 1M 3.75mg S.C. Injection 柳菩林一個月持續性藥效皮下注射劑3.75毫克

■■Leuprolide acetate depot sc inj 3.75mg/1mL amp

Dosage: 1常備品 35309

Adult

· Prostatic carcinoma: IM, SC, 7.5mg once monthly

· Endometriosis: IM, SC, 3.75mg once monthly for 6 consecutive month

· Folliculogenesis for in vitro fertilization and embryo transfer (IVF-ET): IM, SC, 3.75mg single dose

· Uterine leiomyoma: IM, 3.75mg once monthly up to 3 months

Pediatric

· Central precocious puberty: IM, initial 0.3mg/kg/4wks (minimum 7.5mg), ≦25kg: 7.5mg; >25-37.5kg: 11.25mg; ≧37.5kg: 15mg

If the starting dose of Leuprolide does not result in total downregulation, the dose can be titrated upward by 3.75mg every 4 weeks

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 14mg/2.8mL Vial(35306), 3.75mg/1mL Vial(35309)

ADR:

COMMON

·Cardiovascular: Edema (Adults, 8.2% to 20.8%)

·Dermatologic: Acne (central precocious puberty, 3% ; endometriosis 10%), Injection site pain (central precocious puberty, 19% to 21% ; prostate cancer, 19.2%), Injection site reaction (central precocious puberty, 9% ; prostate cancer, 8.2% to 37.5%), Rash (central precocious puberty, 3% ; prostate cancer, 6%)

·Endocrine metabolic: Flushing, Vasomotor (endometriosis, 84% ; prostate cancer, 46.9% to 73.3% ; uterine fibroids, 72.9% to 98%), Increased testosterone level, transient, Serum triglycerides raised (endometriosis, 12% to 32%), Weight increased (central precocious puberty, 7%)

·Gastrointestinal: Constipation (9.9%), Nausea and vomiting (endometriosis, 13%; uterine fibroids, 4.8% to 25%)

·Hematologic: Anemia (prostate cancer, 2.3% to 6.6%)

·Musculoskeletal: Arthralgia (9.3%), Arthropathy (prostate cancer, 4.2% to 16.3%), Decreased bone mineral density, Myalgia (7.9%)

·Neurologic: Asthenia (prostate cancer, 12.2% ; uterine fibroids, 8.4% to 18%), Dizziness (endometriosis, 11%; uterine fibroids, 1.8% to 16%), Headache (central precocious puberty, 3% to 7% ; endometriosis, 32% ; prostate cancer, 7.9% to 10.2% ; uterine fibroids, 25.9% to 65%), Insomnia (uterine fibroids, 31%), Lethargy

·Psychiatric: Depression (Adult, 5%; pediatric, less than 2%), Mood swings (Pediatric, 5%)

·Renal: Dysuria (6%)

·Reproductive: Atrophy of testis (prostate cancer, 3.8% to 20.2%), Vaginitis (endometriosis, 28%; uterine fibroids, 11.4% to 20%)

·Respiratory: Cough (6.6%)

·Other: Constipation (9.9%), Malaise and fatigue (prostate cancer, 6% to 17.5%), Pain (central precocious puberty, 3% ; endometriosis, 19% ; prostate cancer, 23.2% to 32.7% ; uterine fibroids, 8.4% to 24%)

SERIOUS

·Cardiovascular: Heart failure (Adults, less than 5%), Myocardial infarction, Prolonged QT interval

·Endocrine metabolic: Pituitary apoplexy

·Hepatic: Injury of liver

·Immunologic: Anaphylactoid reaction (0.002%)

·Musculoskeletal: Fracture of vertebral column

·Neurologic: Fracture of vertebral column, Seizure (prostate cancer, less than 0.5%)

·Psychiatric: Suicidal thoughts

·Respiratory: Pulmonary embolism

NOTE: 室溫保存

with 1mL amp diluent (contains D-mannitol 50mg, CMC 5mg, Polysorbate 80 1mg)

藥名相似:

外觀相似:

外觀描述: 筆型注射器，注射針筒內含粉末劑部份與1mL注射液部份

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2019493

08.10B Gonadotropin-Releasing Hormone (GnRH) Analogues

35315 X / Unsafe

■■LEUPLIN* Depot 3M 11.25mg inj 柳菩林三個月持續性藥效皮下注射劑

■■Leuprolide acetate 11.25mg pow in vial with 1mL amp solvent

Dosage: 1常備品 35315

Adult

· Advanced prostate cancer: SC, 11.25mg every 3 months

· Endometriosis: SC, 11.25mg every 3 months alone or in combination with norethindrone acetate for a maximum recommended duration of 6 months

· Uterine leiomyomata (fibroids): SC, 11.25mg as a single injection

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 14mg/2.8mL Vial(35306), 3.75mg/1mL Vial(35309), 11.25mg/1mL Vial(35315)

ADR:

COMMON
Edema, acne,injection site pain, injection site reaction, rash, flushing, vasomotor, increased testosterone level, transient, serum triglycerides raised, weight increased , constipation, nausea and vomiting, anemia, arthralgia, arthropathy, decreased bone mineral density, myalgia, asthenia, dizziness, headache , insomnia, lethargy, depression, mood swings, dysuria, atrophy of testis, vaginitis, cough, malaise and fatigue, pain
SERIOUS
Heart failure, myocardial infarction, prolonged QT interval, pituitary apoplexy, injury of liver, anaphylactoid reaction, fracture of vertebral column, fracture of vertebral columnseizure, suicidal thoughts, pulmonary embolism

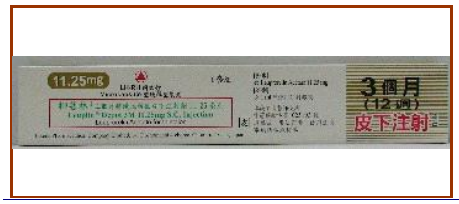
NOTE: 室溫保存

with 1mL amp diluent (contains D-mannitol 50mg, CMC 5mg, Polysorbate 80 1mg)

藥名相似:

外觀相似:

外觀描述: 筆型注射器，注射針筒內含粉末劑部份與1mL注射液部份



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025193

08.10B Gonadotropin-Releasing Hormone (GnRH) Analogues

35317 X / Unsafe

Diphereline P.R. 11.25mg pow & soln for susp for injection(IM) 3-month prolonged release form 達菲林長效注射劑11.25毫克

■■急用Triptorelin pamoate 14.58mg(=Triptorelin 11.25mg) pow in vial with 2mL amp solvent

Dosage: 2急用藥 35317

Adult
· Advanced prostate cancer & endometriosis: IM, 11.25mg every 3 months

NDA

Dosing adjustments in hepatic impairment:

No dosage adjustment is required

Dosing adjustments in renal impairment:

No dosage adjustment is required

P:

ADR:

COMMON
Hypertension, Peripheral edema, Injection site pain, Hot sweats, Gastroenteritis, Nausea, Vomiting, Arthralgia, Backache , Bone pain, Pain in limb, Dizziness, Headache, Insomnia, Dysuria, Urinary retention, Urinary tract infectious disease, Atrophy of testis, Erectile dysfunction, Erectile dysfunction, Pain of breast, Reduced libido, Nasopharyngitis, Upper respiratory infection, Fatigue, Influenza, Pain.
SERIOUS
Pituitary apoplexy, Anaphylaxis, Hypersensitivity reaction, Sepsis, Seizure, Psychiatric symptom, Disorder of puberty, Angioedema, Tumor flare.

NOTE: 室溫保存

· 《Contraindications》Hypersensitivity to triptorelin or any other component of the product; Hypersensitivity to other gonadotropin-releasing hormone (GnRH) agonists or to GnRH; Existing or potential for pregnancy ;
· 女性病人：治療期間及最後一次注射後 1 個月內應採取非荷爾蒙避孕法。
· 男性病人：血中睪固酮濃度不應超過 1 ng/mL毫微克/毫升，應以精確準方法定期檢測。
· with 2mL solvent (Each amp contains mannitol 16mg, water for injection add to 2mL)

藥名相似:

外觀相似:

外觀描述: 土黃色乾粉,『綠』蓋透明玻璃小瓶，附1支 2 mL 溶劑安瓿，1支注射針筒、 2 支注射針

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024528

08.10B Gonadotropin-Releasing Hormone (GnRH) Analogues

37784 X / Unsafe

■■急用ZOLADEX* LA depot 10.8mg/syringe 諾雷德持續性注射劑

■■急用Goserelin LA depot 10.8mg syringe

Dosage: 2急用藥 37784

Adult
·Advanced prostate cancer: SC, 10.8mg every 12 weeks

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 3.6mg/syringe(37808), 10.8mg/syringe(37784, 急用藥)

ADR:

COMMON
Gynecomastia, hot sweats, lethargy, transient pain, lower urinary tract finding, impotence, reduced libido, sexual dysfunction
SERIOUS
Deep venous thrombosis

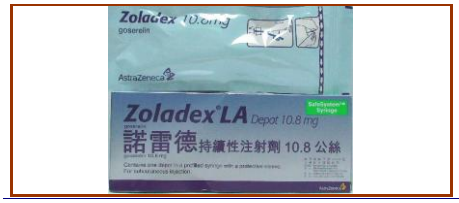
NOTE: 室溫儲存

1. Inject Zoladex* LA depot subcutaneously into the anterior abdominal wall.
2. Zoladex* LA depot is not indicated for use in females.

藥名相似:

外觀相似:

外觀描述: 單一劑量針筒給藥器



08.10B Gonadotropin-Releasing Hormone (GnRH) Analogues

37808 X / Unsafe

ZOLADEX 3.6MG DEPOT 諾雷德持續性注射劑

■■Goserelin depot 3.6mg syringe

Dosage: 1常備品 37808

Adult
·Advanced breast cancer, palliative: SC, 3.6mg every 28 days, for long-term therapy
·Endometriosis: SC, 3.6mg every 28 days, up to 6 months
·Endometrial thinning, prior to endometrial ablation: SC, a single 3.6-mg dose 4 wks before surgery. Alternatively, two 3.6-mg SC doses given 4 wks apart; surgey should be performed 2-4 wks after the second dose
·Advanced prostate cancer, palliative: SC, 3.6mg every 4 wks or 10.8mg every 12 wks, for long-term therapy
·Prostate cancer (stage B2 to C), in combination with radiotherapy and flutamide: starting 8 wks prior to radiotherapy, SC, 3.6mg followed in 28 days by 10.8mg. Alternatively, 4 doses of 3.6mg SC given at 28-day intervals, 2 doses preceding and 2 during radiotherapy

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

No dosage adjustment is required

Dosing adjustments in renal impairment:

No dosage adjustment is required

P: Inj: 3.6mg/syringe (37808)

ADR:

COMMON
Gynecomastia, hot sweats, lethargy, transient pain, lower urinary tract finding, break-through bleeding, impotence, reduced libido, sexual dysfunction
SERIOUS
Deep venous thrombosis

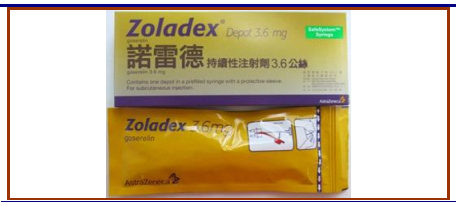
NOTE: 室溫儲存

1. Zoladex* Depot is supplied in a single dose syringe. Inject Zoladex* Depot SQ into the anterior abdominal wall.
2. Contraindications: 10.8mg depot dose in women

藥名相似:

外觀相似:

外觀描述: 單一劑量針筒給藥器



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022137

08.10C Antiestrogens

21606 D / Unsafe

NOLVADEX TABLETS 10MG 諾瓦得士錠 1 0 公絲

■■Tamoxifen citrate 15.2mg (=10mg base) tab

Dosage: 1常備品 21606

Adult
· Breast cancer: PO, 10-20mg bid for 5 years
· Anovulatory infertility: PO, 10mg bid on days 2, 3, 4 and 5 of the menstrual cycle, increased if necessary in subsequent cycles up to 40mg bid
· Ductal carcinoma in situ (DCIS): PO, 20mg qd for 5 years
· Reduction in breast cancer incidence in high risk women: PO, 20mg qd for 5 years

Pediatric
Safety and effectiveness have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment is needed in mild-moderate renal failure

P: Tab: 10mg(21606)

ADR:

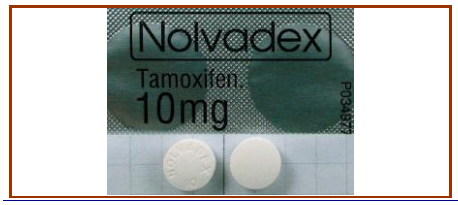
COMMON
Amenorrhea, altered or irregular menses, vaginal discharge, hot flashes
SERIOUS
Cataract formation, cataract surgery, endometrial cancer, uterine sarcoma, pulmonary embolism, stroke

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有"NOLVADEX"及"10"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022154

08.10C Antiestrogens

31290 ɔt be ruled out / Infant risk can

Faslodex* solution for injection 50mg/ml 法洛德注射液 50毫克/毫升

■■Fulvestrant inj 250mg/5mL syringe

Dosage: 1常備品 31290

Adult:

· Breast cancer, Advanced, first-line endocrine therapy in postmenopausal women with hormone receptor-positive, HER2-negative disease: IM, 500 mg into the buttocks; administer as two 5 mL injections, 1 in each buttock, over 1 to 2 minutes each on days 1, 15, 29, and then once per month.

Pediatric
Safety and effectiveness have not been established

Dosing adjustments in hepatic impairment:

moderate (Child-Pugh class B): 250 mg IM on days 1, 15, 29, and once monthly thereafter; administer slowly (1 to 2 minutes per injection) into the buttock as one 5-mL injection

Dosing adjustments in renal impairment:

P: P Inj: 250mg/5mL syringe(37712捐贈)(31290自費)

ADR:

Common
Alopecia, Injection site pain, Injection site reaction, Rash, Abdominal pain, Constipation, Diarrhea, Loss of appetite, Nausea, Stomatitis, Vomiting, Anemia, Leukopenia, Neutropenia, thrombocytopenia, Liver enzymes abnormal raised, Infectious disease, Arthralgia, Backache, Bone pain, asthenia, Headache, Menopausal flushing, Cough, Dyspnea, Increasing frequency of cough, Pharyngitis, Fatigue, Fever.
Serious
Thromboembolic disorder, Hepatitis, Liver failure, Hypersensitivity reaction, Angioedema.

NOTE: 冰箱冷藏，不可冷凍

藥名相似:

外觀相似:

外觀描述: 預充填5mL無色至黃色澄清黏稠注射液,附無菌注射針筒及針頭[每盒2付]針筒上標有"法洛德注射液"字樣

08.10C Antiestrogens

37712 ɔt be ruled out / Infant risk can

捐贈急用FASLODEX* solution for injection 50mg/ml 法洛德注射液 50毫克/毫升

■■捐贈急用Fulvestrant 250mg/5mL syringe

Dosage: 2急用藥 37712

Adult:
· Breast cancer, Advanced, first-line endocrine therapy in postmenopausal women with hormone receptor-positive, HER2-negative disease: IM, 500 mg into the buttocks; administer as two 5 mL injections, 1 in each buttock, over 1 to 2 minutes each on days 1, 15, 29, and then once per month.

Pediatric
Safety and effectiveness have not been established

Dosing adjustments in hepatic impairment:

moderate (Child-Pugh class B): 250 mg IM on days 1, 15, 29, and once monthly thereafter; administer slowly (1 to 2 minutes per injection) into the buttock as one 5-mL injection

Dosing adjustments in renal impairment:

P: P Inj: 250mg/5mL syringe(37712捐贈)(31290自費)

ADR:

Common
Alopecia, Injection site pain, Injection site reaction, Rash, Abdominal pain, Constipation, Diarrhea, Loss of appetite, Nausea, Stomatitis, Vomiting, Anemia, Leukopenia, Neutropenia, thrombocytopenia, Liver enzymes abnormal raised, Infectious disease, Arthralgia, Backache, Bone pain, asthenia, Headache, Menopausal flushing, Cough, Dyspnea, Increasing frequency of cough, Pharyngitis, Fatigue, Fever.
Serious
Thromboembolic disorder, Hepatitis, Liver failure, Hypersensitivity reaction, Angioedema.

NOTE: 冰箱冷藏，不可冷凍

藥名相似:

外觀相似:

外觀描述:

08.10D Antiandrogens

21614 D /

FUPROSTATE TABLETS 護腺寧錠

■■Flutamide 250mg tab

Dosage: 1常備品 21614

Adult
· Metastatic carcinoma of the prostate (stage B2-C): PO, 250mg q8h in conjunction with GnRH analog; begin 8 weeks prior to initiating radiation therapy and continue during radiation therapy
· Metastatic carcinoma of the prostate (stage D2): PO, 250mg q8h in conjunction with GnRH analog; continue until progression

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Discontinue if transaminases increase to 2-3 times the upper limit

Dosing adjustments in renal impairment:

NDA

P: Tab: 250mg (21614)

ADR:

COMMON
Diarrhea, nausea, hot flashes, skin rashes

SERIOUS
Anemia, leukopenia, thrombocytopenia, hepatotoxicity

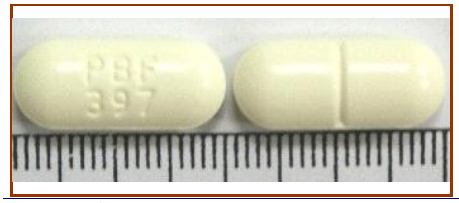
NOTE: 室溫儲存

1. Contraindication:
I) Not indicated for use in women; may cause fetal harm in pregnant women.
II) Severe hepatic impairment (ALT values exceeding twice the upper limit of normal)
2. Should be given simultaneously with LHRH analog (usual dose of Leuprolide is SC 1mg/day or IM 7.5mg once a month).

藥名相似:

外觀相似:

外觀描述: 淺黃色長橢圓錠，一面"PBF""397"另一面中央刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2046018

08.10D Antiandrogens

21617 X / Unsafe

BICALUTAMIDE-ACEPHARM* FILM COATED TABLETS 50MG 癌可泰膜衣錠50毫克

■■Bicalutamide 50mg FC tab

Dosage: 1常備品 21617

Adult
· Metastatic prostate cancer: PO, 50mg qd (combine With GnRH analog)

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Used with caution in patients with moderate-to-severe hepatic impairment.
Discontinue if ALT >2 times ULN or patient develops jaundice

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 50mg(21617)

ADR:

COMMON
Breast pain, gynecomastia, constipation, diarrhea, nausea, hot flashes, infection (pulmonary and upper respiratory tract),
weakness
SERIOUS
Anemia, gastrointestinal or rectal bleeding, hepatotoxicity

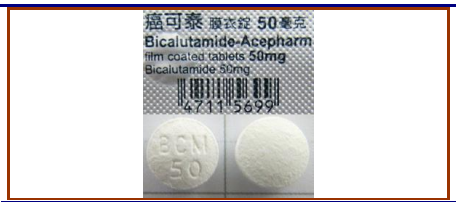
NOTE: 室溫儲存

Contraindications: pregnancy, women, pediatric

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有BCM及50字樣)【107.06.04變更廠牌



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=52026270

08.10D Antiandrogens

25640 ɔt be ruled out / Infant risk can

ANDROCUR TABLETS 安得卡錠

■■Cyproterone acetate 50mg tab

Dosage: 1常備品 25640

Adult:
· Control of libido in severe hypersexuality in adult male: PO, 50mg bid
· Palliative treatment of prostatic carcinoma: PO, initial, 300mg/day div. into 2-3 doses, MD 200-300mg/day

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

肝功能指數未回復至正常值不可使用(仿單)。(乙1090007490:可能引發肝毒性的問題與肝功能監測安全相關)

Dosing adjustments in renal impairment:

NDA

P: Tab: 50mg(25640)

ADR:

· Cardiovascular Effects: Changes in blood pressure (vasomotor), Fluid retention and peripheral edema, Venous thromboembolism, Myocardial ischemia, Congestive heart failure, Pulmonary embolism, Cerebrovascular accident, Myocardial infarction, Electrocardiogram changes.
· Dermatologic Effects: Hot flashes with night sweats.
· Endocrine/Metabolic Effects: Nipple tenderness, Gynecomastia, Breast enlargement, Galactorrhea, Hyperprolactinemia, Vasomotor flushing with night sweats, Lipids abnormal, Weight gain.
· Gastrointestinal Effects: Nausea, Diarrhea, Indigestion.
· Hematologic Effects: Anemia, Blood coagulation disorder.
· Hepatic Effects: Hepatotoxicity.
· Musculoskeletal Effects: Osteoporosis.
· Neurologic Effects: Sedation, Lethargy, Mood Changes, Headache, Depression.
· Ophthalmic Effects: Optic atrophy.
· Renal Effects: Impotence, Menstrual irregularities, Decreased libido.
· Respiratory effects: Lymphocytic pneumonitis, Breathlessness, Respiratory alkalosis, Dyspnea.

NOTE: 室溫儲存

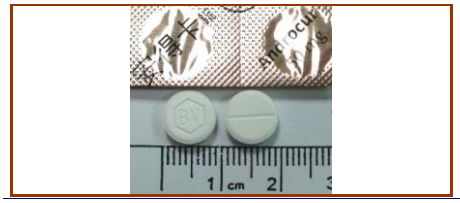
·《Contraindications》Acute liver disease; History of thromboembolic disorders; Hypersensitivity to CYPROTERONE ACETATE; Malignant diseases other than prostatic carcinoma ;
·肝毒性安全資訊(仿單)：
1.肝毒性(包含黃疸、肝炎、肝衰竭)為治療已知風險。

2.禁用於：肝臟疾病、曾或現有肝腫瘤、遺傳性高膽紅素血症、懷孕時曾發生黃疸或持續搔癢。
3.治療前、治療中、一旦出現肝毒性症狀(噁心、嘔吐、上腹部不適、無力、倦怠或黃疸相關症狀，如皮膚或眼睛發黃、茶色尿、發癢等)，皆需監測肝功能指數。若確認為肝毒性，應停用。

藥名相似: Tab: 50mg(25640)

外觀相似:

外觀描述: 白色圓扁錠，一面刻有正六角形圖樣中有"BV"字樣，另一面中央有刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2012554

08.10D Antiandrogens

27556 demonstrated / Infant risk can

XTANDI* soft capsules 40 mg 安可坦軟膠囊40毫克

■■Enzalutamide 40mg soft cap

Dosage: 1常備品 27556

Adult
· Prostate cancer, Castration-resistant: PO, 160mg qd

Pediatric
· Safety and effectiveness have not been established in pediatric patients

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Soft cap: 40mg(27556)

ADR:

COMMON
Hypertension, Peripheral edema, Flushing, Weight decreased, Constipation, Diarrhea, Loss of appetite, Taste sense altered, Neutropenia(All Grades), Arthralgia, Backache, Musculoskeletal pain, Asthenia, Dizziness, Headache, Vertigo, Dyspnea, Upper respiratory infection, Fatigue
SERIOUS
Neutropenia(Grades 3 and 4), Cauda equina syndrome, Posterior reversible encephalopathy syndrome, Seizure, Spinal cord compression

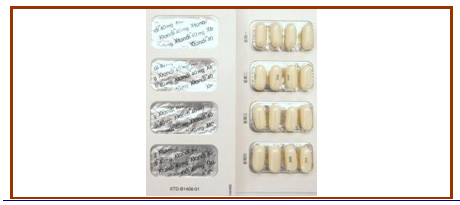
NOTE: 室溫儲存25℃以下

Contraindications: pregnancy

藥名相似:

外觀相似:

外觀描述: 白色軟膠囊，有ENZ字樣



08.10E Aromatase inhibitors

21603 X /

ANAZO F.C. TABLETS 安納柔膜衣錠

■■Anastrozole 1mg FC tab

Dosage: 1常備品 21603

Adult
·Advanced breast cancer in postmenopausal women: PO, 1mg qd

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustments are recommended in patients with mild to moderate hepatic dysfunction

Dosing adjustments in renal impairment:

Dose adjustments are not required in renal impairment.

P: P Tab: 1mg(27603, 急用藥); 1mg(21603)

ADR:

NOTE: 儲存25℃以下

Safety and efficacy not established in premenopausal women

藥名相似: Tab: 1mg(21603)

外觀相似:

外觀描述: 白色圓錠

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1047539

08.10E Aromatase inhibitors

21621 X / Infant risk can

AROMASIN SUGAR COATED TABLETS 25MG 諾曼癌素糖衣錠 2 5 毫克

■■Exemestane 25mg tab

Dosage: 1常備品 21621

Adult:
· Breast cancer, adjuvant, postmenopause, ER-positive: PO, 25mg qd, initiate after 2-3 yrs of tamoxifen until completion of 5 consecutive years of adjuvant endocrine therapy
· Breast cancer, Advanced, postmenopausal, following progression on tamoxifen therapy: 25 mg once daily until tumor progression

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 25mg (21621)

ADR:

COMMON

Alopecia, diaphoresis, menopausal flushing, increased appetite, nausea, alkaline phosphatase raised, arthralgia, headache, insomnia, anxiety, depression, fatigue
SERIOUS
Heart failure, myocardial infarction, gastric ulcer, cholestatic hepatitis, hepatitis, decreased bone mineral density, fracture of bone, cerebrovascular accident

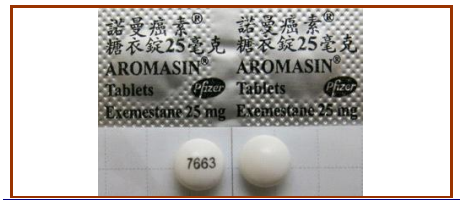
NOTE: 室溫儲存30℃以下

1.Exemestane is not to be used in premenopausal women, and should not be given concomitantly with estrogen.
2.Vitamin D deficiency may occur due to increased prevalence in women with early breast cancer; monitoring recommended.
3.Bone mineral density reductions have been reported; monitoring recommended.

藥名相似: Tab: 25mg (21621)

外觀相似:

外觀描述: 白色圓形糖衣錠，有7663字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023097

08.10E Aromatase inhibitors

21623 X / Infant risk can

LETROZOLE* "Alvogen" FCT 2.5mg 利妥柔"艾威群"膜衣錠2.5毫克

■■Letrozole 2.5mg tab

Dosage: 1常備品 21623

Adult
· Breast cancer, advanced or metastatic, postmenopause: 2.5mg qd, until tumor progression
· Breast cancer, adjvant, postmenopause: 2.5mg qd

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Severe hepatic impairment (Child-Pugh C) and cirrhosis: 2.5 mg every other day

Dosing adjustments in renal impairment:

Severe renal impairment (Clcr<10mL/min): Precaution

P: Tab: 2.5mg(21623)

ADR:

COMMON
Edema, Hot sweats, Sweating, Hypercholesterolemiad, Constipation, Diarrhea, Loss of appetite, Nausea, Vomiting, Arthralgia, Arthritis, Backache, Bone pain, Myalgia, Asthenia, Dizziness, Headache, Insomnia, Somnolence, Dyspnea, Fatigue.
SERIOUS
Heart failure, Myocardial infarction, Pancytopenia, Thromboembolic disorder, Decreased bone mineral density, Fracture of bone, Pleural effusion, Pulmonary embolism.

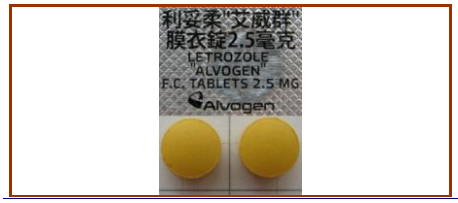
NOTE: 室溫儲存

· 僅有確認停經之婦女可接受Letrozole的乳癌治療。

藥名相似:

外觀相似:

外觀描述: 土黃色圓扁錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=52026206

08.10F Other hormones

27249 X / Unsafe

ZYTIGA Tablets 250mg 澤珂錠 250毫克

■■急用Abiraterone acetate 250mg tab

Dosage: 2急用藥 27249

Adult
· Metastatic castration-resistant prostate cancer: PO, ac, 1000mg qd in combination with prednisone 5mg bid

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

(1)Preexisting hepatic impairment:
· Child-Pugh class A: No dosage adjustment needed
· Child-Pugh class B: 250mg qd. Permanently discontinue if ALT and/or AST increase >5X ULN or total bilirubin increase >3X ULN
· Child-Pugh class C: Avoid use
(2)Hepatotoxicity during treatment:
· ALT and/or AST >5X ULN or total bilirubin >3X ULN: Withhold treatment until LFTs return to baseline or ALT and AST ?2.5X ULN and total bilirubin ?1.5X ULN, then reinitiate at 750mg qd
· Recurrent hepatotoxicity on 750mg/day: Withhold treatment until LFTs return to baseline or ALT and AST ?2.5X ULN and total bilirubin ?1.5X ULN, then reinitiate at 500mg qd
· Recurrent hepatotoxicity on 500mg/day: Discontinue treatment
· The safety of retreatment in patients who develop AST or ALT ≧20X ULN and/or bilirubin ≧10X ULN is unknown.

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 250mg (27249)

ADR:

COMMON
Edema, hypertension, contusion, flushing, hypercholesterolemia, hyperglycemia, hypertriglyceridemia, hypokalemia, hypophosphatemia, diarrhea, vomiting, anemia, lymphocytopenia, ALT/SGPT level raised, AST/SGOT level raised, joint swelling, urinary tract infectious disease, cough, dyspnea, fatigue

SERIOUS
Cardiac dysrhythmia, cardiorespiratory arrest, chest pain, heart failure, myocardial infarction, sudden cardiac death, adrenal insufficiency, serum bilirubin raised

NOTE: 室溫儲存30 °C以下

· Swallow whole; do not crush or chew.
· Administer on an empty stomach (at least 1h before or 2h after a meal).

藥名相似:

外觀相似:

外觀描述: 白色橢圓形錠，有AA250字樣

08.10F Other hormones

31280 **x / Caution**

Firmagon 80mg, Powder and Solvent for Solution for Injection 輔美康注射劑80毫克

■■Degarelix 80mg pow and solvent for slon for inj

Dosage: 1常備品 31280

Adult
· Advanced prostate cancer: SC, initial 240 mg(as 2 injections of 120 mg each); MD 80 mg once monthly.

Pediatric
· Safety and efficacy not established

Dosing adjustments in hepatic impairment:

Mild to moderate impairment: Dose adjustment is not necessary.
Severe impairment: Use with caution.

Dosing adjustments in renal impairment:

Mild to moderate impairment: Dose adjustment is not necessary.
Severe impairment: Use with caution.

P: Inj: 80mg vial(31280), 120mg vial(37990)

ADR:

COMMON
Hot sweats(26%), injection site reaction (35% to 44%), weight increased (9% to 11%), Increased liver aminotransferase level
SERIOUS
Hypersensitivity reaction, prolonged QT interval

NOTE: 儲存30℃以下

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『藍』蓋透明玻璃小瓶，附4.2mL溶劑

08.10F Other hormones

37990 **X / Infant risk can**

Firmagon 120mg, Powder and Solvent for Solution for Injection 輔美康注射劑120毫克

■■Degarelix 120mg pow in vial

Dosage: 1常備品 37990

Adult
· Advanced prostate cancer: SC, initial 240 mg(as 2 injections of 120 mg each); MD 80 mg once monthly.

Pediatric
· Safety and efficacy not established

Dosing adjustments in hepatic impairment:

mild-to-moderate hepatic impairment: no dosage adjustment needed.
severe hepatic impairment: Use with caution

Dosing adjustments in renal impairment:

mild-to-moderate renal impairment: no dosage adjustment needed.
severe renal impairment: Use with caution

P: Inj: 80mg vial(31280), 120mg vial(37990)

ADR:

COMMON
Hot sweats(26%), injection site reaction (35% to 44%), weight increased (9% to 11%), Increased liver aminotransferase level
SERIOUS
Hypersensitivity reaction, prolonged QT interval

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『白』蓋透明玻璃小瓶，附3mL溶劑

08.10G Immunomodulating Agents

27204 **C / Unknown(有**

LEVAZOL* TABLETS 40MG (LEVAMISOLE) "S.T." 力維舒錠４０公絲（樂瓦米索）

■■Levamisole 40mg tab

Dosage: 1常備品 27204

Adult
·Adjunctive therapy in combination with fluorouracil in Duke's stage C colon cancer: PO, initial 50mg q8h

for 3 days, started within 7-30 days of surgery, then 50mg q8h for 3days every 2wks. (fluorouracil is always given concomitantly).

Pediatric
·Ascariasis: PO, single doses of 3mg/kg
·Pediculosis: PO, 3.5mg/kg/daily for 10 days
·Nephrotic syndrome: PO, 2.5 mg/kg on alternate days.

Dosing adjustments in hepatic impairment:

Dosage adjustment required.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: DECARIS* 50mg, LEVAZOL* 40mg(27204)

ADR:

N/V, diarrhea, myelosuppression, neurologic syndrome, vasculitis

NOTE: 室溫儲存25℃以下

藥名相似:

外觀相似: Metisone* Methylprednisolone (25601), Eltro

外觀描述: 橘色橢圓扁錠，一面中央有刻痕

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1025466

08.10G Immunomodulating Agents

27213 **X / Unsafe**

Thado Capsules 50 mg 賽得膠囊 50 毫克

■■Thalidomide 50mg cap

Dosage: 1常備品 27213

Adult
·Multiple myeloma: PO, 200mg qd (combination with dexamethasone 40 mg orally once daily on days 1 to 4 , 9 to 12, and 17 to 20 every 28 days treatment cycles.)
·Multiple myeloma: PO, 200-400 mg qd in combination with melphalan and prednisone

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: 50mg(27213多發性骨髓瘤)(27246痲瘋結節性紅斑, 急用藥)

ADR:

COMMON
Edema, rash, hypocalcemia, constipation, nausea, leukopenia, confusional state, somnolence, tremor
SERIOUS
Stevens-Johnson syndrome, toxic epidermal necrolysis, teratogenesis, neutropenia, thrombosis, peripheral neuropathy, seizure (rare), pulmonary embolism

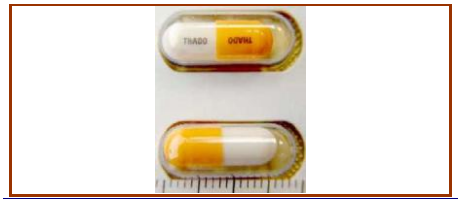
NOTE: 室溫儲存

·Thalidomide can cause severe, life-threatening birth defects and is contraindicated in pregnant women.
·Dosage may be administered once daily at bedtime or in 2-3 divided doses; it should be taken on an empty stomach or at least 1 hour after meals.
·Thalidomide also appears active for treating breast cancer, prostate cancer, Kaposi's sarcoma, glioblastoma, multiple myeloma, unresponsive chronic graft-versus-host disease, discoid lupus erythematosus, Behcet's syndrome, refractory oropharyngeal ulceration and wasting in AIDS patients.

藥名相似:

外觀相似:

外觀描述: 黃色/白色膠囊，有THADO字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048969

08.10G Immunomodulating Agents

27244 **X / Unsafe**

Revlimid Capsules 5mg 瑞復美膠囊5毫克

■■急用Lenalidomide 5mg cap

Dosage: 2急用藥 27244

Adult
·Multiple myeloma in patients who have received at least one prior therapy: PO, 25mg qd for 21 days of a 28-day cycle in combination with dexamethasone. The recommended dose of dexamethasone is 40mg qd on days 1-4, 9-12 and 17-20 of each cycle for the first 4 cycles, followed by 40mg qd on days 1-4 of each cycle

Pediatric
·Safety and efficacy have not been established in patients less than 18 years old.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 30-60mL/min: 10mg q24h
Clcr < 30mL/min (not on dialysis): 15mg q48h
Clcr < 30mL/min (on dialysis): 5mg q24h.
Administer after dialysis.

P: Cap: 25mg(27248), 15mg(27247), 10mg(27245), 5mg(27244)

ADR:

COMMON
Peripheral edema, Pruritus, Rash, Hypokalemia, Weight decreased, Constipation, Diarrhea, Gastroenteritis, Nausea, All Grades Anemia, All Grades Leukopenia, All Grades Neutropenia, All Grades Thrombocytopenia, Arthralgia, Backache, Cramp, Asthenia, Dizziness, Headache, Insomnia, Tremor, Blurred vision, Bleeding from nose,

Bronchitis, Cough, Dyspnea, Nasopharyngitis, Pharyngitis, Upper respiratory infection, Fatigue, Fever.
SERIOUS
Grade 3 or 4 Atrial fibrillation, Cerebrovascular accident, Grade 3 or 4 Congestive heart failure, Myocardial infarction (Less than 5%), Grade 3 or 4 Syncope, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Acute myeloid leukemia, Grade 3 or 4 Anemia, All Grades Deep venous thrombosis, Grade 3 or 4 Deep venous thrombosis, Grade 3 or 4 Febrile neutropenia, Hematologic neoplasm, Grade 3 or 4 Leukopenia, Myelodysplastic syndrome, Grade 3 or 4 Neutropenia, Grade 3 or 4 Thrombocytopenia, Thrombosis, Hepatotoxicity, Liver failure, Anaphylaxis, Drug reaction with eosinophilia and systemic symptoms, Hypersensitivity reaction, Rhabdomyolysis, Grade 3 or 4 Cataract, Acute kidney injury, nontraumatic, acute Interstitial nephritis, Hypoxia, Infectious disease of lung, Pleural effusion, Pneumonia, Pneumonitis, Grade 3 or 4 Pulmonary embolism, Pulmonary hypertension, Respiratory distress, Angioedema, Multiple organ failure, Secondary malignant neoplastic disease, Sepsis, Tumor flare, Tumor lysis syndrome.

NOTE: 室溫儲存

·《Contraindications》Pregnancy; known teratogen, pregnancy testing required and women of childbearing potential must take adequate precautions to prevent pregnancy for at least 4 weeks prior to initiation of treatment, during treatment, and for at least 4 weeks following discontinuation of treatment; Severe hypersensitivity to lenalidomide (eg, angioedema, Stevens-Johnson syndrome, toxic epidermal necrolysis) ;
·Swallow whole; do not break, chew or open.
·Use two forms of effective birth control to avoid pregnancy for 4 weeks before, during treatment and for 4 weeks after treatment ends.

藥名相似:

外觀相似:

外觀描述: 白色膠囊，有"REV"及"5mg"字樣

08.10G Immunomodulating Agents

27245 X / Unsafe

Revlimid Capsules 10mg 瑞復美膠囊10毫克

■■急用Lenalidomide 10mg cap

Dosage: 2急用藥 27245

Adult
·Multiple myeloma in patients who have received at least one prior therapy: PO, 25mg qd for 21 days of a 28-day cycle in combination with dexamethasone. The recommended dose of dexamethasone is 40mg qd on days 1-4, 9-12 and 17-20 of each cycle for the first 4 cycles, followed by 40mg qd on days 1-4 of each cycle

Pediatric
·Safety and efficacy have not been established in patients less than 18 years old.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 30-60mL/min: 10mg q24h
Clcr < 30mL/min (not on dialysis): 15mg q48h
Clcr < 30mL/min (on dialysis): 5mg q24h. Administer after dialysis.

P: Cap: 25mg(27248), 15mg(27247), 10mg(27245), 5mg(27244)

ADR:

COMMON
Peripheral edema, Pruritus, Rash, Hypokalemia, Weight decreased, Constipation, Diarrhea, Gastroenteritis, Nausea, All Grades Anemia, All Grades Leukopenia, All Grades Neutropenia, All Grades Thrombocytopenia, Arthralgia, Backache, Cramp, Asthenia, Dizziness, Headache, Insomnia, Tremor, Blurred vision, Bleeding from nose, Bronchitis, Cough, Dyspnea, Nasopharyngitis, Pharyngitis, Upper respiratory infection, Fatigue, Fever.
SERIOUS
Grade 3 or 4 Atrial fibrillation, Cerebrovascular accident, Grade 3 or 4 Congestive heart failure, Myocardial infarction (Less than 5%), Grade 3 or 4 Syncope, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Acute myeloid leukemia, Grade 3 or 4 Anemia, All Grades Deep venous thrombosis, Grade 3 or 4 Deep venous thrombosis, Grade 3 or 4 Febrile neutropenia, Hematologic neoplasm, Grade 3 or 4 Leukopenia, Myelodysplastic syndrome, Grade 3 or 4 Neutropenia, Grade 3 or 4 Thrombocytopenia, Thrombosis, Hepatotoxicity, Liver failure, Anaphylaxis, Drug reaction with eosinophilia and systemic symptoms, Hypersensitivity reaction, Rhabdomyolysis, Grade 3 or 4 Cataract, Acute kidney injury, nontraumatic, acute Interstitial nephritis, Hypoxia, Infectious disease of lung, Pleural effusion, Pneumonia, Pneumonitis, Grade 3 or 4 Pulmonary embolism, Pulmonary hypertension, Respiratory distress, Angioedema, Multiple organ failure, Secondary malignant neoplastic disease, Sepsis, Tumor flare, Tumor lysis syndrome.

NOTE: 室溫儲存

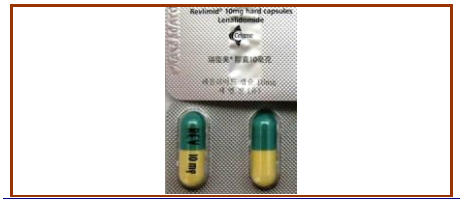
·《Contraindications》Pregnancy; known teratogen, pregnancy testing required and women of childbearing potential must take adequate precautions to prevent pregnancy for at least 4 weeks prior to initiation of treatment, during treatment, and for at least 4 weeks following discontinuation of treatment; Severe hypersensitivity to lenalidomide (eg, angioedema, Stevens-Johnson syndrome, toxic epidermal necrolysis) ;
·Swallow whole; do not break, chew or open.
·Use two forms of effective birth control to avoid

pregnancy for 4 weeks before, during treatment and for 4 weeks after treatment ends.

藥名相似:

外觀相似:

外觀描述: 黃色/淺綠色膠囊，印有REV及10mg字樣



08.10G Immunomodulating Agents

27246 **X / Unsafe**

THADO CAPSULES 50MG 賽得 膠囊 5 0 毫克

■■(罕藥)急用Thalidomide 50mg cap

Dosage: 2急用藥 27246

Adult

·Cutaneous erythema nodosum leprosum (ENL): PO, initial 100 to 300mg/day.Max. 400mg/day. Dosing should continue until active reaction subsides, then tapered in 50mg decrements every 2-4 wks

·Prevent recurrence of ENL: PO, Minimum dose necessary should be used; taper every 3-6 mons in decrements of 50mg every 2-4 wks

Prediatric

·Erythema nodosum leprosum (ENL) ?12 years: Prophylaxis; every 3 to 6 mons in decrements of 50 mg every 2 to 4 wks.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: 50mg(27213多發性骨髓瘤)(27246痲瘋結節性紅斑, 急用藥)

ADR:

COMMON

Edema, rash, hypocalcemia, constipation, nausea, leukopenia, confusional state, somnolence, tremor

SERIOUS

Stevens-Johnson syndrome, toxic epidermal necrolysis, teratogenesis, neutropenia, thrombosis, peripheral neuropathy, seizure (rare), pulmonary embolism

NOTE: 室溫儲存

·Thalidomide can cause severe, life-threatening birth defects and is contraindicated in pregnant women.

·Dosage may be administered once daily at bedtime or in 2-3 divided doses; it should be taken on an empty stomach or at least 1 hour after meals.

藥名相似:

外觀相似:

外觀描述: 黃色/白色膠囊，有THADO字樣

08.10G Immunomodulating Agents

27247 **X / Unsafe**

Revlimid Capsules 15mg 瑞復美膠囊15毫克

■■急用Lenalidomide 15mg cap

Dosage: 2急用藥 27247

Adult

·Multiple myeloma in patients who have received at least one prior therapy: PO, 25mg qd for 21 days of a 28-day cycle in combination with dexamethasone. The recommended dose of dexamethasone is 40mg qd on days 1-4, 9-12 and 17-20 of each cycle for the first 4 cycles, followed by 40mg qd on days 1-4 of each cycle

Pediatric

·Safety and efficacy have not been established in patients less than 18 years old.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 30-60mL/min: 10mg q24h
Clcr < 30mL/min (not on dialysis): 15mg q48h
Clcr < 30mL/min (on dialysis): 5mg q24h. Administer after dialysis.

P: Cap: 25mg(27248), 15mg(27247)

ADR:

COMMON

Peripheral edema, Pruritus, Rash, Hypokalemia, Weight decreased, Constipation, Diarrhea, Gastroenteritis, Nausea, All Grades Anemia, All Grades Leukopenia, All Grades Neutropenia, All Grades Thrombocytopenia, Arthralgia, Backache, Cramp, Asthenia, Dizziness, Headache, Insomnia, Tremor, Blurred vision, Bleeding from nose, Bronchitis, Cough, Dyspnea, Nasopharyngitis, Pharyngitis, Upper respiratory infection, Fatigue, Fever.

SERIOUS

Grade 3 or 4 Atrial fibrillation, Cerebrovascular accident, Grade 3 or 4 Congestive heart failure, Myocardial infarction (Less than 5%), Grade 3 or 4 Syncope, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Acute myeloid leukemia, Grade 3 or 4 Anemia, All Grades Deep venous thrombosis, Grade 3 or 4 Deep venous thrombosis, Grade 3 or 4 Febrile neutropenia, Hematologic neoplasm, Grade 3 or 4 Leukopenia, Myelodysplastic syndrome, Grade 3 or 4 Neutropenia, Grade 3 or 4 Thrombocytopenia, Thrombosis, Hepatotoxicity, Liver failure, Anaphylaxis, Drug reaction with eosinophilia and systemic symptoms, Hypersensitivity reaction, Rhabdomyolysis, Grade 3 or 4 Cataract, Acute kidney injury, nontraumatic, acute Interstitial nephritis, Hypoxia, Infectious disease of lung,

Pleural effusion, Pneumonia, Pneumonitis, Grade 3 or 4 Pulmonary embolism, Pulmonary hypertension, Respiratory distress, Angioedema, Multiple organ failure, Secondary malignant neoplastic disease, Sepsis, Tumor flare, Tumor lysis syndrome.

NOTE: 室溫儲存

·《Contraindications》Pregnancy; known teratogen, pregnancy testing required and women of childbearing potential must take adequate precautions to prevent pregnancy for at least 4 weeks prior to initiation of treatment, during treatment, and for at least 4 weeks following discontinuation of treatment; Severe hypersensitivity to lenalidomide (eg, angioedema, Stevens-Johnson syndrome, toxic epidermal necrolysis) ;
·Swallow whole; do not break, chew or open.
·Use two forms of effective birth control to avoid pregnancy for 4 weeks before, during treatment and for 4 weeks after treatment ends.

藥名相似:

外觀相似:

外觀描述: 白色/藍色膠囊，印有REV及15mg字樣

08.10G Immunomodulating Agents

27248 **X / Unsafe**

Revlimid Capsules 25mg 瑞復美膠囊25毫克

■■急用Lenalidomide 25mg cap

Dosage: 2急用藥 27248

Adult
·Multiple myeloma in patients who have received at least one prior therapy: PO, 25mg qd for 21 days of a 28-day cycle in combination with dexamethasone. The recommended dose of dexamethasone is 40mg qd on days 1-4, 9-12 and 17-20 of each cycle for the first 4 cycles, followed by 40mg qd on days 1-4 of each cycle

Pediatric
·Safety and efficacy have not been established in patients less than 18 years old.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 30-60mL/min: 10mg q24h
Clcr < 30mL/min (not on dialysis): 15mg q48h
Clcr < 30mL/min (on dialysis): 5mg q24h.
Administer after dialysis.

P: Cap: 25mg(27248), 15mg(27247)

ADR:

COMMON
Peripheral edema, Pruritus, Rash, Hypokalemia, Weight decreased, Constipation, Diarrhea, Gastroenteritis, Nausea, All Grades Anemia, All Grades Leukopenia, All Grades Neutropenia, All Grades Thrombocytopenia, Arthralgia, Backache, Cramp, Asthenia, Dizziness, Headache, Insomnia, Tremor, Blurred vision, Bleeding from nose, Bronchitis, Cough, Dyspnea, Nasopharyngitis, Pharyngitis, Upper respiratory infection, Fatigue, Fever.
SERIOUS
Grade 3 or 4 Atrial fibrillation, Cerebrovascular accident, Grade 3 or 4 Congestive heart failure, Myocardial infarction (Less than 5%), Grade 3 or 4 Syncope, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Acute myeloid leukemia, Grade 3 or 4 Anemia, All Grades Deep venous thrombosis, Grade 3 or 4 Deep venous thrombosis, Grade 3 or 4 Febrile neutropenia, Hematologic neoplasm, Grade 3 or 4 Leukopenia, Myelodysplastic syndrome, Grade 3 or 4 Neutropenia, Grade 3 or 4 Thrombocytopenia, Thrombosis, Hepatotoxicity, Liver failure, Anaphylaxis, Drug reaction with eosinophilia and systemic symptoms, Hypersensitivity reaction, Rhabdomyolysis, Grade 3 or 4 Cataract, Acute kidney injury, nontraumatic, acute Interstitial nephritis, Hypoxia, Infectious disease of lung, Pleural effusion, Pneumonia, Pneumonitis, Grade 3 or 4 Pulmonary embolism, Pulmonary hypertension, Respiratory distress, Angioedema, Multiple organ failure, Secondary malignant neoplastic disease, Sepsis, Tumor flare, Tumor lysis syndrome.

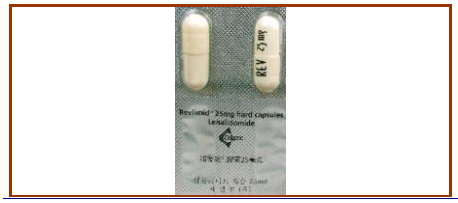
NOTE: 室溫儲存

·《Contraindications》Pregnancy; known teratogen, pregnancy testing required and women of childbearing potential must take adequate precautions to prevent pregnancy for at least 4 weeks prior to initiation of treatment, during treatment, and for at least 4 weeks following discontinuation of treatment; Severe hypersensitivity to lenalidomide (eg, angioedema, Stevens-Johnson syndrome, toxic epidermal necrolysis) ;
·Swallow whole; do not break, chew or open.
·Use two forms of effective birth control to avoid pregnancy for 4 weeks before, during treatment and for 4 weeks after treatment ends.

藥名相似:

外觀相似:

外觀描述: 白色膠囊，印有REV及25mg字樣



08.10G Immunomodulating Agents

27942 **demonstrated / Infant risk can**

POMALYST 4mg capsules 鉑美特膠囊4毫克

■■急用Pomalidomide 4mg cap

Dosage: 2急用藥 27942

·Multiple myeloma in patients who have received at least one prior therapy: PO, 4mg qd for 21 days of a 28-day cycle in combination with dexamethasone. The recommended dose of dexamethasone is 40mg qd on days 1, 8, 15, and 22 of each 28-day cycle (<75 years) or dexamethasone 20 mg qd on days 1, 8, 15, and 22 of each 28-day cycle (>75 years)

·Safety and efficacy in pediatric patients have not been established

Dosing adjustments in hepatic impairment:

serum bilirubin >2 mg/dL and AST/ALT > 3 times ULN: Avoid use

Dosing adjustments in renal impairment:

serum creatinine > 3mg/dL: Avoid use

P: Cap: 25mg(27248), 15mg(27247)

ADR:

COMMON
Peripheral edema, pruritus, rash, hypokalemia, weight decreased, constipation, diarrhea, nausea, anemia, leukopenia, neutropenia, thrombocytopenia, arthralgia, backache, cramp, asthenia, dizziness, headache, insomnia, tremor, blurred vision, cough, dyspnea, epistaxis, nasopharyngitis, pharyngitis, upper respiratory infection fatigue, feve, infectious disease
SERIOUS
Atrial fibrillation (grade 3/4), cerebrovascular accident, congestive heart failure (grade 3/4), myocardial infarction, syncope (grade 3/4), Stevens-Johnson syndrome, toxic epidermal necrolysis, anemia (grade 3/4), deep venous thrombosis, febrile neutropenia (grade 3/4), leukopenia (grade 3/4), neutropenia (grade 3/4), thrombocytopenia (grade 3/4), thrombosis, liver failure, cataract (grade 3/4), acute interstitial nephritis, hypoxia, pleural effusion, pneumonia, pneumonitis, pulmonary embolism (grade 3/4), pulmonary hypertension (grade 3/4), respiratory distress (grade 3/4), angioedema, multiple organ failure, secondary malignant neoplastic disease, tumor flare, tumor lysis syndrome

NOTE: 室溫儲存

·Swallow whole; do not break, chew or open.
·Use two forms of effective birth control to avoid pregnancy for 4 weeks before, during treatment and for 4 weeks after treatment ends.
·在dexamethasone加thalidomide類似物的療程中加入pembrolizumab時，多發性骨髓瘤患者的死亡率會升高。

藥名相似:

外觀相似:

外觀描述: 深藍/淺藍色膠囊，有POML及 4mg字樣

08.12A Platinum Compounds

31205 **D / Unknown(有**

■■Carboplatin inj 450mg/45mL vial

Dosage: 1常備品 31205

Adult
· Ovarian cancer-combination therapy: 300mg/m(2) once Q 4 wks x 6 cycles or target AUC 4-6
· Calvert dosing:Dose(mg)=target (AUC)x(GFR+25)

Pediatric
· Safety and effectiveness in pediatric patients have not been established
· 175-600mg/m(2) IV has been used in various protocols

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

For the initial course of therapy
Clcr 41-59mL/min: Give 250mg/m2
Clcr 16-40mL/min: Give 200mg/m2

P: Inj: 450mg/45mL Vial(31205)

ADR:

NOTE: 室溫儲存15-30℃避光

1. Do not use with infusion sets/needles containing aluminum.

藥名相似:

外觀相似:

外觀描述: 45mL注射液，『黃』蓋透明玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024804

08.12A Platinum Compounds

31250 **D / Unknown(有**

OXALIP* INJECTION 歐力普注射劑

■■Oxaliplatin inj 50mg/10mL vial

Dosage: 1常備品 31250

Adult
· Colorectal cancer, metastatic: IV, 85mg/m(2) in 250-500 mL D5W over 2 hrs repeat every 2 weeks
· Carcinoma of stomach, advanced/metastatic: 85 mg/m(2) repeat every 2 week

Pediatric
· Safety and effectiveness have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Use with caution

P: Inj: 50mg/10mL Vial(31250, 急用37796)

ADR:

COMMON

Abdominal pain, anorexia, diarrhea, N/V, stomatitis, back pain, cough, fatigue, fever
SERIOUS
Anaphylactic/hypersensitivity reactions, anemia, leukopenia, neutropenia, thrombocytopenia, dyspnea, edema, elevated liver enzymes, febrile neutropenia
neuropathies (acute and persistent), thromboembolism, pharyngolaryngeal dysesthesia

NOTE: 室溫儲存

1.Antiemetic premedicate (5-HT3 blocker with or without dexamethasone) is recommended
2.Cold temperatures can precipitate/exacerbate neurologic symptoms-avoid during the infusion of oxaliplatin
3.Never reconstitute/dilute with a chloride-containing solution;
4.Avoid aluminum parts when preparing/mixing oxaliplatin
5.Incompatible with alkaline media (ie, solutions of 5-fluorouracil)
6.Prepare oxaliplatin in 250-500 Ml D5W

藥名相似:

外觀相似:

外觀描述: 透明溶液、『藍』蓋褐色玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044508

08.12A Platinum Compounds

31265 D /

Kemoplat Injection 1mg/ml 克莫抗癌注射劑1毫克/毫升

■■Cisplatin inj 50mg/50mL vial

Dosage: 1常備品 31265

Adult
· Bladder cancer, advanced: IV, single agent 50-70 mg/m(2) per cycle every 3-4 weeks
· Ovarian cancer, metastatic (single): IV, 100mg/m(2)/cycle every 4 weeks as a single agent; (combination): IV, 75-100mg/m(2)/cycle every 4 weeks (day 1) in combination with cyclophosphamide
· Ovarian cancer, metastatic: Intraperitoneally, 90-200mg/m(2) q3w
· Testicular cancer, metastatic: IV, 20mg/m(2) every day for 5 days per cycle with other approved agents

Pediatric: NDA

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

GFR 10-50mL/min: 75% of the usual dose
GFR<10mL/min: 50% of the usual dose given at the normal dosage interval

P: Inj: 50mg/50mL Vial(31265)

ADR:

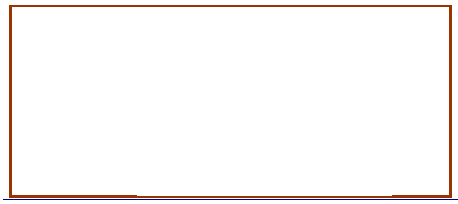
COMMON
Electrolyte imbalance
SERIOUS
Nausea, vomiting, myelosuppression, peripheral neuropathy, ototoxicity, nephrotoxicity

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 50mL注射液．『綠』蓋棕色不透明玻璃瓶



08.12A Platinum Compounds

31279 ɔt be ruled out / Infant risk can

ORECTALIP IV INJECTION 5MG/ML "Sinphar" "杏輝" 杏瑞鉑靜脈注射液5毫克/毫升

■■癌Oxaliplatin inj 100MG/20mL vial

Dosage: 1常備品 31279

ADULT
· Colorectal cancer, metastatic: 85 mg/m(2) IV in 250-500 mL D5W over 2 hrs repeat every 2 weeks

PEDIATRIC
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

· No dosage adjustment needed

Dosing adjustments in renal impairment:

· CrCl≧30 mL/minute: No dosage adjustment needed
· CrCl< 30 mL/minute: Reduce dose from 85 mg/m2 to 65 mg/m2

P: P Inj: 100mg/20mL(31279), 50mg/10mL (31250)

ADR:

COMMON
Abdominal pain, anorexia, diarrhea, N/V, stomatitis, back pain, cough, fatigue, fever
SERIOUS
Anaphylactic/hypersensitivity reactions, anemia, leukopenia, neutropenia, thrombocytopenia, dyspnea, edema, elevated liver enzymes, febrile neutropenia
neuropathies (acute and persistent), thromboembolism, pharyngolaryngeal dysesthesia

NOTE: 室溫儲存

1.Antiemetic premedicate (5-HT3 blocker with or without dexamethasone) is recommended
2.Cold temperatures can precipitate/exacerbate neurologic symptoms-avoid during the infusion of oxaliplatin
3.Never reconstitute/dilute with a chloride-containing solution;
4.Avoid aluminum parts when preparing/mixing oxaliplatin
5.Incompatible with alkaline media (ie, solutions of 5-fluorouracil)

6.Prepare oxaliplatin in 250-500 Ml D5W

藥名相似:

外觀相似:

外觀描述:

08.12B Monoclonal Antibodies

31243 **D / Unknown(有**

Herceptin Vial 440mg 賀癌平 凍晶注射劑440毫克

■■Trastuzumab 440mg pow in vial with 20mL solvent

Dosage: 1常備品 31243

Adult

· Breast cancer: loading dose, 4mg/kg IV over 90 min; maintenance dose: 2mg/kg IV over 30minutes weekly or loading dose 8 mg/kg IV over 90 min; maintenance dose 6 mg/kg IV over 30-90 min every 3 weeks

· Gastric cancer, metastatic, HER2 overexpression: loading dose 8 mg/kg IV over 90 min; maintenance dose 6 mg/kg IV over 30-90 min every 3 weeks

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 440mg Vial(31243)

ADR:

COMMON

·Rash, weight decreased, diarrhea, nausea, stomatitis, vomiting, anemia, neutropenia, thrombocytopenia, infectious disease, headache, insomnia, cough, fatigue, fever, shivering.

SERIOUS

·Cardiac dysrhythmia, heart failure, left ventricular cardiac dysfunction, myocardial ischemia, febrile neutropenia, neutropenia, thrombocytopenia, thrombosis, hypersensitivity reaction, renal failure, dyspnea, acute interstitial pneumonia, pulmonary hypertension, pulmonary toxicity, infusion reaction, tumor lysis syndrome.

NOTE: 冰箱儲存

1.Do not give IV push or bolus
2.Reconstitute with 20mL SWFI or BWFI to a concentration of 21mg/mL; then dilute with NS (NOT use D5W)
3. Reconstituted soliution is stable for 28 days under refrigeration.

藥名相似:

外觀相似:

外觀描述: 每盒含一綠蓋透明玻璃瓶內裝乾粉,及白蓋透明玻璃瓶含20ml稀釋液

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=60000961

08.12B Monoclonal Antibodies

31244 **C / Unsafe**

Mabthera solution for IV Infusion 莫須瘤注射劑

■■Rituximab inj 500mg/50mL vial

Dosage: 1常備品 31244

Adult

· Lymphoma, non-Hodgkin's: IV infusion, 375mg/m(2) once weekly for 4 or 8 doses; may retreat with additional 4 doses with progressive disease

· Lymphoma, non-Hodgkin's: in combination with ibritumomab tiuxetan, IV infusion, 250mg/m(2) within 4 hr prior to administration of indium-111 ibritumomab tiuxetan, then 7-9 days later within 4 hr prior to administration of yttrium-90 ibritumomab tiuxetan

· Chronic lymphoid leukemia: 375 mg/m(2) IV for first cycle and 500 mg/m(2) for subsequent cycles, in combination with fludarabine and cyclophosphamide

· Rheumatoid arthritis: 1000 mg followed by a second 1000 mg 2 weeks later in combination with MTX every 24 weeks

Pediatric: NDA

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 500mg/50mL Vial(31244); 100mg/10mL Vial(31245)

ADR:

COMMON

Asthenia, dizziness, headache, nausea, vomiting, pruritus, rash

SERIOUS

Angina, cardiac arrhythmias, lymphopenia (frequent), hemolytic anemia (rare), transient aplastic anemia (rare), infection, sepsis, infusion-related symptom complex (fever, chills/rigors, nausea, urticaria, angioedema, bronchospasm, hypotension) (frequent), lichenoid dermatitis, paraneoplastic pemphigus, Stevens-Johnson syndrome, renal toxicity, toxic epidermal necrolysis, vesiculobullous dermatitis, tumor lysis syndrome (rare)

NOTE: 冰箱儲存

1.Premedicate with acetaminophen and diphenhydramine before each infusion
2.Infusion time at initial: 6-8 hrs, subsequent infusion time: 4-6 hrs
3.Do not administer as an IV push or bolus

藥名相似:

外觀相似:

外觀描述: 50mL透明注射液『灰』蓋透明玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000928

08.12B Monoclonal Antibodies

31245 **C / Unsafe**

Mabthera solution for IV Infusion 莫須瘤注射劑

■■Rituximab inj 100mg/10mL vial

Dosage: 1常備品 31245

Adult

· Lymphoma, non-Hodgkin's: IV infusion, 375mg/m(2) once weekly for 4 or 8 doses; may retreat with additional 4 doses with progressive disease

· Lymphoma, non-Hodgkin's: in combination with ibritumomab tiuxetan, IV infusion, 250mg/m(2) within 4 hr prior to administration of indium-111 ibritumomab tiuxetan, then 7-9 days later within 4 hr prior to administration of yttrium-90 ibritumomab tiuxetan

· Chronic lymphoid leukemia: 375 mg/m(2) IV for first cycle and 500 mg/m(2) for subsequent cycles, in combination with fludarabine and cyclophosphamide

· Rheumatoid arthritis: 1000 mg followed by a second 1000 mg 2 weeks later in combination with MTX every 24 weeks

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 500mg/50mL Vial(31244); 100mg/10mL Vial(31245)

ADR:

COMMON

Asthenia, dizziness, headache, nausea, vomiting, pruritus, rash

SERIOUS

Angina, cardiac arrhythmias, lymphopenia, hemolytic anemia, transient aplastic anemia infection, sepsis, infusion-related symptom complex (fever, chills/rigors, nausea, urticaria, angioedema, bronchospasm, hypotension), lichenoid dermatitis, paraneoplastic pemphigus, Stevens-Johnson syndrome, renal toxicity, toxic epidermal necrolysis, vesiculobullous dermatitis, tumor lysis syndrome

NOTE: 冰箱冷藏2-8℃，不可冷凍。

1.Premedicate with acetaminophen and diphenhydramine before each infusion
2.Infusion time at initial: 6-8 hrs, subsequent infusion time: 4-6 hrs
3.Do not administer as an IV push or bolus

藥名相似:

外觀相似:

外觀描述: 10mL透明注射液『紅』蓋透明玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000928

08.12B Monoclonal Antibodies

31248 **C / Unsafe**

AVASTIN INJECTION 癌思停 注射劑

■■Bevacizumab 100mg/4mL vial

Dosage: 1常備品 31248

Adult

·Metastatic breast cancer, HER2-negative, as first-line therapy in combination with paclitaxel: IV infusion, 10mg/kg every 14 days in combination with paclitaxel

·Metastatic colorectal cancer in combination with 5-fluorouracil-based chemotherapy as first-line or second-line therapy: IV infusion, 5 or 10mg/kg every 2 weeks

·Non-small cell lung cancer, first-line treatment in combination with paclitaxel and carboplatin for unresectable, locally advanced, recurrent or metastatic non-squamous cell disease: IV infusion, 15mg/kg every 3 weeks

·Glioblastoma multiforme: 10 mg/kg IV every 2 weeks

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 100mg(31248)(眼科以次計價, 37879)

ADR:

COMMON

Alopecia, abdominal pain, constipation, loss of appetite, stomatitis, asthenia, dizziness, headache, proteinuria, change in voice, dyspnea, epistaxis, upper respiratory infection

SERIOUS

Arterial thromboembolism (up to 8.5%), congestive heart failure, deep venous thrombosis, hypertension, thromboembolic disorder, venous thromboembolism, impaired wound healing, wound dehiscence, hyponatremia, diarrhea, gastrointestinal hemorrhage, gastrointestinal perforation, tracheoesophageal fistula, bleeding, leukopenia, neutropenia, thrombocytopenia, severe complication of infusion, asthenia, reversible posterior leukoencephalopathy syndrome, nephrotic syndrome, hemoptysis, pulmonary hemorrhage

NOTE: 冰箱冷藏，不可冷凍。

1. Infuse the initial dose over 90 mins; if tolerated,

rate may be increased with subsequent doses; given over 60 mins for the second infusion; given over 30 mins for subsequent infusions.

藥名相似:

外觀相似:

外觀描述: 4mL透明注射液『灰』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000807

08.12B Monoclonal Antibodies

31273 **C / Unsafe**

MABTHERA* solution for subcutaneous injection 莫須瘤皮下注射劑

■■急用Rituximab inj 1400mg/11.7mL vial

Dosage: 2急用藥 31273

Adult

· Lymphoma, non-Hodgkin's: IV infusion, 375mg/m(2) once weekly for 4 or 8 doses; may retreat with additional 4 doses with progressive disease

· Lymphoma, non-Hodgkin's: in combination with ibritumomab tiuxetan, IV infusion, 250mg/m(2) within 4 hr prior to administration of indium-111 ibritumomab tiuxetan, then 7-9 days later within 4 hr prior to administration of yttrium-90 ibritumomab tiuxetan

· Chronic lymphoid leukemia: 375 mg/m(2) IV for first cycle and 500 mg/m(2) for subsequent cycles, in combination with fludarabine and cyclophosphamide

· Rheumatoid arthritis: 1000 mg followed by a second 1000 mg 2 weeks later in combination with MTX every 24 weeks

Pediatric: NDA

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 500mg/50mL Vial(31244); 100mg/10mL Vial(31245); SC: 1400mg/11.7mL Vial(31273)

ADR:

COMMON
Asthenia, dizziness, headache, nausea, vomiting, pruritus, rash
SERIOUS
Angina, cardiac arrhythmias, lymphopenia (frequent), hemolytic anemia (rare), transient aplastic anemia (rare), infection, sepsis, infusion-related symptom complex (fever, chills/rigors, nausea, urticaria, angioedema, bronchospasm, hypotension) (frequent), lichenoid dermatitis, paraneoplastic pemphigus, Stevens-Johnson syndrome, renal toxicity, toxic epidermal necrolysis, vesiculobullous dermatitis, tumor lysis syndrome (rare)

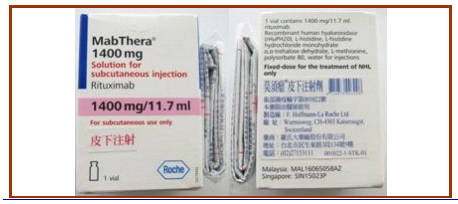
NOTE: 冷藏2-8℃

1.Premedicate with acetaminophen and diphenhydramine before each infusion
2.Infusion time at initial: 6-8 hrs, subsequent infusion time: 4-6 hrs
3.Do not administer as an IV push or bolus

藥名相似:

外觀相似:

外觀描述: 50mL透明注射液『灰』蓋透明玻璃瓶



08.12B Monoclonal Antibodies

37535 **D / Unknown(有**

Perjeta Vial 420mg 賀疾妥注射液420毫克

■■Pertuzumab inj 420mg/14mL vial

Dosage: 1常備品 37535

Adult

· Metastatic breast cancer, HER2 (+): IV infusion, initial 840 mg over 60 mins followed by MD 420 mg over 30-60 mins q3W in combination with trastuzumab and docetaxel

Pediatric

· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 30-90 mL/min: no dose adjustments needed
Clcr< 30 mL/min: NDA

P: Inj: 420mg/14mL vial (37535)

ADR:

COMMON
Alopecia , rash, decrease in appetite, diarrhea, Inflammatory disease of mucous membrane, nausea, vomiting, anemia, neutropenia, asthenia, headache, peripheral neuropathy , fatigue
SERIOUS
Left ventricular cardiac dysfunction, febrile neutropenia, leukopenia, neutropenia, anaphylaxis, hypersensitivity reaction

NOTE: 冰箱儲存

· Pertuzumab and trastuzumab may be administered in any order. Docetaxel should be given after pertuzumab and trastuzumab.

· Observe patients for 30-60 minutes after each pertuzumab infusion.

藥名相似:

外觀相似:

外觀描述: 14mL注射液，咖啡蓋玻璃小瓶。

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000942

08.12B Monoclonal Antibodies

37543 **D / Unsafe**

Keytruda powder for injection 吉舒達凍晶注射劑50毫克

■■急用Pembrolizumab inj 50mg pow in vial

Dosage: 2急用藥 37543

Adult
·Melanoma、NSCLC、lymphoma、Head and neck cancer: IV infusion over 30 mins, 2mg/kg or 200mg q3w until disease progression or unacceptable toxicity

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

(1)Hepatic impairment prior to treatment
·Mild hepatic impairment (total bilirubin ?ULN and AST >ULN or total bilirubin >1-1.5X ULN and any AST): No dosage adjustment needed
·Moderate (total bilirubin >1.5-3X ULN and any AST)or severe (total bilirubin >3X ULN and any AST) hepatic impairment: NDA
(2)Hepatotoxicity during treatment
·For patients with baseline grade 2 ALT or AST abnormalities due to liver metastasis, permanently discontinue if AST or ALT increases by ?50% relative to baseline and persists at least 1 wk
·AST or ALT > 3-5X ULN or total bilirubin > 1.5-3X ULN: Withhold therapy
·AST or ALT > 5X ULN or total bilirubin > 3X ULN: Permanently discontinue

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 50mg vial(37543)

ADR:

COMMON
Pruritus, rash, constipation, decrease in appetite, diarrhea, nausea, arthralgia, cough, fatigue, hypercholesterolemia, hyperglycemia, hypertriglyceridemia, hypoalbuminemia, hyponatremia, alkaline phosphatase raised, AST/SGOT level raised, dyspnea.
SERIOUS
Erythroderma, vasculitis, adrenal insufficiency, hypophysitis, anemia (Grade 3 or 4), hemolytic anemia, hepatitis, pancreatitis, veno-occlusive disease of the liver, Eaton-Lambert syndrome, rhabdomyolysis, optic neuritis, uveitis, nephritis, renal failure, pneumonitis, sepsis, confusional state.

NOTE: 冰箱冷藏，不可冷凍。

·Administer through an IV line containing a sterile, nonpyrogenic, low-protein binding 0.2 to 5 micron inline or add-on filter.
·Immune-mediated rashes, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (with fatal cases; [TEN]), exfoliative dermatitis, and bullous pemphigoid have been reported; monitoring recommended. Therapy interruption or discontinuation may be necessary. Permanently discontinue therapy with confirmed SJS or TEN

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『綠』蓋透明玻璃小瓶

08.12B Monoclonal Antibodies

37544 **D / Unsafe**

Keytruda Injection 吉舒達注射劑

■■Pembrolizumab inj 100mg/4mL vial

Dosage: 1常備品 37544

Adult
·Melanoma、NSCLC、lymphoma、Head and neck cancer: IV infusion over 30 mins, 2mg/kg or 200mg q3w until disease progression or unacceptable toxicity

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

(1)Hepatic impairment prior to treatment
·Mild hepatic impairment (total bilirubin ?ULN and AST >ULN or total bilirubin >1-1.5X ULN and any AST): No dosage adjustment needed
·Moderate (total bilirubin >1.5-3X ULN and any AST)or severe (total bilirubin >3X ULN and any AST) hepatic impairment: NDA
(2)Hepatotoxicity during treatment
·For patients with baseline grade 2 ALT or AST abnormalities due to liver metastasis, permanently discontinue if AST or ALT increases by ?50% relative to baseline and persists at least 1 wk
·AST or ALT > 3-5X ULN or total bilirubin > 1.5-3X ULN: Withhold therapy
·AST or ALT > 5X ULN or total bilirubin > 3X ULN: Permanently discontinue

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 50mg vial(37543), 100mg/4mL vial(37544)

ADR:

COMMON
Pruritus, rash, constipation, decrease in appetite, diarrhea, nausea, arthralgia, cough, fatigue, hypercholesterolemia, hyperglycemia, hypertriglyceridemia, hypoalbuminemia, hyponatremia, alkaline phosphatase raised, AST/SGOT level raised, dyspnea.
SERIOUS
Erythroderma, vasculitis, adrenal insufficiency, hypophysitis, anemia (Grade 3 or 4), hemolytic anemia, hepatitis, pancreatitis, veno-occlusive disease of the liver, Eaton-Lambert syndrome,

rhabdomyolysis, optic neuritis, uveitis, nephritis, renal failure, pneumonitis, sepsis, confusional state.

NOTE: 冰箱冷藏，不可冷凍。

·Administer through an IV line containing a sterile, nonpyrogenic, low-protein binding 0.2 to 5 micron inline or add-on filter.
·Immune-mediated rashes, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (with fatal cases; [TEN]), exfoliative dermatitis, and bullous pemphigoid have been reported; monitoring recommended. Therapy interruption or discontinuation may be necessary. Permanently discontinue therapy with confirmed SJS or TEN

藥名相似:

外觀相似:

外觀描述: 4mL注射液、『藍』蓋透明玻璃小瓶

08.12B Monoclonal Antibodies

37545 **X / Unsafe**

OPDIVO * injection 100mg/10mL 無

■■捐贈急用Nivolumab inj 100mg/10mL vial

Dosage: 2急用藥 37545

Adult: IV infusion, over 1hr
·Unresectable or metastatic melanoma: (Single agent) 3 mg/kg q 2 wks; (In combination with ipilimumab) 1 mg/kg, followed by ipilimumab 3 mg/kg on the same day q 3 wks for 4 doses, then single-agent nivolumab 3 mg/kg q 2 wks.
·Metastatic non-small cell lung cancer with progression on or after platinum-based chemotherapy: 3 mg/kg q 2 wks
·Advanced renal cell carcinoma: 3 mg/kg q 2 wks

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

(1)Hepatitis in non-hepatocellular carcinoma:
· ALT or AST > 3-5× ULN or total bilirubin >1.5-3× ULN: withhold nivolumab until resolution to Grade 0 or 1.
· ALT or AST > 5× ULN or total bilirubin >3× ULN: permanently discontinue.
(2)Hepatitis in hepatocellular carcinoma:
· ALT or AST normal at baseline and ALT or AST > 3-5× ULN: withhold until resolution to baseline.
· ALT or AST > 1-3× ULN at baseline and ALT or AST > 5-10× ULN: withhold until resolution to baseline.
· ALT or AST > 3-5× ULN at baseline and ALT or AST > 8-10× ULN: withhold until resolution to baseline.
· ALT or AST > 10× ULN or total bilirubin >3× ULN: permanently discontinue.

Dosing adjustments in renal impairment:

· Nephritis or renal dysfunction(Scr > 1.5-6× ULN): withhold until resolution to Grade 0 or 1.
· Nephritis or renal dysfunction(Scr > 6× ULN): permanently discontinue.

P: P 100mg/10mL vial (37545, 急用藥)

ADR:

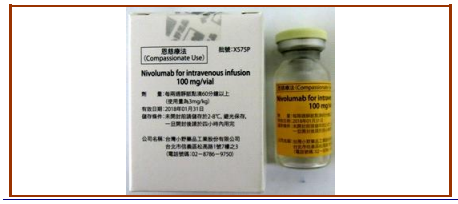
COMMON
Pruritus, rash, hyperkalemia, hypocalcemia, hyponatremia, serum cholesterol raised, serum triglycerides raised, constipation, decrease in appetite, nausea, vomiting, anemia, lymphocytopenia, alkaline phosphatase raised, arthralgia, backache, musculoskeletal pain, asthenia, headache, serum creatinine raised, cough, dyspnea, fatigue
SERIOUS
Rash(Immune-mediated), toxic epidermal necrolysis, adrenal insufficiency, diabetes mellitus, diabetic ketoacidosis, hypercalcemia, hyperglycemia, hyperthyroidism, hypophysitis, hypopituitarism, hypothyroidism, thyroiditis, colitis, diarrhea, duodenitis, gastritis, pancreatitis, perforation of colon, anemiaaa(Grade 3 or 4), lymphocytopenia(Grade 3 or 4), neutropenia(Grade 3 or 4), ALT/SGPT level raised, AST/SGOT level raised, hepatitis, serum bilirubin raised, sarcoidosis, Eaton-Lambert syndrome, demyelination of spinal cord, encephalitis, Guillain-Barre syndrome, neuropathy(autoimmune), uveitis, nephritis, renal impairment, pleural effusion, pneumonitis, pulmonary embolism, respiratory failure, infusion reaction

NOTE: 冰箱冷藏，不可冷凍。

藥名相似:

外觀相似:

外觀描述:



08.12B Monoclonal Antibodies

37622 **ɔt be ruled out / Infant risk can**

Tecentriq 癌自禦 注射劑

■■Atezolizumab 840mg vial

Dosage: 2急用藥 37622

Adult:
· Triple-negative breast cancer, unresectable locally advanced or metastatic disease with PD-L1 expression; in combination with paclitaxel protein-bound: IV, 840 mg infusion over 60 minutes for the first infusion and if tolerated over 30 minutes thereafter on days 1 and 15, followed by paclitaxel protein-bound 100 mg/m(2) on days 1, 8, and 15 of each 28-day cycle until disease progression or unacceptable toxicity

Pediatric
· Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

·Hepatic impairment (mild): No adjustment needed
·Hepatic toxicity (Grade 2, AST/ALT greater than 3 and up to 5 times ULN or total bilirubin greater than 1.5 and up to 3 times ULN): Withhold dose and provide steroids at a dose of 1 to 2 mg/kg/day predniSONE equivalents followed by corticosteroid taper; may resume when recovery to Grade 0 or 1.
·Hepatic toxicity (Grade 3 or 4, AST/ALT greater than 5 times the ULN or total bilirubin greater than 3 times the ULN): Permanently discontinue therapy.

Dosing adjustments in renal impairment:

·Renal impairment: No adjustment required

P: P Inj: 840mg/14mL vial (37622), 1200mg/20mL vial(37625,自費)(37722, 捐贈專案)

ADR:

COMMOM
Constipation, Decrease in appetite, Diarrhea, Nausea, Cough, Dyspnea,Fatigue.

SERIOUS
Myocarditis, Adrenal insufficiency, Diabetes mellitus, Hyperthyroidism, Hypophysitis, Hypothyroidism, Abdominal pain, Colitis, Pancreatitis, Hepatitis, Eaton-Lambert syndrome, Myasthenia gravis, Encephalitis, Guillain-Barre syndrome, Meningitis, Hematuria, Urinary tract infectious disease, Interstitial lung disease, Pneumonitis, Fever, Infectious disease, Infusion reaction.

NOTE: 冰箱冷藏，不可冷凍。

藥名相似:

外觀相似:

外觀描述:

08.12B Monoclonal Antibodies

37625 **ɔt be ruled out / Infant risk can**

Tecentriq 癌自禦 注射劑

■■Atezolizumab inj 1200mg/20mL vial

Dosage: 1常備品 37625

Adult: IV infusion
·Non-small cell lung cancer, Metastatic, with progression during or after platinum-based chemotherapy; patients with ALK or EGFR genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving atezolizumab: 1200 mg IV infusion over 60 minutes every 3 weeks until symptomatic disease progression or unacceptable toxicity; if first infusion is tolerated, may infuse all subsequent doses over 30 minutes.
Metastatic urothelial carcinoma, Or locally advanced, in patients not eligible for cisplatin-containing chemotherapy, or with progression during or after platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant chemotherapy: 1200 mg IV infusion over 60 minutes every 3 weeks until disease progression or unacceptable toxicity; if first infusion is tolerated, may infuse all subsequent doses over 30 minutes.

Pediatric
· Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

·Hepatic impairment (mild): No adjustment needed
·Hepatic toxicity (Grade 2, AST/ALT greater than 3 and up to 5 times ULN or total bilirubin greater than 1.5 and up to 3 times ULN): Withhold dose and provide steroids at a dose of 1 to 2 mg/kg/day predniSONE equivalents followed by corticosteroid taper; may resume when recovery to Grade 0 or 1.
·Hepatic toxicity (Grade 3 or 4, AST/ALT greater than 5 times the ULN or total bilirubin greater than 3 times the ULN): Permanently discontinue therapy.

Dosing adjustments in renal impairment:

·Renal impairment: No adjustment required

P: P Inj: 1200mg/20mL vial(37625,自費)(37722, 捐贈專案)

ADR:

COMMOM
Constipation, Decrease in appetite, Diarrhea, Nausea, Cough, Dyspnea,Fatigue.

SERIOUS
Myocarditis, Adrenal insufficiency, Diabetes mellitus, Hyperthyroidism, Hypophysitis, Hypothyroidism, Abdominal pain, Colitis, Pancreatitis, Hepatitis, Eaton-Lambert syndrome, Myasthenia gravis, Encephalitis, Guillain-Barre syndrome, Meningitis, Hematuria, Urinary tract infectious disease, Interstitial lung disease, Pneumonitis, Fever, Infectious disease, Infusion reaction.

NOTE: 冰箱冷藏，不可冷凍。

藥名相似:

外觀相似:

外觀描述: 藍綠色塑膠蓋透明玻璃小瓶裝，白底黑字標籤有藍綠色及紅色區塊

08.12B Monoclonal Antibodies

37626 **D / Infant risk can**

Herceptin solution for injection 賀癌平 皮下注射劑

■■Trastuzumab inj for SC 600mg/5mL vial

Dosage: 1常備品 37626

Adult:
·HER2-positive breast cancer: SC, 600 mg once

every 3 weeks (no loading dose is required).

Pediatric:
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 440mg (31243), SC: 600mg/5mL(37626)

ADR:

COMMON
·Rash, weight decreased, diarrhea, nausea, stomatitis, vomiting, anemia, neutropenia, thrombocytopenia, infectious disease, headache, insomnia, cough, fatigue, fever, shivering.
SERIOUS
·Cardiac dysrhythmia, heart failure, left ventricular cardiac dysfunction, myocardial ischemia, febrile neutropenia, neutropenia, thrombocytopenia, thrombosis, hypersensitivity reaction, renal failure, dyspnea, acute interstitial pneumonia, pulmonary hypertension, pulmonary toxicity, infusion reaction, tumor lysis syndrome.

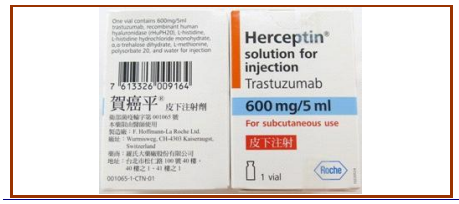
NOTE: 冰箱冷藏2-8℃

皮下注射劑含玻尿酸酵素，可增加藥物擴散及吸收，不適用於靜脈注射。

藥名相似:

外觀相似:

外觀描述: 5mL皮下注射液，每盒含一透明玻璃瓶



08.12B Monoclonal Antibodies

37627 **C / Unknown(有**

CYRAMZA injection 欣銳擇 注射劑

■■急用Ramucirumab inj 100mg/10mL vial

Dosage: 2急用藥 37627

Adult
· Advanced or metastatic gastric cancer: IV infusion over 60 min, 8 mg/kg q 2 wks monotherapy or combination with paclitaxel 80 mg/m(2) IV infusion on days 1, 8, and 15 every 28 days until disease progression or unacceptable toxicity

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: P Inj: 500mg/50mL vial (37628), 100mg/10mL vial (37627)

ADR:

COMMON
Hypertension, diarrhea, neutropenia, epistaxis, fatigue
SERIOUS
Hypertension, impaired wound healing, bowel obstruction, gastrointestinal hemorrhage, gastrointestinal perforation, anemia, arterial thromboembolism, febrile neutropenia, hemorrhage, neutropenia, deterioration of liver cirrhosis, infusion reaction, posterior reversible encephalopathy syndrome, nephrotic syndrome, proteinuria.

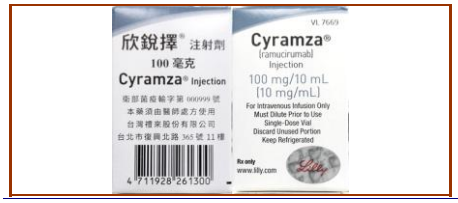
NOTE: 冰箱冷藏，不可冷凍。

NOTE
· Premedicate with IV histamine H1 antagonist (eg, diphenhydramine HCl) prior to ramucirumab infusion; if grade 1 or 2 infusion reaction has occurred previously, also give dexamethasone (or equivalent) and acetaminophen.
· Administer ramucirumab prior to paclitaxel when giving in combination.
· Use NS to flush line at the end of infusion.

藥名相似:

外觀相似:

外觀描述: 10mL注射液，玻璃小瓶



08.12B Monoclonal Antibodies

37628 **C / Unknown(有**

CYRAMZA injection 欣銳擇 注射劑

■■急用Ramucirumab inj 500mg/50mL vial

Dosage: 2急用藥 37628

Adult
· Advanced or metastatic gastric cancer: IV infusion over 60 min, 8 mg/kg q 2 wks monotherapy or combination with paclitaxel 80 mg/m(2) IV infusion on days 1, 8, and 15 every 28 days until disease progression or unacceptable toxicity

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: P Inj: 500mg/50mL vial (37628), 100mg/10mL vial (37627)

ADR:

COMMON
Hypertension, diarrhea, neutropenia, epistaxis, fatigue
SERIOUS
Hypertension, impaired wound healing, bowel obstruction, gastrointestinal hemorrhage, gastrointestinal perforation, anemia, arterial thromboembolism, febrile neutropenia, hemorrhage, neutropenia, deterioration of liver

cirrhosis, infusion reaction, posterior reversible encephalopathy syndrome, nephrotic syndrome, proteinuria.

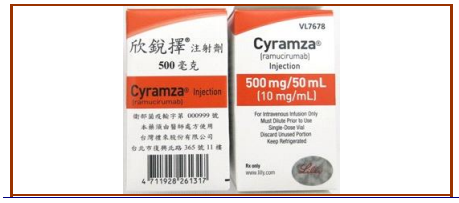
NOTE: 冰箱冷藏，不可冷凍。

NOTE□
· Premedicate with IV histamine H1 antagonist (eg, diphenhydramine HCl) prior to ramucirumab infusion; if grade 1 or 2 infusion reaction has occurred previously, also give dexamethasone (or equivalent) and acetaminophen.
· Administer ramucirumab prior to paclitaxel when giving in combination.
· Use NS to flush line at the end of infusion.

藥名相似:

外觀相似:

外觀描述: 50mL注射液，玻璃小瓶



08.12B Monoclonal Antibodies

37629 **ɔt be ruled out / Infant risk can**

ADCETRIS 50 mg powder for concentrate for solution for infusion 雅詩力 凍晶注射劑 50毫克

■■急用Brentuximab vedotin 50mg vial

Dosage: 2急用藥 37629

Adult
· Anaplastic large T-cell systemic malignant lymphoma, Hodgkin's disease: IV infusion, 1.8 mg/kg(up to 180 mg) over 30 mins every 3 weeks until disease progression or unacceptable toxicity.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Mild (Child-Pugh A): Reduce dose to 1.2 mg/kg(Max.120 mg).
Moderate to severe (Child-Pugh B or C): Avoid use.

Dosing adjustments in renal impairment:

Mild or moderate (CrCl 30 to 80 mL/min): No dosage adjustment required.
Severe (CrCl less than 30 mL/min): Avoid use.

P: Inj: 50mg Vial(37629)

ADR:

COMMON
Rash, abdominal pain, diarrhea, nausea, vomiting, anemia, neutropenia, thrombocytopenia, sensory neuropathy, cough, upper respiratory infection, fatigue, fever
SERIOUS
Supraventricular arrhythmia, Stevens-Johnson syndrome, toxic epidermal necrolysis, pancreatitis, anemia, neutropenia, thrombocytopenia, hepatotoxicity, anaphylaxis, infectious disease, Septic shock, pain in limb, progressive multifocal leukoencephalopathy, pyelonephritis, urinary tract infectious disease, pneumonitis, pneumothorax, pulmonary embolism, pulmonary toxicity, Tumor lysis syndrome.

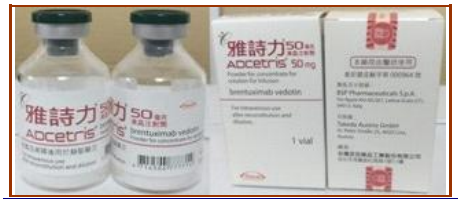
NOTE: 冰箱冷藏，不可冷凍。

· Do not shake or dilute cetuximab.
· It should be infused over 60 mins. Max. infusion rate 10mg/min.

藥名相似:

外觀相似:

外觀描述: 凍晶乾粉，『黑』蓋玻璃小瓶



08.12B Monoclonal Antibodies

37631 **ɔt be ruled out / Infant risk can**

BESPONSA 1 mg Powder for Concentrate for Solution for infusion 沛斯博凍晶注射劑1毫克

■■急用Inotuzumab Ozogamicin 1mg pow in vial

Dosage: 2急用藥 37631

Adult (IV infusion > 1 hr)
·Pre B-cell acute lymphoblastic leukemia, relapsed or refractory: IV infusion, cycle 1, 0.8 mg/m(2) on day 1 and 0.5 mg/m(2) on days 8 and 15 for a total dose of 1.8 mg/m(2) per 3-week cycle; subsequent cycles (CR or CRi achieved), 0.5 mg/m(2) on days 1, 8, and 15 for a total dose of 1.5 mg/m(2) per 4-week cycle; subsequent cycles (CR or CRi not achieved), 0.8 mg/m(2) on day 1 and 0.5 mg/m(2) on days 8 and 15 for a total dose of 1.8 mg/m(2) per 4-week cycle

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

·Total bilirubin ≦1.5 times ULN and AST/ALT ≦2.5 times ULN: No dosage adjustment needed
·Total bilirubin >1.5 times ULN and/or AST/ALT >2.5 times ULN: NDA

Dosing adjustments in renal impairment:

·CrCl 15-89 mL/minute: No dosage adjustment needed
·ESRD with or without hemodialysis: NDA

P: P Inj: 1mg(37631)

ADR:

COMMON
Abdominal pain, nausea, all grades anemia, all grades hemorrhage, all grades leukopenia, all grades lymphocytopenia, all grades neutropenia, all grades thrombocytopenia, ALT/SGPT level raised, AST/SGOT level raised, gamma-glutamyl transferase raised, hepatocellular liver damage, hyperbilirubinemia, infectious disease, headache, fatigue, fever

SERIOUS
Prolonged QT interval, hemorrhage into peritoneal cavity, febrile neutropenia, grade 3 or 4 hemorrhage, myelosuppression, grade 3 or 4 neutropenia, grade 3 or 4 thrombocytopenia, hepatotoxicity, veno-occlusive disease of the liver, grade 3 or 4 infectious disease, infusion reaction

NOTE: 避光冷藏，不可冷凍。

·Hepatotoxicity, including fatal and life-threatening VOD occurred in patients who received inotuzumab ozogamicin.
·A higher post-HSCT non-relapse mortality rate occurred in patients receiving inotuzumab ozogamicin.

藥名相似:

外觀相似:

外觀描述:

08.12B Monoclonal Antibodies

37640 **X / Infant risk can**

OPDIVO* (nivolumab) Injection 10mg/mL 保疾伏

■■急用Nivolumab inj 100mg/10mL vial

Dosage: 2急用藥 37640

Adult: IV infusion, over 1hr
·Unresectable or metastatic melanoma: (Single agent) 3 mg/kg q 2 wks; (In combination with ipilimumab) 1 mg/kg, followed by ipilimumab 3 mg/kg on the same day q 3 wks for 4 doses, then single-agent nivolumab 3 mg/kg q 2 wks.
·Metastatic non-small cell lung cancer with progression on or after platinum-based chemotherapy: 3 mg/kg q 2 wks
·Advanced renal cell carcinoma, metastatic gastric cancer, Squamous-cell Carcinoma of the Head and Neck,Urothelial Carcinoma, Hepatocellular Carcinoma, Classical Hodgkin Lymphoma : 3 mg/kg q 2 wks
·Metastatic colorectal cancer: (Single agent) 3 mg/kg q 2 wks; (In combination with ipilimumab) 3 mg/kg, followed by ipilimumab 1 mg/kg on the same day q 3 wks for 4 doses, then single-agent nivolumab 3 mg/kg q 2 wks.
·Esophageal squamous cell carcinoma: 240mg q 2 wks.

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

(1)Hepatitis in non-hepatocellular carcinoma:
· ALT or AST > 3-5× ULN or total bilirubin >1.5-3× ULN: withhold nivolumab until resolution to Grade 0 or 1.
· ALT or AST > 5× ULN or total bilirubin >3× ULN: permanently discontinue.
(2)Hepatitis in hepatocellular carcinoma:
· ALT or AST normal at baseline and ALT or AST > 3-5× ULN: withhold until resolution to baseline.
· ALT or AST > 1-3× ULN at baseline and ALT or AST > 5-10× ULN: withhold until resolution to baseline.
· ALT or AST > 3-5× ULN at baseline and ALT or AST > 8-10× ULN: withhold until resolution to baseline.
· ALT or AST > 10× ULN or total bilirubin >3× ULN: permanently discontinue.

Dosing adjustments in renal impairment:

· Nephritis or renal dysfunction(Scr > 1.5-6× ULN): withhold until resolution to Grade 0 or 1.
· Nephritis or renal dysfunction(Scr > 6× ULN): permanently discontinue.

P: P 100mg/10mL vial (37640, 急用藥)(37545, 捐贈專案)

ADR:

COMMON
Pruritus, Rash, Hyperglycemia, Abdominal pain, Constipation, Decrease in appetite, Nausea, Vomiting, Arthralgia, Backache, Musculoskeletal pain, Headache, Peripheral neuropathy, Cough, Dyspnea, Upper respiratory infection, Fatigue.
SERIOUS
Immune-mediated Myocarditis, Immune-mediated Pericarditis, Immune-mediated Vasculitis, Immune-mediated Rash, Immune-mediated Stevens-Johnson syndrome, Immune-mediated Toxic epidermal necrolysis, Immune-mediated Adrenal insufficiency, Diabetic ketoacidosis, Immune-mediated Hyperthyroidism, Immune-mediated Hypophysitis, Immune-mediated Hypopituitarism, Immune-mediated Hypothyroidism, Immune-mediated Thyroiditis, Immune-mediated Type 1 diabetes mellitus, Immune-mediated Colitis, Diarrhea, Immune-mediated Duodenitis, Immune-mediated Gastritis, Immune-mediated Pancreatitis, Perforation of colon, Immune-mediated Aplastic anemia, Autoimmune hemolytic anemia, Immune-mediated Hepatitis, Veno-occlusive disease of the liver, Graft versus host disease, Immune-mediated Histiocytic necrotizing lymphadenitis, Immune-mediated Sarcoidosis, Immune-mediated Eaton-Lambert syndrome, Immune-mediated Myositis, Immune-mediated Rhabdomyolysis, Immune-mediated Demyelination of spinal cord, Immune-mediated Encephalitis, Immune-mediated Guillain-Barre syndrome, Immune-mediated Neuropathy, Immune-mediated Iritis, ocular Myasthenia gravis, Immune-mediated Uveitis, Immune-mediated Nephritis, Immune-mediated Renal impairment, Urinary tract infectious disease, Pleural effusion, Pneumonia, Immune-mediated Pneumonitis, Pulmonary embolism, Respiratory failure, Respiratory tract infection, Cytomegalovirus infection, Disorder characterized by fever, Steroid-requiring, Sepsis.

NOTE: 冰箱冷藏，不可冷凍。

藥名相似:

外觀相似:

外觀描述: 『淺綠』蓋透明玻璃小瓶

08.12B Monoclonal Antibodies

37641 X / Infant risk can

OPDIVO (nivolumab) Injection 10mg/mL 保疾伏

■■急用Nivolumab inj 20mg/2mL vial

Dosage: 2急用藥 37641

Adult: IV infusion, over 1hr
·Unresectable or metastatic melanoma: (Single agent) 3mg/kg q2wks; (In combination with ipilimumab) 1 mg/kg, followed by ipilimumab 3 mg/kg on the same day q3wks for 4doses, then single-agent nivolumab 3 mg/kg q2wks.
·Metastatic non-small cell lung cancer with progression on or after platinum-based chemotherapy: 3 mg/kg q 2 wks
·Advanced renal cell carcinoma, metastatic gastric cancer, Squamous-cell Carcinoma of the Head and Neck,Urothelial Carcinoma, Hepatocellular Carcinoma, Classical Hodgkin Lymphoma : 3 mg/kg q2 wks
·Metastatic colorectal cancer: (Single agent) 3 mg/kg q 2 wks; (In combination with ipilimumab) 3 mg/kg, followed by ipilimumab 1 mg/kg on the same day q 3 wks for 4 doses, then single-agent nivolumab 3 mg/kg q 2 wks.
·Esophageal squamous cell carcinoma: 240mg q 2 wks.

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

(1)Hepatitis in non-hepatocellular carcinoma:
· ALT or AST > 3-5× ULN or total bilirubin >1.5-3× ULN: withhold nivolumab until resolution to Grade 0 or 1.
· ALT or AST > 5× ULN or total bilirubin >3× ULN: permanently discontinue.
(2)Hepatitis in hepatocellular carcinoma:
· ALT or AST normal at baseline and ALT or AST > 3-5× ULN: withhold until resolution to baseline.
· ALT or AST > 1-3× ULN at baseline and ALT or AST > 5-10× ULN: withhold until resolution to baseline.
· ALT or AST > 3-5× ULN at baseline and ALT or AST > 8-10× ULN: withhold until resolution to baseline.
· ALT or AST > 10× ULN or total bilirubin >3× ULN: permanently discontinue.

Dosing adjustments in renal impairment:

· Nephritis or renal dysfunction(Scr > 1.5-6× ULN): withhold until resolution to Grade 0 or 1.
· Nephritis or renal dysfunction(Scr > 6× ULN): permanently discontinue.

P: P Inj: 100mg/10mL vial(37640)(37545, 捐贈專案), 20mg/2mL vial(37641)

ADR:

COMMON
Pruritus, Rash, Hyperglycemia, Abdominal pain, Constipation, Decrease in appetite, Nausea, Vomiting, Arthralgia, Backache, Musculoskeletal pain, Headache, Peripheral neuropathy, Cough, Dyspnea, Upper respiratory infection, Fatigue.
SERIOUS
Immune-mediated Myocarditis, Immune-mediated Pericarditis, Immune-mediated Vasculitis, Immune-mediated Rash, Immune-mediated Stevens-Johnson syndrome, Immune-mediated Toxic epidermal necrolysis, Immune-mediated Adrenal insufficiency, Diabetic ketoacidosis, Immune-mediated Hyperthyroidism, Immune-mediated Hypophysitis, Immune-mediated Hypopituitarism, Immune-mediated Hypothyroidism, Immune-mediated Thyroiditis, Immune-mediated Type 1 diabetes mellitus, Immune-mediated Colitis, Diarrhea, Immune-mediated Duodenitis, Immune-mediated Gastritis, Immune-mediated Pancreatitis, Perforation of colon, Immune-mediated Aplastic anemia, Autoimmune hemolytic anemia, Immune-mediated Hepatitis, Veno-occlusive disease of the liver, Graft versus host disease, Immune-mediated Histiocytic necrotizing lymphadenitis, Immune-mediated Sarcoidosis, Immune-mediated Eaton-Lambert syndrome, Immune-mediated Myositis, Immune-mediated Rhabdomyolysis, Immune-mediated Demyelination of spinal cord, Immune-mediated Encephalitis, Immune-mediated Guillain-Barre syndrome, Immune-mediated Neuropathy, Immune-mediated Iritis, ocular Myasthenia gravis, Immune-mediated Uveitis, Immune-mediated Nephritis, Immune-mediated Renal impairment, Urinary tract infectious disease, Pleural effusion, Pneumonia, Immune-mediated Pneumonitis, Pulmonary embolism, Respiratory failure, Respiratory tract infection, Cytomegalovirus infection, Disorder characterized by fever, Steroid-requiring, Sepsis.

NOTE: 冰箱冷藏，不可冷凍。

藥名相似:

外觀相似:

外觀描述: 『藍』蓋透明玻璃小瓶

08.12B Monoclonal Antibodies

37642 ɔt be ruled out / Infant risk can

BLINCYTO* for Injection 百利妥注射劑

■■急用Blinatumomab inj 35mcg pow in vial

Dosage: 2急用藥 37642

Adult: IV infusion
·Philadelphia chromosome-negative precursor B-cell acute lymphoblastic:

(1)< 45 kg Induction cycle: 5 mcg/m(2)/day (MAX, 9 mcg/day) continuous IV infusion on days 1-7 and 15 mcg/m(2)/day(MAX, 28 mcg/day) continuous infusion on days 8-28, followed by 2 weeks of no treatment. sequence cycle : 15 mcg/m(2)/day (MAX, 28 mcg/day) continuous IV infusion on days 1- 28 followed by 2 weeks of no treatment.(MICROMEDEX)
(2)>45 kg Induction cycle: 9 mcg/day continuous IV infusion on days 1-7 and 28mcg/day continuous infusion on days 8-28, followed by 2 weeks of no treatment. sequence cycle : 28 mcg/day continuous IV infusion on days 1- 28 followed by 2 weeks of no treatment.

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild impairment: No dosage adjustment needed
Moderate to severe impairment: NDA

Dosing adjustments in renal impairment:

Mild to moderate impairment: No dosage adjustment needed
Severe impairment: NDA

P: P Inj: 35mcg/vial(37642)(37723, 捐贈專案)

ADR:

COMMON
Anemia, neutropenia, thrombocytopenia, headache, fever, infectious disease, infusion reaction.
SERIOUS
Pancreatitis, Grade 3 or higher anemia, Grade 3 or higher leukopenia, Grade 3 or higher neutropenia, Grade 3 or higher thrombocytopenia, cytokine release syndrome , hypersensitivity reaction, leukoencephalopathy, neurotoxicity, depression, tumor lysis syndrome.

NOTE: 儲存2-8°C，避光

1. Premedication, dexamethasone 20 mg 1 hour before the first dose of each cycle, before a step dose (eg, cycle 1 day 8), and when restarting an infusion after an interruption of 4 or more hours.
2. Cytokine Release Syndrome (CRS), which may be life-threatening or fatal, occurred in patients receiving blinatumomab. Neurological toxicities, which may be severe, life-threatening, or fatal, occurred in patients receiving blinatumomab. Interrupt or discontinue blinatumomab as recommended.
3.與 CRS 有關的嚴重不良事件包括發燒、頭痛、噁心、無力、低血壓、ALT或AST增加、總膽紅素增加
4.神經毒性包括腦病變、痙攣、語言障礙、意識障礙、意識混亂且失去方向感以及協調平衡障礙。
5.應將 "細胞激素釋放症候群"與"神經毒性" 可能產生的症狀衛教病人，以自我監測是否發生相關病徵。
6.注意不同體重病人的每日建議劑量，體重≥45 kg者應使用固定劑量。

藥名相似:

外觀相似:

外觀描述: 凍晶粉末，『黃』蓋透明玻璃小瓶及『紅』蓋IV溶液穩定劑

08.12B Monoclonal Antibodies

37643 ɔt be ruled out / Infant risk can

LARTRUVO* injection 樂除瘤注射劑

■■急用Olaratumab 500mg/50mL vial

Dosage: 2急用藥 37643

Adult
·Soft tissue sarcoma, Histologic subtype appropriate for an anthracycline-containing regimen which is not amenable to curative treatment with radiotherapy or surgery, in combination with doxorubicin: IV infusion over 60 minutes, 15 mg/kg on days 1 and 8 of each 21-day cycle until disease progression or unacceptable toxicity; give with doxorubicin 75 mg/m(2) IV on day 1 of each 21-day cycle for the first 8 cycles.

Pedatric
·Safety and effectiveness not established in pediatric patients.

Dosing adjustments in hepatic impairment:

Mild or moderate impairment: No dosage adjustment is necessary.
Severe hepatic impairment: NDA

Dosing adjustments in renal impairment:

Mild or moderate impairment: No dosage adjustment is necessary.
Severe impairment (CrCl <30 mL/min): NDA

P: P Inj: 500mg/50mL vial(37643)

ADR:

COMMON
· Alopecia, inflammatory disease of mucous membrane, nausea, vomiting, musculoskeletal pain, fatigue.
SERIOUS
· Infusion reaction.

NOTE:

·Premedication, give diphenhydramine 25 to 50 mg IV and dexamethasone 10 to 20 mg IV prior to olaratumab on day 1 of cycle 1.
·Grade 4 neutropenia lasting longer than 1 week, neutropenic fever, or infection: Discontinue until absolute neutrophil count is 1000/mcL or greater and then resume at a permanently reduced dose of 12 mg/kg.
·Infusion-related reaction: Interrupt infusion for Grade 1 or 2 event and resume at 50% the initial infusion rate after resolution. Permanently discontinue for a Grade 3 or 4 event.

藥名相似:

外觀相似:

外觀描述:

08.12B Monoclonal Antibodies

37644 **ɔt be ruled out / Infant risk can**

DARZALEX* Concentrate for solution for infusion 20mg/ml 兆科注射劑20毫克/毫升

■■急用Daratumumab 400mg/20mL vial

Dosage: 2急用藥 37644

Adult

·Multiple myeloma: IV infusion, 16 mg/kg actual body weight IV weekly during weeks 1 to 6 (total of 6 doses), then every 3 weeks during weeks 7 to 54 (total of 16 doses), then every 4 weeks from week 55 until disease progression; in combination with bortezomib 1.3 mg/m(2) subQ twice weekly during weeks 1, 2, 4 and 5 for the first 6-week cycle (cycle 1; 8 doses), followed by once weekly during weeks 1, 2, 4 and 5 for 8 more 6-week cycles (cycles 2 to 9; 4 doses per cycle); melphalan 9 mg/m(2), and predniSONE 60 mg/m(2) orally on days 1 to 4 of the nine 6-week cycles (cycles 1 to 9). Continue until disease progression or unacceptable toxicity

Pedatric

·Safety and effectiveness not established in pediatric patients.

Dosing adjustments in hepatic impairment:

Mild or moderate impairment: No dosage adjustment is necessary.
Severe hepatic impairment: NDA

Dosing adjustments in renal impairment:

Mild or moderate impairment: No dosage adjustment is necessary.
Severe impairment (CrCl <30 mL/min): NDA

P: P Inj: 400mg/20mL vial(37644)

ADR:

COMMON

Peripheral edema, Diarrhea, Nausea, Backache, Spasm, Dizziness, Insomnia, Peripheral neuropathy, Bronchitis, Cough, Upper respiratory infection, Fatigue, Fever.

SERIOUS

Pneumonia, General health deterioration, Infusion reaction.

NOTE: 冰箱冷藏，不可冷凍。

·《Contraindications》History of severe hypersensitivity (eg, anaphylactic reaction) to daratumumab or any of the components of the product

·Premedication: MethylPREDNISolone 100 mg IV (or equivalent IV dose of intermediate-acting or long-acting corticosteroid) plus an oral antipyretic (acetaminophen 650 to 1000 mg) plus an oral or IV antihistamine (diphenhydrAMINE 25 to 50 mg or equivalent) 1 to 3 hours before every infusion; after second infusion, corticosteroid dose may be reduced (methylPREDNISolone 60 mg oral or IV)

·Post-infusion medication: MethylPREDNISolone 20 mg orally (or equivalent dose of an intermediate-acting or long-acting corticosteroid) on each of the 2 days following all infusions (beginning the day after the infusion) .

·Post-infusion medication for patients with COPD: Consider short- and long-acting bronchodilators and inhaled corticosteroids; may discontinue inhaled post-infusion medications if no major infusion reaction to first 4 infusions.

·Concomitant medication: Start antiviral prophylaxis for herpes zoster reactivation within 1 week of daratumumab initiation and continue for 3 months following treatment

·輸注反應-加註本藥可能會引發嚴重和/或危急嚴重的輸注反應，包含過敏反應。大部份輸注反應都是發生於第一次輸注期間且為第1、2級不良反應。

．為避免胎兒暴露於藥品，具生育能力的婦女在治療期間應採取有效的避孕措施，在停止使用治療後亦應繼續避孕3個月。

．B型肝炎病毒再活化-臨床試驗接受治療的病人中，少於1%被通報有B型肝炎病毒再活化的情形(包含致命性案例)。

藥名相似:

外觀相似:

外觀描述: 20mL注射液，玻璃小瓶

08.12B Monoclonal Antibodies

37645 **ɔt be ruled out / Infant risk can**

Darzalex Concentrate for solution for infusion 20mg/ml 兆科注射劑20毫克/毫升

■■急用Daratumumab 100mg/5mL vial

Dosage: 2急用藥 37645

Adult: (based on actual body weight)

·Multiple myeloma (newly diagnosed):

- In combination with D-VMP regimen; in patients ineligible for ASCT: IV infusion, 16 mg/kg QW during wks 1-6 (total of 6 doses), then Q3W during wks 7-54 (total of 16 doses), then Q4W from wk 55 until disease progression
- In combination with DRd regimen; in patients ineligible for ASCT: IV infusion, 16 mg/kg QW for wks 1-8, Q2W for wks 9-24, and Q4W from wk 25 until disease progression
- In combination with DVTd regimen; in patients eligible for ASCT: Induction, 16 mg/kg QW during wks 1-8 (total of 8 doses), then Q2W during wks 9-16 (total of 4 doses), then stop for high dose CT and ASCT; Consolidation, 16 mg/kg Q2W during wks 1-8 (total of 4 doses)

·Multiple myeloma (relapsed/refractory):

- Monotherapy OR in combination with DRd regimen OR in combination with DPd regimen: IV infusion, 16 mg/kg QW for wks 1-8, Q2W for wks 9-24, and Q4W from wk 25 until disease progression

- In combination with DVd regimen: IV infusion, 16 mg/kg QW for wks 1-9, Q3W for wks 10-24, and Q4W from wk 25 until disease progression

Pediatric

· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

· Mild or moderate: No dosage adjustment needed
· Severe: NDA

Dosing adjustments in renal impairment:

· CrCl 15-89 mL/min: No dosage adjustment needed

P: P Inj: 100mg/5mL(37645), 400mg/20mL vial(37644)

ADR:

COMMON
Peripheral edema, Diarrhea, Nausea, Backache, Spasm, Dizziness, Insomnia, Peripheral neuropathy, Bronchitis, Cough, Upper respiratory infection, Fatigue, Fever.
SERIOUS
Pneumonia, General health deterioration, Infusion reaction.

NOTE: 冰箱冷藏，不可冷凍。

·《Contraindications》History of severe hypersensitivity (eg, anaphylactic reaction) to daratumumab or any of the components of the product

· Premedications: Administer 1-3 hrs prior to each infusion. If dexamethasone is the background regimen-specific corticosteroid, the dexamethasone treatment dose will serve as the corticosteroid premedication on daratumumab infusion days. Additional background regimen-specific corticosteroids (eg, prednisone) should NOT be administered on daratumumab infusion days when patients receive dexamethasone (or equivalent) as a premedication.

- Monotherapy: Methylprednisolone IV 100 mg or equivalent intermediate- or long-acting corticosteroid; following the second infusion, the dose may be decreased (eg, methylprednisolone 60 mg [IV or oral] or equivalent).

- Combination therapy: Dexamethasone 20 mg (or equivalent) prior to each daratumumab infusion; administer IV prior to the first infusion; oral administration may be considered prior to subsequent infusions plus oral antipyretic (acetaminophen 650-1,000 mg) plus oral or IV antihistamine (diphenhydramine 25-50 mg or equivalent).

· Postinfusion medication:

- Monotherapy: Administer an oral intermediate- or long-acting corticosteroid (eg, methylprednisolone 20 mg or equivalent) on the first and second day after all daratumumab infusions.

- Combination therapy: Consider administering low-dose oral methylprednisolone (≦20 mg) or equivalent on the first day after the daratumumab infusion. If dexamethasone or prednisone is administered the day after the daratumumab infusion as part of background combination chemotherapy regimen, additional postinfusion corticosteroid therapy may not be necessary.

- In patients with a history of COPD, also consider short- and long-acting bronchodilators and inhaled corticosteroids postinfusion. If no major infusion reactions occur during the first 4 daratumumab infusions, these additional inhaled postinfusion medications may be discontinued.

·輸注反應-加註本藥可能會引發嚴重和/或危急嚴重的輸注反應，包含過敏反應。大部份輸注反應都是發生於第一次輸注期間且為第1、2級不良反應。

· 為避免胎兒暴露於藥品，具生育能力的婦女在治療期間應採取有效的避孕措施，在停止使用治療後亦應繼續避孕3個月。

· B型肝炎病毒再活化-臨床試驗接受治療的病人中，少於1%被通報有B型肝炎病毒再活化的情形(包含致命性案例)。

藥名相似:

外觀相似:

外觀描述: 5mL注射液，玻璃小瓶

08.12B Monoclonal Antibodies

37646 **ɔt be ruled out / Infant risk can**

BAVENCIO* 20mg/mL Concentrate for Solution for Infusion 百穩益注射劑20毫克/毫升

■■急用Avelumab inj 200mg/10mL vial

Dosage: 2急用藥 37646

Adult: IV infusion, over 1hr
·Metastatic Merkel cell carcinoma, Metastatic urothelial carcinoma : 800mg q2wks until disease progression or unacceptable toxicity.
·Advanced Renal cell carcinoma, first-line treatment: 10mg/kg q2wks with axitinib PO 5mg q12h until disease progression or unacceptable toxicity.

Pediatric

· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild impairment: No dosage adjustment needed
Moderate to severe impairment: NDA
·Hepatitis, AST or ALT > 3 and up to 5 times ULN or total bilirubin.> 1.5 and up to 3 times ULN: Administer corticosteroids 1 to 2 mg/kg/day predniSONE or equivalents followed by taper and withhold avelumab until resolution to Grade 0 or 1 toxicity. May resume after resolution and corticosteroid taper.
·Hepatitis, AST or ALT >5 times ULN or total bilirubin >3 times ULN: Administer corticosteroids 1 to 2 mg/kg/day predniSONE or equivalents followed by taper and permanently discontinue avelumab.

Dosing adjustments in renal impairment:

Mild to moderate impairment: No dosage adjustment needed
Severe impairment: NDA.

·Renal dysfunction and nephritis, serum creatinine>1.5 and up to 6 times ULN: Administer corticosteroids 1 to 2 mg/kg/day predniSONE or equivalents followed by taper and withhold avelumab until resolution to Grade 0 or 1 toxicity. May resume after resolution and corticosteroid taper.
·Renal dysfunction and nephritis, serum creatinine > 6 times ULN: Administer corticosteroids 1 to 2 mg/kg/day predniSONE or equivalents followed by taper and permanently discontinue avelumab.

P: P Inj: 200mg/10mL vial(37646)

ADR:

COMMON
Hypertension, Peripheral edema, Hand-foot syndrome due to cytotoxic therapy, Rash, Abdominal pain, Decrease in appetite, Diarrhea, Inflammatory disease of mucous membrane , Nausea, Anemia, Musculoskeletal pain, Headache, Urinary tract infectious disease, Cough, Dyspnea, Difficulty speaking, Fatigue.
SERIOUS
Cardiovascular event risk, Hypertensive crisis, Myocarditis, Sudden cardiac death, Cellulitis, Immune-mediated Adrenal insufficiency, Immune-mediated Disorder of thyroid gland, Immune-mediated Hyperthyroidism, Immune-mediated Hypothyroidism, Immune-mediated Thyroiditis, Type 1 diabetes mellitus, Immune-mediated Colitis, Ileus, Acute Necrotizing pancreatitis, Immune-mediated Acute hepatitis, Elevated liver enzymes level, Hepatotoxicity, Nonspecific immune reaction, Increased creatine kinase level, Cerebrovascular accident, ocular Myasthenia gravis, Immune-mediated Uveitis, Immune-mediated Nephritis, Renal failure, Immune-mediated Pneumonitis, Infusion reaction.

NOTE: 冰箱冷藏2-8℃，不可冷凍。

·《Contraindications》Specific contraindications have not been determined.
·如發生中度(第2級)肝毒性，暫停和axitinib合併治療；如出現嚴重或有生命危險(第3或4級)的肝毒性，永久停用合併治療。視需要使用皮質類固醇。
·其他免疫相關不良反應-增列致死案例的胰臟炎。
·重大心血管不良事件-本藥併用axitinib可能導致嚴重和致死的心血管不良事件。應考慮用藥前測量病人的左心室射出率，並定期評估。若發生第3-4級心血管事件，停止合併治療。
·輸注時單獨使用一條管線，仿單建議需要用0.22μfilter過濾，靜脈輸注60分鐘，輸注結束時要用0.9%N/S沖洗管線。
·治療開始、治療期間應監測病人甲狀腺功能的變化。

藥名相似:

外觀相似:

外觀描述: 10mL注射劑透明濃縮液，『黃』蓋透明玻璃小瓶

08.12B Monoclonal Antibodies

37647 ɔt be ruled out / Infant risk can

IMFINZI* Injection 50 mg/ml 抑癌寧注射劑

■■急用Durvalumab inj 120mg/2.4mL vial

Dosage: 2急用藥 37647

Adult
IV infusion over 60 minutes
·Metastatic urothelial carcinoma/ locally advanced, with disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant/ adjuvant treatment with platinum-containing chemotherapy: 10 mg/kg q2wks until disease progression or unacceptable toxicity
·Non-small cell lung cancer, unresectable stage III, without progression following concurrent platinum-based chemotherapy: 10 mg/kg q2wks until disease progression or unacceptable toxicity, or a Max. of 12 months.

Pediatric
Safety and effectivenesshave not been established.

Dosing adjustments in hepatic impairment:

Mild impairment: No dosage adjustment needed
Moderate to severe impairment: NDA

Dosing adjustments in renal impairment:

Mild impairment: No dosage adjustment needed
Moderate to severe impairment: NDA

P: Inj: 500mg/10mL vial(37648急用,37716 捐贈專案) ; 120mg/2.4mL vial(37647)

ADR:

COMMON
Constipation, musculoskeletal pain, cough, dyspnea, upper respiratory infection, fatigue
SERIOUS
Immune-mediated rash/ adrenal insufficiency/ hyperthyroidism/ hypophysitis/ hypothyroidism/ thyroiditis/ Type 1 DM/ colitis/ diarrhea/ hepatitis/ nephritis/ pneumonitis, interstitial lung disease, Immune thrombocytopenic purpura

NOTE: 冰箱冷藏，不可冷凍。

Withhold or discontinue IMFINZI to manage adverse reactions as described in product information. No dose reductions are recommended.

藥名相似:

外觀相似:

外觀描述: 『白』蓋透明玻璃小瓶

08.12B Monoclonal Antibodies

37648 ɔt be ruled out / Infant risk can

IMFINZI* Injection 50 mg/ml 抑癌寧注射劑

■■急用Durvalumab inj 500mg/10mL vial

Dosage: 2急用藥 37648

Adult
IV infusion over 60 minutes
·Metastatic urothelial carcinoma/ locally advanced, with disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant/ adjuvant treatment with platinum-containing chemotherapy: 10 mg/kg q2wks until disease progression or unacceptable toxicity
·Non-small cell lung cancer, unresectable stage III, without progression following concurrent platinum-based chemotherapy: 10 mg/kg q2wks until disease progression or unacceptable toxicity, or a Max. of 12 months.

Pediatric
Safety and effectivenesshave not been established.

Dosing adjustments in hepatic impairment:

Mild to moderate impairment: No dosage adjustment needed
Severe impairment: NDA

Dosing adjustments in renal impairment:

Mild to moderate impairment: No dosage adjustment needed
Severe impairment: NDA

P: Inj: 500mg/10mL vial(37648急用,37716 捐贈專案); 120mg/2.4mL vial(37647)

ADR:

COMMON
Constipation, musculoskeletal pain, cough, dyspnea, upper respiratory infection, fatigue
SERIOUS
Immune-mediated rash/ adrenal insufficiency/ hyperthyroidism/ hypophysitis/ hypothyroidism/ thyroiditis/ Type 1 DM/ colitis/ diarrhea/ hepatitis/ nephritis/ pneumonitis, interstitial lung disease, Immune thrombocytopenic purpura

NOTE: 冰箱冷藏，不可冷凍。

Withhold or discontinue IMFINZI to manage adverse reactions as described in product information. No dose reductions are recommended.

藥名相似:

外觀相似:

外觀描述: 『白』蓋透明玻璃小瓶

08.12B Monoclonal Antibodies

37651 ɔt be ruled out / Infant risk can

Ilaris 150mg/mL solution for injection 易來力注射液150毫克/毫升

■■急用Canakinumab 150mg/1mL vial

Dosage: 2急用藥 37651

Adult
· Cryopyrin associated periodic syndrome, familial cold urticaria,
Muckle-Wells syndrome: SC, 150mg(>40kg) or 2mg/kg (15-40 kg) Q8W, may increase to 300mg or 4mg/kg Q8W if inadequate response
· Deficiency of mevalonate kinase, familial Mediterranean fever, hyper-IgD periodic fever syndrome (HIDS), TNF receptor-associated periodic fever syndrome (TRAPS): SC, 150mg(>40kg) or 2mg/kg (15-40 kg) Q4W, may increase to 300mg or 4mg/kg Q4W if inadequate response

Pediatric (>2 yrs, BW>=7.5kg)
Same as Adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: P Inj: 150mg/1mL(37651, 急用)

ADR:

COMMON
Injection site reaction, weight increased, diarrhea, gastroenteritis, nausea, upper abdominal pain, infectious disease, musculoskeletal pain, headache, vertigo, bronchitis , nasopharyngitis, pharyngitis, rhinitis, influenza
SERIOUS
Serious infectious disease, macrophage activation syndrome, reactivation tuberculosis, upper respiratory infection

NOTE: 冰箱冷藏，不可冷凍。

藥名相似:

外觀相似:

外觀描述:

08.12B Monoclonal Antibodies

37715 ɔt be ruled out / Infant risk can

BAVENCIO* 20mg/mL Concentrate for Solution for Infusion 百穩益注射劑20毫克/毫升

■■捐贈急用Avelumab inj 200mg/10mL vial

Dosage: 2急用藥 37715

Adult: IV infusion, over 1hr
·Metastatic Merkel cell carcinoma, Metastatic urothelial carcinoma : 800mg q2wks until disease progression or unacceptable toxicity.

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild impairment: No dosage adjustment needed
Moderate to severe impairment: NDA

·Hepatitis, AST or ALT > 3 and up to 5 times ULN or total bilirubin.> 1.5 and up to 3 times ULN: Administer corticosteroids 1 to 2 mg/kg/day predniSONE or equivalents followed by taper and withhold avelumab until resolution to Grade 0 or 1 toxicity. May resume after resolution and corticosteroid taper.
·Hepatitis, AST or ALT >5 times ULN or total bilirubin >3 times ULN: Administer corticosteroids 1 to 2 mg/kg/day predniSONE or equivalents followed by taper and permanently discontinue avelumab.

Dosing adjustments in renal impairment:

Mild to moderate impairment: No dosage adjustment needed
Severe impairment: NDA.
·Renal dysfunction and nephritis, serum creatinine>1.5 and up to 6 times ULN: Administer corticosteroids 1 to 2 mg/kg/day predniSONE or equivalents followed by taper and withhold avelumab until resolution to Grade 0 or 1 toxicity. May resume after resolution and corticosteroid taper.
·Renal dysfunction and nephritis, serum creatinine > 6 times ULN: Administer corticosteroids 1 to 2 mg/kg/day predniSONE or equivalents followed by taper and permanently discontinue avelumab.

P: P Inj: 200mg/10mL vial(37646, 捐贈37715)

ADR:

COMMON
·Peripheral edema, rash, decrease in appetite, diarrhea, nausea, anemia, musculoskeletal pain, urinary tract infectious disease, fatigue.
SERIOUS
·Hypertensive crisis, cellulitis, adrenal insufficiency(immune-mediated), disorder of thyroid gland(immune-mediated),Hyperthyroidism(immune-mediated), Hypothyroidism(immune-mediated),Thyroiditis(immune-mediated), Type 1 diabetes mellitus, colitis(immune-mediated), intestinal obstruction co-occurrent and due to decreased peristalsis, acute hepatitis(immune-mediated), elevated liver enzymes level, nonspecific immune reaction, increased creatine kinase level, nephritis(immune-mediated), renal failure, pneumonitis(immune-mediated), infusion reaction.

NOTE: 冰箱冷藏2-8℃，不可冷凍。

·輸注時單獨使用一條管線，仿單建議需要用0.22μfilter過濾，靜脈輸注60分鐘，輸注結束時要用0.9%N/S沖洗管線。
·治療開始、治療期間應監測病人甲狀腺功能的變化。

藥名相似:

外觀相似:

外觀描述: 10mL注射劑透明濃縮液，『黃』蓋透明玻璃小瓶

08.12B Monoclonal Antibodies

37770 **ɔt be ruled out / Infant risk can**

DARZALEX* Concentrate for solution for infusion 20mg/ml 兆科注射劑20毫克/毫升

■■捐贈急用Daratumumab 400mg/20mL vial

Dosage: 2急用藥 37770

Adult
·Multiple myeloma: IV infusion, 16 mg/kg actual body weight IV weekly during weeks 1 to 6 (total of 6 doses), then every 3 weeks during weeks 7 to 54 (total of 16 doses), then every 4 weeks from week 55 until disease progression; in combination with bortezomib 1.3 mg/m(2) subQ twice weekly during weeks 1, 2, 4 and 5 for the first 6-week cycle (cycle 1; 8 doses), followed by once weekly during weeks 1, 2, 4 and 5 for 8 more 6-week cycles (cycles 2 to 9; 4 doses per cycle); melphalan 9 mg/m(2), and predniSONE 60 mg/m(2) orally on days 1 to 4 of the nine 6-week cycles (cycles 1 to 9). Continue until disease progression or unacceptable toxicity

Pedatric
·Safety and effectiveness not established in pediatric patients.

Dosing adjustments in hepatic impairment:

Mild or moderate impairment: No dosage adjustment is necessary.
Severe hepatic impairment: NDA

Dosing adjustments in renal impairment:

Mild or moderate impairment: No dosage adjustment is necessary.
Severe impairment (CrCl <30 mL/min): NDA

P: P Inj: 400mg/20mL vial(37644)(37770, 捐贈藥品)

ADR:

COMMON
Peripheral edema, Diarrhea, Nausea, Backache, Spasm, Dizziness, Insomnia, Peripheral neuropathy, Cough, Upper respiratory infection, Fatigue, Fever
SERIOUS
Pneumonia, General health deterioration, Infusion reaction

NOTE: 冰箱冷藏，不可冷凍。

Premedication: MethylPREDNISolone 100 mg IV (or equivalent IV dose of intermediate-acting or long-acting corticosteroid) plus an oral antipyretic (acetaminophen 650 to 1000 mg) plus an oral or IV antihistamine (diphenhydrAMINE 25 to 50 mg or equivalent) 1 to 3 hours before every infusion; after second infusion, corticosteroid dose may be reduced (methylPREDNISolone 60 mg oral or IV)
·Post-infusion medication: MethylPREDNISolone 20 mg orally (or equivalent dose of an intermediate-acting or long-acting corticosteroid) on each of the 2 days following all infusions (beginning the day

after the infusion) .
·Post-infusion medication for patients with COPD: Consider short- and long-acting bronchodilators and inhaled corticosteroids; may discontinue inhaled post-infusion medications if no major infusion reaction to first 4 infusions.
·Concomitant medication: Start antiviral prophylaxis for herpes zoster reactivation within 1 week of daratumumab initiation and continue for 3 months following treatment t.
·輸注反應-加註本藥可能會引發嚴重和/或危急嚴重的輸注反應，包含過敏反應。大部份輸注反應都是發生於第一次輸注期間且為第1、2級不良反應。

藥名相似:

外觀相似:

外觀描述: 20mL注射液，玻璃小瓶)

08.12B Monoclonal Antibodies

37778 **C / Caution**

Gazyva solution for infusion 癌即瓦注射劑

■■捐贈急用Obinutuzumab 1000mg/40mL soln for infusion

Dosage: 2急用藥 37778

Adult
· Chronic lymphoid leukemia(previously untreated) in combination with chlorambucil: 28-day cycles cycles 1: day 1, 100 mg IV infusion at 25 mg/hr over 4 hours (do not increase infusion rate); day 2, 900 mg IV infusion at 50 mg/hr (may increase by 50 mg/hr every 30 min to max.rate of 400 mg/hr); day 8 and day 15, 1000 mg IV infusion at a starting rate of 100 mg/hr (may increase by 100 mg/hr increments every 30 min to maxi. Rate of 400 mg/hr);
Cycles 2-6, day 1, 1000 mg IV infusion at a starting rate of 100 mg/hr (may increase by 100 mg/hr increments every 30 min to maxi. Rate of 400 mg/hr).

Pediatric
· Safety and effectiveness not established in pediatric patients

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr ?30 mL/min: No dosage adjustment necessary
Clcr <30 mL/min: NDA

P:

ADR:

Common
Anemia (12%), neutropenia(38% to 41%), thrombocytopenia(14% to 15%), disorder of musculoskeletal system (18%), cough (10%),fever (All grades, 9% to 10%; grade 3 or 4, less than 1%)
Serious
Grade 3 or 4 anemia(5%), fatal hemorrhage, grade 3 or 4 leukopenia(4% to 5%), grade 3 or 4 neutropenia(33% to 35%), Grade 3 or 4 thrombocytopenia(10% to 11%), progressive multifocal leukoencephalopathy, infusion reaction, tumor lysis syndrome (2%)

NOTE: 2-8度C，應避光保存，不可冷凍

1. premedicate all patients with acetaminophen 650 to 1000 mg at least 30 minutes before infusion (all cycles), dexamethasone 20 mg IV or methylprednisolone 80 mg IV at least 1 hour before infusion (cycle 1, days 1 and 2), antihistamine (eg, diphenhydramine 50 mg) at least 30 minutes before infusion (cycle 1, days 1 and 2); premedicate patients with an infusion reaction of grade 1 or higher with a previous infusion with antihistamine (eg, diphenhydramine 50 mg) at least 30 minutes before infusion; premedicate patients with a grade 3 infusion reaction with a previous infusion or with a lymphocyte count of greater than 25 x 10(9)/L before the next treatment with dexamethasone 20 mg IV or methylprednisolone 80 mg IV at least 1 hour before infusion; for patients with neutropenia, consider antimicrobial, antiviral, and antifungal premedication; for patients with high tumor burden or circulating absolute lymphocyte count greater than 25 x 10(9)/L, premedicate with antihyperuricemics (eg, allopurinol) starting 12 to 24 hours before infusion and ensure adequate hydration
2.for patients on antihypertensive medications, consider withholding those medications for 12 hours before, during, and 1 hour after infusion

藥名相似:

外觀相似:

外觀描述: 40mL透明注射液『灰』蓋透明玻璃瓶

08.12B Monoclonal Antibodies

37786 **C / Infant risk can**

Erbitux 5mg/ml Solution for infusion 爾必得舒 注射液 5 毫克/毫升

■■Cetuximab inj 100mg/20mLvial

Dosage: 1常備品 37786

Adult
· Head and neck cancer, relapsed/refractory: IV infusion, in combination with platinum-based C/T: LD 400mg/m2 infused over 120 mins followed weekly by 250mg/m2
· Metastatic colorectal cancer: IV infusion, LD 400mg/m2 infused over 120 mins followed weekly by 250mg/m2

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 100mg/20mL Vial(37786)

ADR:

COMMON

Any grade Acneiform eruption, Disorder of hair, Dry skin, Nail changes, Pruritus, Rash, Any grade Hypomagnesemia, Weight decreasing, Constipation, Diarrhea, Nausea, Neutropenia, Infectious disease, Asthenia, Headache, Sensory neuropathy, Dyspnea, Fatigue, Late effect of radiation, Pain.

SERIOUS

Cardiorespiratory arrest, Sudden cardiac death, Abscess, Grade 3 or 4 Acneiform eruption, Bullous eruption, Mucocutaneous, Radiation dermatitis, Grades 3 and 4 Hypomagnesemia, Grades 3 and 4 Leukopenia, Grades 3 and 4 Neutropenia, Grade 3 or 4 Venous thromboembolism, Hypersensitivity reaction, Sepsis, Renal failure, Interstitial lung disease, Pulmonary embolism, Grades 3 and 4 Infusion reaction.

NOTE: 冰箱冷藏，不可冷凍

· Do not shake cetuximab.

· It should be infused over 60 mins. Max. infusion rate 10mg/min.

· 如經診斷為間質性肺部疾病(ILD)，需停止使用並且給予適當的治療。

· 輸液給藥法：

(1)請用適當無菌針筒由藥瓶中抽出用量，將其注入空輸液袋內，再進行輸注。切勿使用IV set直接插入藥瓶，以避免橡皮塞掉入藥瓶中。

(2)可原液輸注或以0.9%N/S稀釋後輸注。

(3)單獨使用一條管線輸注，結束要用0.9%N/S沖洗管線。

(4)輸注速率:不可大於2mL/min(10mg/min)。

(5)可用輸注幫浦、重力滴注或注射器幫浦輸注。

藥名相似:

外觀相似:

外觀描述: 20mL注射液，灰蓋玻璃小瓶，外包裝橘色標示

08.12B Monoclonal Antibodies

37980 D / Unknown(有

Kadcyla 賀癌寧凍晶注射劑

■■急用Ado-trastuzumab emtansine (T-DM1) 100mg vial

Dosage: 2急用藥 37980

Adult

· Metastatic breast cancer, HER2(+): IV infusion, 3.6 mg/kg every 3 wks (first infusion over 90 mins, subsequent infusions over 30 mins if prior infusions were well tolerated)

Pediatric

· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

If hepatotoxicity occurs, dosage adjusted as follows:

(1) ALT, AST elevations

· Grade 3 (5-20X ULN): Withhold until recover to ? grade 2, then resume with one dose level reduction.

· Grade 4 (20X ULN): Permanently DC treatment.

(2)Hyperbilirubinemia

· Grade 2 (1.5-3X ULN): Withhold until recovers to ? grade 1 (?1.5X ULN), then resume at the same dose level.

· Grade 3 (3-10X ULN): Withhold until bilirubin recovers to ? grade 1, then resume with one dose level reduction.

· Grade 4 (>10X ULN): Permanently DC treatment.

· Concomitant ALT, AST >3X ULN and total bilirubin >2 X ULN: Permanently DC treatment

Dosing adjustments in renal impairment:

Clcr ?30 mL/min: No dosage adjustment necessary

Clcr <30 mL/min: NDA

P: Inj: T-DM1 160mg vial(37537捐贈), KADCYLA* 160mg vial(37981), KADCYLA* 100mg vial(37980),

ADR:

COMMON

Constipation, nausea, thrombocytopenia, increased liver enzymes, musculoskeletal pain, headache, fatigue

SERIOUS

Left ventricular cardiac dysfunction, injection site extravasation, anemia, neutropenia, thrombocytopenia, hepatotoxicity, increased liver enzymes, injury of liver, anaphylactoid reaction, peripheral nerve disease, dyspnea, interstitial lung disease, pneumonitis

NOTE: 冰箱冷藏，不可冷凍。

· Do not substitute KADCYLA (T-DM1) for or with trastuzumab.

· Dose level reduction for adverse events:

1st dose reduction: reduce to 3 mg/kg

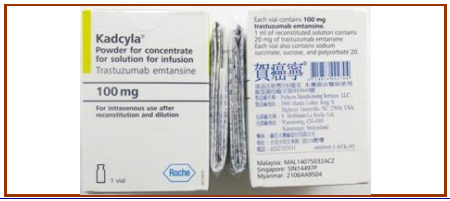
2nd dose reduction: reduce to 2.4 mg/kg

Further dose reductions: DC treatment

藥名相似:

外觀相似:

外觀描述:



08.12B Monoclonal Antibodies

37981 D / Unknown(有

KADCYLA* 160mg vial 賀癌寧凍晶注射劑

■■急用Ado-trastuzumab emtansine (T-DM1) 160mg vial

Dosage: 2急用藥 37981

Adult

· Metastatic breast cancer, HER2(+): IV infusion, 3.6 mg/kg every 3 wks (first infusion over 90 mins,

subsequent infusions over 30 mins if prior infusions were well tolerated)

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA
If hepatotoxicity occurs, dosage adjusted as follows:
(1) ALT, AST elevations
· Grade 3 (5-20X ULN): Withhold until recover to ? grade 2, then resume with one dose level reduction.
· Grade 4 (20X ULN): Permanently DC treatment.
(2)Hyperbilirubinemia
· Grade 2 (1.5-3X ULN): Withhold until recovers to ? grade 1 (?1.5X ULN), then resume at the same dose level.
· Grade 3 (3-10X ULN): Withhold until bilirubin recovers to ? grade 1, then resume with one dose level reduction.
· Grade 4 (>10X ULN): Permanently DC treatment.
· Concomitant ALT, AST >3X ULN and total bilirubin >2 X ULN: Permanently DC treatment

Dosing adjustments in renal impairment:

Clcr ?30 mL/min: No dosage adjustment necessary
Clcr <30 mL/min: NDA

P: Inj: T-DM1 160mg vial(37537捐贈), KADCYLA* 160mg vial(37981), KADCYLA* 100mg vial(37980)

ADR:

COMMON
Constipation, nausea, thrombocytopenia, increased liver enzymes, musculoskeletal pain, headache, fatigue
SERIOUS
Left ventricular cardiac dysfunction, injection site extravasation, anemia, neutropenia, thrombocytopenia, hepatotoxicity, increased liver enzymes, injury of liver, anaphylactoid reaction, peripheral nerve disease, dyspnea, interstitial lung disease, pneumonitis

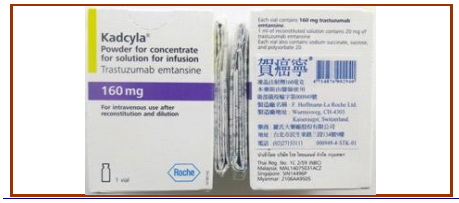
NOTE: 冰箱冷藏，不可冷凍。

· Do not substitute KADCYLA (T-DM1) for or with trastuzumab.
· Dose level reduction for adverse events:
1st dose reduction: reduce to 3 mg/kg
2nd dose reduction: reduce to 2.4 mg/kg
Further dose reductions: DC treatment

藥名相似:

外觀相似:

外觀描述:



08.12B Monoclonal Antibodies

37982 **C / Caution**

Gazyva solution for infusion 癌即瓦注射劑

■■急用Obinutuzumab inj 1000mg/40mL soln for infusion

Dosage: 2急用藥 37982

Adult
· Chronic lymphoid leukemia(previously untreated) in combination with chlorambucil: 28-day cycles
cycles 1: day 1, 100 mg IV infusion at 25 mg/hr over 4 hours (do not increase infusion rate); day 2, 900 mg IV infusion at 50 mg/hr (may increase by 50 mg/hr every 30 min to max.rate of 400 mg/hr); day 8 and day 15, 1000 mg IV infusion at a starting rate of 100 mg/hr (may increase by 100 mg/hr increments every 30 min to maxi. Rate of 400 mg/hr);
Cycles 2-6, day 1, 1000 mg IV infusion at a starting rate of 100 mg/hr (may increase by 100 mg/hr increments every 30 min to maxi. Rate of 400 mg/hr).

Pediatric
· Safety and effectiveness not established in pediatric patients

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr ?30 mL/min: No dosage adjustment necessary
Clcr <30 mL/min: NDA

P: Inj: 1000mg/40mL vial(37982)

ADR:

Common
Anemia (12%), neutropenia(38% to 41%), thrombocytopenia(14% to 15%), disorder of musculoskeletal system (18%), cough (10%),fever (All grades, 9% to 10%; grade 3 or 4, less than 1%)
Serious
Grade 3 or 4 anemia(5%), fatal hemorrhage, grade 3 or 4 leukopenia(4% to 5%), grade 3 or 4 neutropenia(33% to 35%), Grade 3 or 4 thrombocytopenia(10% to 11%), progressive multifocal leukoencephalopathy, infusion reaction, tumor lysis syndrome (2%)

NOTE: 2-8度C，應避光保存，不可冷凍

1. premedicate all patients with acetaminophen 650 to 1000 mg at least 30 minutes before infusion (all cycles), dexamethasone 20 mg IV or methylprednisolone 80 mg IV at least 1 hour before infusion (cycle 1, days 1 and 2), antihistamine (eg, diphenhydramine 50 mg) at least 30 minutes before infusion (cycle 1, days 1 and 2); premedicate patients with an infusion reaction of grade 1 or higher with a previous infusion with antihistamine (eg, diphenhydramine 50 mg) at least 30 minutes before infusion; premedicate patients with a grade 3 infusion reaction with a previous infusion or with a lymphocyte count of greater than 25 x 10(9)/L before the next treatment with dexamethasone 20 mg IV or methylprednisolone 80 mg IV at least 1 hour before infusion; for patients with neutropenia, consider antimicrobial, antiviral, and antifungal premedication; for patients with high tumor burden or circulating absolute lymphocyte count greater than 25 x 10(9)/L, premedicate with antihyperuricemics (eg, allopurinol) starting 12 to 24 hours before infusion and ensure adequate hydration
2.for patients on antihypertensive medications,

consider withholding those medications for 12 hours before, during, and 1 hour after infusion

藥名相似:

外觀相似:

外觀描述: 40mL透明注射液『灰』蓋透明玻璃瓶

08.12B Monoclonal Antibodies

37985 **ɔt be ruled out / Infant risk can**

YERVOY* (ipilimumab) Injection 5mg/mL 益伏注射劑 5 毫克/毫升

■■急用Ipilimumab 50mg/10mL vial

Dosage: 2急用藥 37985

·Unresectable or metastatic malignant melanoma: IV infusion over 90 min, 3 mg/kg every 3 weeks for 4 doses; permanently discontinue if treatment cannot be completed within 16 weeks.
·Renal cell carcinoma in combination with nivolumab as first-line treatment of advanced disease in patients with intermediate or poor risk: IV infusion over 30 min, 1 mg/kg on the same day with nivolumab, Q3W for 4 doses; after 3wks MD monotherapy of nivolumab until disease progression or unacceptable toxicity.
·Metastatic colorectal cancer, In combination with nivolumab, after progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan - Microsatellite instability-high, Or mismatch repair deficient: IV infusion over 30 min, 1 mg/kg Q3W for 4 doses; MD monotherapy of nivolumab until disease progression or unacceptable toxicity.

≧ 12yr
·Unresectable or metastatic malignant melanoma: IV infusion over 90 min, 3 mg/kg every 3 weeks for 4 doses; permanently discontinue if treatment cannot be completed within 16 weeks.

Dosing adjustments in hepatic impairment:

(1)Impairment at baseline:
·Mild hepatic impairment (total bilirubin > 1-1.5X ULN or AST > ULN): No dosage adjustment required
·Moderate (total bilirubin > 1.5-3X ULN and any AST) or severe impairment (total bilirubin >3X ULN and any AST): No dosage adjustment provided in manufacturer's labeling (has not been studied)
(2)Impairment during treatment:
·Grade 2(AST or ALT >2.5 to ?5X ULN or bilirubin >1.5 to ?3X ULN): Temporarily withhold treatment. It may resume with complete or partial resolution (to ?grade 1) of symptoms.
·Grade 3-5 (ALT or AST >5X ULN, or total bilirubin >3X ULN): Permanently discontinue.

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 50mg/10mL vial(37985)

ADR:

COMMON
Pruritus, Rash, Abdominal pain, Colitis, Immune-mediated, Decrease in appetite, Diarrhea, Nausea, Vomiting, Arthralgia, Musculoskeletal pain, Cough, Dyspnea, Fatigue, Fever.
SERIOUS
Immune-mediated Myocarditis, Immune-mediated Pericarditis, Immune-mediated Dermatitis, Immune-mediated Adrenal insufficiency, Immune-mediated Disorder of endocrine system, Immune-mediated Hyperthyroidism, Immune-mediated Hypogonadism, Immune-mediated Hypophysitis, Immune-mediated Hypopituitarism, Enterocolitis, Immune-mediated Pancreatitis, Perforation of intestine, Autoimmune hemolytic anemia, Immune-mediated Eosinophil count raised, Immune-mediated Hepatitis, Immune-mediated Hepatotoxicity, Immune-mediated Myositis, Immune-mediated Polymyositis, Immune-mediated Encephalitis, Guillain-Barre syndrome, Immune-mediated Meningitis, Immune-mediated Neuropathy, Peripheral motor neuropathy, Blurred vision, Immune-mediated Iritis, Myasthenia gravis, ocular, Immune-mediated Orbital myositis, Reduced visual acuity, Immune-mediated Uveitis, Immune-mediated Nephritis, Renal failure, Immune-mediated Pneumonitis, Infusion reaction.

NOTE: 冰箱冷藏，不可冷凍。

·Infuse over 90 mins using an in-line, sterile, nonpyrogenic, low-protein-binding filter.
·The IV line should be flushed with 0.9% NS or D5W after each dose.

藥名相似:

外觀相似:

外觀描述: 透明注射液，『淺藍』蓋透明玻璃小瓶，白底黑字標籤有淺藍/淺綠色區塊

08.12B Monoclonal Antibodies

37986 **C / Caution**

Vectibix solution for infusion 維必施 注射劑

■■急用Panitumumab inj 100mg/5mL vial

Dosage: 2急用藥 37986

·Metastatic colorectal cancer, wild-type KRAS (exon 2 in codons 12 or 13), first-line therapy in combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin): IV infusion, 6 mg/kg q 2w
·Metastatic colorectal cancer, wild-type KRAS (exon 2 in codons 12 or 13), monotherapy progression following fluoropyrimidine-, oxaliplatin-, and irinotecan-containing regimen: IV infusion, 6 mg/kg q 2w

· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 100mg/5mL vial(37986)

ADR:

COMMON
Peripheral edema, acneiform eruption, fissure in skin, generalized exfoliative dermatitis, nail changes, paronychia, pruritus, rash, hypomagnesemia, abdominal pain, constipation, diarrhea, nausea, vomiting, eye symptom, cough, dyspnea, fatigue
SERIOUS
Dermatologic toxicity, hypomagnesemia, abdominal pain, constipation, diarrhea, anaphylaxis, infusion reaction, sepsis, keratitis , acute renal failure, interstitial lung disease, pulmonary fibrosis

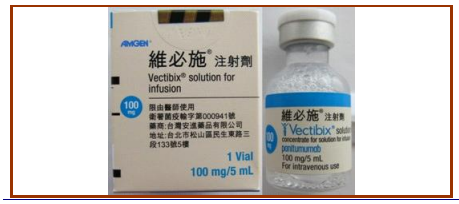
NOTE: 冰箱冷藏 2-8°C。

·Doses ≦1000 mg, infuse over 60mins; if tolerated, subsequent doses may be administered over 30-60 mins. Doses >1000 mg, infuse over 90 mins.
· If good tolerance after first-time infusion, susequent infusion may be adjuseted to 30-60 mins.
·Men and women should use an effective form of birth control for 6 months after treatment ends.
·It is recommended that women do not breast feed during treatmentwith Vectibix and for 2 months after the last dose.
·If a diagnosis of ulcerative keratitis is confirmed, treatment with Vectibix should be interrupted or discontinued. If keratitis is diagnosed, the benefits and risks of continuing treatment should becarefully considered.

藥名相似:

外觀相似:

外觀描述: 『白』蓋透明玻璃小瓶



08.12C Protein Kinase Inhibitors

21711 **D / Unsafe**

GLIVEC FILM-COATED TABLETS 100MG 基利克膜衣錠 100毫克

■■Imatinib mesylate 100mg tab

Dosage: 1常備品 21711

Adult
· CML-chronic phase: PO, 400mg qd; in the absence of significant toxicity, higher dose (600mg qd) may be given to patients failing to achieve satisfactory hematologic response or experiencing disease progression
· CML-accelerated phase/blast crises: PO, 600mg qd; in the absence of significant toxicity, higher dose (400mg bid) may be given to patients failing to achieve satisfactory hematologic response or experiencing disease progression
· ALL, Ph+: 400-600 mg qd
· Gastrointestinal stromal tumors (GIST): PO, 400 or 600mg qd

Pediatric:(> = 2 yrs)
· CML-chronic phase, recurrent or resistant: 260 mg/m(2)/day
· CML-chronic phase, newly diagnosed: 340 mg/m(2)/day; max: 600 mg/day

Dosing adjustments in hepatic impairment:

1. Liver transaminases> 5 times institutional upper limit of normal(IULN) or elevations in serum bilirubin > 3 times IULN: Imatinib should be stopped.
2. Transaminase < 2.5 times IULN and serum bilirubin < 1.5 times IULN: Reduced dose

Dosing adjustments in renal impairment:

1. Clcr 40-59 ml/min: max dose 600 mg/day
2. Clcr 20-39 ml/min: 50% of starting recommended dose; may be increased as tolerated; max dose 400 mg/day
3. Clcr <20 ml/min: Use with caution

P: Tab: 100mg(21711, GLIVEC*)(21715 IVIC*)

ADR:

COMMON
Fluid retention (pleural/pericardial effusion, ascites), muscle cramps, nausea/vomiting, diarrhea
SERIOUS
Hepatoxicity, myelosuppression (neutropenia, thrombocytopenia)

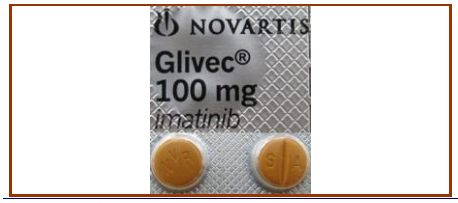
NOTE: 室溫保存

1. Take with food and a large glass of water to minimize GI irritation. Tablets may be dispersed in water or apple juice, stir until dissolved and use immediately.

藥名相似:

外觀相似:

外觀描述: 土黃圓扁錠,有NVR及SA字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024027

08.12C Protein Kinase Inhibitors

21714 **D / Unsafe**

Tasigna Capsules 200 mg 泰息安 膠囊 200 毫克

■■急用Nilotinib 200mg cap

Dosage: 2急用藥 21714

Adult
· Accelerated or chronic phase chronic myeloid leukemia with resistance or intolerance to imatinib: PO, 400mg q12h until disease progression or unacceptable toxicity

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Bilirubin or hepatic transaminase levels ≧ grade 3: Withhold nilotinib. Resume at a dose of 400mg qd if bilirubin and transaminase levels return to ≦ grade 1

Dosing adjustments in renal impairment:

NDA

P: Cap: 200mg(21714), 150mg(21716)

ADR:

COMMON
Peripheral edema, dry skin, pruritus, rash, hyperglycemia (grades 3 or 4), hypophosphatemia (grades 3 or 4), constipation, diarrhea, increased serum lipase level (grade 3 or 4), nausea, vomiting, arthralgia, bone pain, myalgia, pain in limb, muscle spasm, asthenia, headache, fatigue, cough, dyspnea, nasopharyngitis, fever
SERIOUS
Sudden death, prolonged QT interval, hypokalemia/hyponatremia (grades 3 or 4), anemia (grade 3 or 4), febrile neutropenia, neutropenia (grade 3 or 4), thrombocytopenia (grade 3 or 4), ALT(SGPT)/AST(SGOT) level raised (grade 3 or 4), hyperbilirubinemia (grade 3 or 4), intracranial hemorrhage, pneumonia

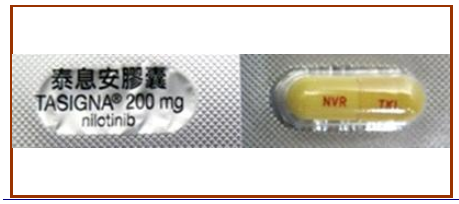
NOTE: 室溫儲存

· It should be taken on an empty stomach, at least 1 hour before or 2 hours after food
· It should be swallowed whole with water

藥名相似:

外觀相似:

外觀描述: 淡黃色膠囊，印有NVR/TKI字樣



08.12C Protein Kinase Inhibitors

21715 **D / Unsafe**

IVIC* Film-Coated Tablets 100mg 癌微可膜衣錠100毫克

■■Imatinib mesylate 100mg tab

Dosage: 1常備品 21715

Adult
· CML-chronic phase: PO, 400mg qd; in the absence of significant toxicity, higher dose (600mg qd) may be given to patients failing to achieve satisfactory hematologic response or experiencing disease progression
· CML-accelerated phase/blast crises: PO, 600mg qd; in the absence of significant toxicity, higher dose (400mg bid) may be given to patients failing to achieve satisfactory hematologic response or experiencing disease progression
· ALL, Ph+: 400-600 mg qd
· Gastrointestinal stromal tumors (GIST): PO, 400 or 600mg qd

Pediatric:(> = 2 yrs)
· CML-chronic phase, recurrent or resistant: 260 mg/m(2)/day
· CML-chronic phase, newly diagnosed: 340 mg/m(2)/day; max: 600 mg/day

Dosing adjustments in hepatic impairment:

1. Liver transaminases> 5 times institutional upper limit of normal(IULN) or elevations in serum bilirubin > 3 times IULN: Imatinib should be stopped.
2. Transaminase < 2.5 times IULN and serum bilirubin < 1.5 times IULN: Reduced dose

Dosing adjustments in renal impairment:

1. Clcr 40-59 ml/min: max dose 600 mg/day
2. Clcr 20-39 ml/min: 50% of starting recommended dose; may be increased as tolerated; max dose 400 mg/day
3. Clcr <20 ml/min: Use with caution

P: Tab: 100mg(21711, GLIVEC*)(21715 IVIC*)

ADR:

COMMON
Fluid retention (pleural/pericardial effusion, ascites), muscle cramps, nausea/vomiting, diarrhea
SERIOUS
Hepatoxicity, myelosuppression (neutropenia, thrombocytopenia)

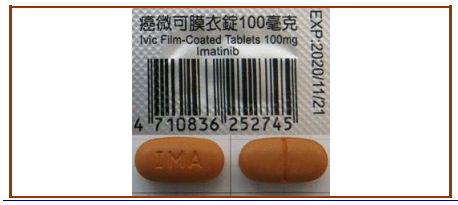
NOTE: 室溫保存

1. Take with food and a large glass of water to minimize GI irritation. Tablets may be dispersed in water or apple juice, stir until dissolved and use immediately.

藥名相似:

外觀相似:

外觀描述: 棕色橢圓型錠，一面中央有刻痕，另一面有"IMA"字樣



08.12C Protein Kinase Inhibitors

21716 **D / Unsafe**

Tasigna Capsules 150mg 泰息安膠囊150毫克

■■急用Nilotinib 150mg cap

Dosage: 2急用藥 21716

Adult
· Newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia in chronic phase: PO, 300mg q12h

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Initial 200mg q12h, may increase to 300mg q12h based on tolerability

Dosing adjustments in renal impairment:

NDA

P: Cap: 200mg(21714), 150mg(21716)

ADR:

COMMON
Pruritus, rash, abdominal pain, constipation, diarrhea, nausea, vomiting, arthralgia, backache, myalgia, pain in limb, asthenia, headache, cough, nasopharyngitis, fatigue, fever
SERIOUS
Prolonged QT interval, hypocalcemia/hypokalemia/hyponatremia/hypophosphatemia (grades 3 or 4), high lipase level in serum (grades 3 or 4),anemia (grade 3 or 4), febrile neutropenia, neutropenia (grade 3 or 4), thrombocytopenia (grade 3 or 4), ALT(SGPT)/AST(SGOT) level raised (grade 3 or 4), hyperbilirubinemia (grade 3 or 4), intracranial hemorrhage, pneumonia, tumor lysis syndrome

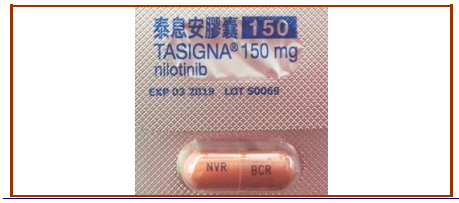
NOTE: 室溫儲存

· It should be taken on an empty stomach, at least 1 hour before or 2 hours after food
· It should be swallowed whole with water

藥名相似:

外觀相似:

外觀描述: 紅色膠囊，印有NVR/BCR字樣



08.12C Protein Kinase Inhibitors

21717 **demonstrated / Infant risk can**

Alvotinib* 400mg Film-Coated tablets 艾亭寧膜衣錠400毫克

急用■■Imatinib mesylate 400mg tab

Dosage: 2急用藥 21717

Adult
· CML-chronic phase: PO, 400mg qd; in the absence of significant toxicity, higher dose (600mg qd) may be given to patients failing to achieve satisfactory hematologic response or experiencing disease progression
· CML-accelerated phase/blast crises: PO, 600mg qd; in the absence of significant toxicity, higher dose (400mg bid) may be given to patients failing to achieve satisfactory hematologic response or experiencing disease progression
· ALL, Ph+: 400-600 mg qd
· Gastrointestinal stromal tumors (GIST): PO, 400 or 600mg qd

Pediatric:(> = 2 yrs)
· CML-chronic phase, recurrent or resistant: 260 mg/m(2)/day
· CML-chronic phase, newly diagnosed: 340 mg/m(2)/day; max: 600 mg/day

Dosing adjustments in hepatic impairment:

1. Liver transaminases> 5 times institutional upper limit of normal(IULN) or elevations in serum bilirubin > 3 times IULN: Imatinib should be stopped.
2. Transaminase < 2.5 times IULN and serum bilirubin < 1.5 times IULN: Reduced dose

Dosing adjustments in renal impairment:

1. Clcr 40-59 ml/min: max dose 600 mg/day
2. Clcr 20-39 ml/min: 50% of starting recommended dose; may be increased as tolerated; max dose 400 mg/day
3. Clcr <20 ml/min: Use with caution

P: P Tab: 400mg(21717), 100mg(21711 GLIVEC*), 100mg(21715 IVIC*)

ADR:

COMMON
Fluid retention (pleural/pericardial effusion, ascites), muscle cramps, nausea/vomiting, diarrhea
SERIOUS
Hepatoxicity, myelosuppression (neutropenia, thrombocytopenia)

NOTE: 室溫保存

1. Take with food and a large glass of water to minimize GI irritation. Tablets may be dispersed in water or apple juice, stir until dissolved and use immediately.

藥名相似:

外觀相似:

外觀描述: 棕色橢圓型錠，一面中央有刻痕，另一面有"400"字樣

08.12C Protein Kinase Inhibitors

21722 **D /**

Tarceva Film-coated tablets 150mg "瑞士"得舒緩膜衣錠150毫克

■■Erlotinib 150mg tab

Dosage: 1常備品 21722

Adult
· Non-small cell lung cancer(advanced/metastatic NSCLC after failure of prior chemotherapy): PO, 150mg once daily
· NDA

Dosing adjustments in hepatic impairment:

1. Normal hepatic function at baseline: T bilirubin >3 times ULN: interrupt or discontinue
2. Baseline hepatic impairment: severe changes in liver function: interrupt or discontinue

Dosing adjustments in renal impairment:

NDA

P: Tab: 100mg(21723), 150mg(21722)

ADR:

COMMON
Rash, diarrhea, loss of appetite, nausea, vomiting, headache, conjunctivitis, keratoconjunctivitis sicca, fatigue
SERIOUS

Myocardial infarction, gastrointestinal hemorrhage, deep venous thrombosis, microangiopathic hemolytic anemia with thrombocytopenia, hyperbilirubinemia, increased liver enzymes, cerebrovascular accident, renal failure, renal impairment

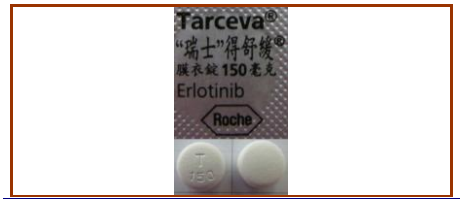
NOTE: 儲存30℃以下

· It should be taken on an empty stomach (at least 1 hour before or 2 hours after the ingestion of food)

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有"T"及"150"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=52026874

08.12C Protein Kinase Inhibitors

21723 **D /**

Tarceva Film-coated tablets 100mg "瑞士"得舒緩膜衣錠100毫克

■■Erlotinib 100mg tab

Dosage: 1常備品 21723

Adult

· Non-small cell lung cancer(advanced/metastatic NSCLC after failure of prior chemotherapy): PO, 150mg once daily

·

Dosing adjustments in hepatic impairment:

1. Normal hepatic function at baseline: T bilirubin >3 times ULN: interrupt or discontinue
2. Baseline hepatic impairment: severe changes in liver function: interrupt or discontinue

Dosing adjustments in renal impairment:

NDA

P: Tab: 100mg(21723), 150mg(21722)

ADR:

COMMON
Rash, diarrhea, loss of appetite, nausea, vomiting, headache, conjunctivitis, keratoconjunctivitis sicca, fatigue
SERIOUS
Myocardial infarction, gastrointestinal hemorrhage, deep venous thrombosis, microangiopathic hemolytic anemia with thrombocytopenia, hyperbilirubinemia, increased liver enzymes, cerebrovascular accident, renal failure, renal impairment

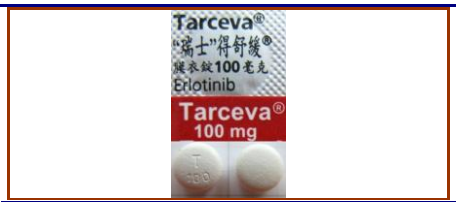
NOTE: 儲存30℃以下

· It should be taken on an empty stomach (at least 1 hour before or 2 hours after the ingestion of food)

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，有T及100字樣刻痕



08.12C Protein Kinase Inhibitors

21724 **ɔt be ruled out / Infant risk can**

Ternibin F.C. Tablets 250mg 癌必莎爾膜衣錠250毫克

■■Gefitinib 250mg tab

Dosage: 1常備品 21724

ADULT

· Non-small cell lung cancer, metastatic, first-line therapy, EGFR exon 19 deletions or exon 21 substitution mutations: PO, 250 mg QD without regard to food until disease progression or unacceptable toxicity

PEDIATRIC

· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Use with caution

P: P Tab: 250mg(21724)(27524)

ADR:

COMMON
Disorder of skin, decrease in appetite, diarrhea, nausea, vomiting, ALT/SGPT level raised, AST/SGOT level raised, asthenia, disorder of eye, proteinuria
SERIOUS
Bullous dermatosis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, gastrointestinal perforation, pancreatitis, hepatotoxicity, keratitis, interstitial lung disease, pneumonia, pulmonary embolism, respiratory failure

NOTE: 室溫保存

· For patients who have difficulty swallowing solids, it may be dissolved in half a glass of non-carbonated drinking water. Liquids other than water should not be used. Disperse tablet in water without crushing it (approximately 10 mins) and drink liquid immediately. Rinse the glass with half a glass of water and drink

藥名相似:

外觀相似:

外觀描述: 棕色圓錠,有CCP及265字樣

08.12C Protein Kinase Inhibitors

27417 **ɔt be ruled out / Infant risk can**

Alunbrig film-coated tablets 180mg 癌能畢 膜衣錠180毫

克

■■急用Brigatinib 180mg FC tab

Dosage: 2急用藥 27417

ADULT
·Anaplastic lymphoma kinase positive non-small cell lung cancer, metastatic, in patients who have progressed on or are intolerant of crizotinib: PO, 90mg QD for the first 7 days; if 90mg is tolerated for first 7 days, increase dose to 180mg QD until disease progression or unacceptable toxicity

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

·Mild or moderate (Child-Pugh A or B): No dosage adjustment needed
·Severe (Child-Pugh C): Reduce the once daily dose by approximately 40% (ie, from 180mg to 120mg, 120mg to 90mg, or from 90mg to 60mg)

Dosing adjustments in renal impairment:

·Mild or moderate (CrCl 30-89 mL/min): No dosage adjustment needed
·Severe (CrCl 15-29 mL/min): Reduce the once daily dose by approximately 50% (ie, from 180mg to 90mg, or from 90mg to 60mg)

P: P Tab: 180mg(27417)

ADR:

COMMON
Hyperglycemia, diarrhea, increased serum lipase level, nausea, serum amylase raised, increased creatine kinase level, headache, cough, dyspnea, fatigue
SERIOUS
Interstitial lung disease, pneumonia, pneumonitis

NOTE: 室溫儲存

·Swallow the tablet whole. Do not crush, break, or chew it
·Dosing adjustment for toxicity: If the dose received was 90mg QD, then first dose reduction is 60mg QD, second dose reduction is permanently discontinue. If the dose received was 180mg QD, then first dose reduction is 120mg QD, second dose reduction is 90mg QD, third dose reduction is 60mg QD. Permanently discontinue if unable to tolerate the 60mg QD dose.

藥名相似:

外觀相似:

外觀描述: 灰白色橢圓錠，有「U13」字樣

08.12C Protein Kinase Inhibitors

27524 D /

IRESSA* FILM-COATED TABLETS 250MG 艾瑞莎 膜衣錠 ２５０公絲

■■Gefitinib 250mg tab

Dosage: 1常備品 27524

Adult
· Non-small cell lung cancer(advanced/metastatic NSCLC who have failed both platinum and docetaxel-based chemotherapies): PO, 250mg once daily

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Use with caution

P: Tab: 250mg(27524)

ADR:

COMMON
Acne, dry skin, pruritus, loss of appetite, nausea, vomiting, asthenia
SERIOUS
Rash, diarrhea, disorder of eye, new onset eye pain, aberrant eyelash, corneal erosion/ ulcer,interstitial lung disease, interstitial pneumonia, pneumonitis and alveolitis

NOTE: 室溫保存30℃以下

· For patients who have difficulty swallowing solids, it may be dissolved in half a glass of non-carbonated drinking water. Liquids other than water should not be used. Disperse tablet in water without crushing it (approximately 10 mins) and drink liquid immediately. Rinse the glass with half a glass of water and drink

藥名相似:

外觀相似:

外觀描述: 磚紅色圓扁錠,有IRESSA及250字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023808

08.12C Protein Kinase Inhibitors

27532 D / Infant risk can

Sutent Capsules 12.5mg 紓癌特膠囊12.5毫克

■■Sunitinib 12.5mg cap

Dosage: 1常備品 27532

Adult
·Advanced renal cell carcinoma, gastrointestinal stromal tumor (after disease progression on or intolerance to imatinib): PO, 50mg once daily in a repeated 6-week cycle (4 weeks on, 2 weeks off)PO, 50mg once daily in a repeated 6-week cycle (4 weeks on, 2 weeks off) or 50 mg orally once daily for 2 weeks on followed by 1 week off for individual intolerate.
· Pancreatic neuroendocrine tumors: 37.5 mg once daily

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Sunitinib has not been studied in patients with severe hepatic impairment. Sunitinib therapy is not recommended for patients with severe liver impairment (Child-Pugh C)

Dosing adjustments in renal impairment:

Not necessary

P:

ADR:

COMMON

Yellow Discoloration of skin, Dry skin, Rash, Hypothyroidism, Abdominal pain, Constipation, Diarrhea, Indigestion, Inflammatory disease of mucous membrane, Loss of appetite, Nausea, Pain of oral cavity structure, Taste sense altered , Vomiting, Anemia, Hemorrhage, Leukopenia, Lymphocytopenia, Neutropenic disorder, Liver function tests abnormal, Pain in limb, Asthenia, Increased uric acid level, Bleeding from nose, Cough, Fatigue.

SERIOUS

Hypertension, Left ventricular cardiac dysfunction, Prolonged QT interval, Torsades de pointes, Erythema multiforme, Necrotizing fasciitis, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Severe hypothyroidism, Gastrointestinal perforation, Increased serum lipase level, Pancreatitis, Hemorrhage, Tumor, Microangiopathic hemolytic anemia, Thrombocytopenia, Thrombotic microangiopathy, Hepatotoxicity, Liver failure, Osteonecrosis of jaw, Posterior reversible encephalopathy syndrome, Nephrotic syndrome, Proteinuria, Hemoptysis, Pulmonary embolism, Pulmonary hemorrhage, Radiation recall syndrome, Pneumonitis, Tumor lysis syndrome.

NOTE: 室溫儲存15-30°C

·《Contraindications》Specific contraindications have not been determined；

·Dose modification is recommended in patients using concomitant CYP3A4 inhibitors or inducers

·Dose adjustment of 12.5mg increments is recommended based on individual safety and tolerability

·仿單內容變更，摘述如下：(版本USPI 201211-1)

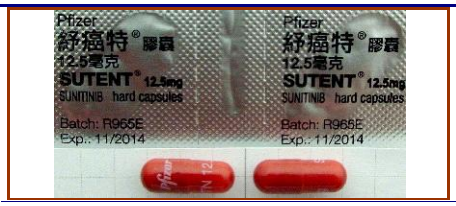
1.上市後的使用經驗：增列(A)栓塞性微血管病變、血小板減少引發的出血(建議暫停本藥，待症狀緩解後由醫師判斷是否繼續治療)。(B)過敏反應。?嚴重感染(併有或未併有嗜中性白血球減少症)、包括會陰部在內的壞死性筋膜炎。(D)腫瘤溶解症候群。(E)廔管形成，有時伴有腫瘤壞死及/或縮小、ONJ、肌肉病變及/或橫紋肌溶解症(併有或未併有急性腎衰竭)。(F)腎功能不全及/或腎衰竭、蛋白尿、少數發生腎病症候群。(出現腎病症候群者應停用)。(G)肺栓塞、肺出血。(H)壞疽性膿皮症。(I)動脈血栓栓塞事件。

2.更新致癌性、致突變性、生育力損害之相關資訊。

藥名相似:

外觀相似:

外觀描述: 紅褐色膠囊，有pfizer及STN 12.5mg字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024593

08.12C Protein Kinase Inhibitors

27538 demonstrated / Infant risk can

SPRYCEL Film-coated Tablets 50mg 柏萊膜衣錠 50 毫克

■■急用Dasatinib 50mg FC tab

Dosage: 2急用藥 27538

Adult

· Accelerated or blast phase chronic myeloid leukemia, Philadelphia chromosome-positive acute lymphoid leukemia with resistance or intolerance to imatinib: PO, 70mg bid, may be increased to 100mg bid in patients who do not achieve a hematologic or cytogenetic response

· Chronic phase chronic myeloid leukemia with resistance or intolerance to imatinib: PO, 100mg qd, may be increased to 140mg qd in patients who do not achieve a hematologic or cytogenetic response

Pediatric

·Safety and efficacy have not been established in patients less than 18 years old.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 50mg (27538)

ADR:

COMMON

Localized edema, Superficial, Rash, Body fluid retention, Abdominal pain, Diarrhea, Nausea, Vomiting, All Grades Febrile neutropenia, Musculoskeletal pain, Headache, Dyspnea, Fatigue, Fever.

SERIOUS

Congestive heart failure, Or cardiac dysfunction, Pericardial effusion, Prolonged QT interval, Altered growth and development, Pediatric, Gastrointestinal hemorrhage, Hemorrhagic colitis, Grade 3 or 4 Anemia, Grade 3 or 4 Febrile neutropenia, All Grades Hemorrhage, Grade 3 or 4 Hemorrhage, Myelosuppression, Grade 3 or 4 Neutropenia, Grade 3 or 4 Thrombocytopenia, Ascites, Hepatitis, Bacteremia, Hypersensitivity reaction, Infectious disease, Cerebral hemorrhage, Pleural effusion, Pneumonia, Pulmonary edema, Pulmonary hypertension, Sepsis.

NOTE: 室溫儲存15~30℃

· Swallow whole; do not break, crush or chew

· Doses should be increased or reduced in 20mg increments per dose based on safety and tolerability

· Antacids should be administered at least 2 hrs prior to or 2 hrs after dasatinib

· 慢性CML病人，建議治療初每2週進行一次CBC評估

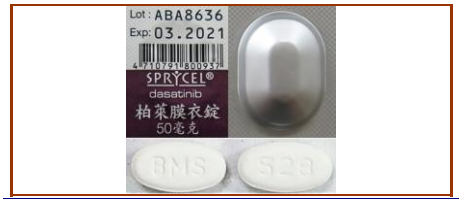
· 持續12週，之後調整每3個月評估一次。晚期CML或Ph+ALL病人，建議治療最初2個月每週進行一次CBC評

估，之後調整為每月一次。
・骨髓抑制-加註對於接受本藥併用化療的Ph+ ALL兒童病人，每次化療療程開始前和臨床上有需要時進行CBC評估。在化療鞏固療程期間，每兩天進行CBC評估直到復原。

藥名相似:

外觀相似:

外觀描述: 白色橢圓形錠，一面有BMS字樣，另一面有528字樣



08.12C Protein Kinase Inhibitors

27550 **demonstrated / Infant risk can**

SPRYCEL Film-coated Tablets 20mg 柏萊膜衣錠 20 毫克

■■急用Dasatinib 20mg FC tab

Dosage: 2急用藥 27550

Adult
・Accelerated or blast phase chronic myeloid leukemia, Philadelphia chromosome-positive acute lymphoid leukemia with resistance or intolerance to imatinib: PO, 140mg qd, may be increased to 180mg/day in patients who do not achieve a hematologic or cytogenetic response
・Chronic phase chronic myeloid leukemia with resistance or intolerance to imatinib: PO, 100mg qd, may be increased to 140mg qd in patients who do not achieve a hematologic or cytogenetic response

Pediatric
·Safety and efficacy have not been established in patients less than 18 years old.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed; use with caution

Dosing adjustments in renal impairment:

NDA

P: Tab: 20mg(27550), 50mg (27538)

ADR:

COMMON
Localized edema, Superficial, Rash, Body fluid retention, Abdominal pain, Diarrhea, Nausea, Vomiting, All Grades Febrile neutropenia, Musculoskeletal pain, Headache, Dyspnea, Fatigue, Fever.
SERIOUS
Congestive heart failure, Or cardiac dysfunction, Pericardial effusion, Prolonged QT interval, Altered growth and development, Pediatric, Gastrointestinal hemorrhage, Hemorrhagic colitis, Grade 3 or 4 Anemia, Grade 3 or 4 Febrile neutropenia, All Grades Hemorrhage, Grade 3 or 4 Hemorrhage, Myelosuppression, Grade 3 or 4 Neutropenia, Grade 3 or 4 Thrombocytopenia, Ascites, Hepatitis, Bacteremia, Hypersensitivity reaction, Infectious disease, Cerebral hemorrhage, Pleural effusion, Pneumonia, Pulmonary edema, Pulmonary hypertension, Sepsis.

NOTE: 室溫儲存15~30℃

・Swallow whole; do not break, crush or chew
・Antacids should be administered at least 2 hrs prior to or 2 hrs after dasatinib
・骨髓抑制-加註對於接受本藥併用化療的Ph+ ALL兒童病人，每次化療療程開始前和臨床上有需要時進行CBC評估。在化療鞏固療程期間，每兩天進行CBC評估直到復原。

藥名相似:

外觀相似:

外觀描述: 白色圓形錠，一面有BMS字樣，另一面有527字樣

08.12C Protein Kinase Inhibitors

27568 **X / Unsafe**

TAGRISSO* FC tab 80 mg 泰格莎膜衣錠

■■急用Osimertinib 80mg tab

Dosage: 2急用藥 27568

Adult
·Metastatic non-small cell lung cancer with T790M EGFR mutation-positive: PO, 80mg qd, with or without food

PPediatric
·Safety and efficacy has not been established

Dosing adjustments in hepatic impairment:

Mild impairment: no adjustment adjustment needed
Moderate to severe impairment: NDA

Dosing adjustments in renal impairment:

CrCl 30-89 mL/min: No dosage adjustment needed
CrCl <30 mL/min and ESRD: NDA

P: Tab: 80mg(27974, 捐贈專案; 27568, 急用)

ADR:

COMMON
Dry skin, nail changes, rash, diarrhea, lymphocytopenia, thrombocytopenia
SERIOUS
Prolonged QT interval, anemia (Grade 3 or 4), hyponatremia (Grade 3 or 4), lymphocytopenia (Grade 3 or 4), neutropenia (Grade 3 or 4), thrombocytopenia (Grade 3 or 4), venous thromboembolism, venous thromboembolism (Grade 3 or 4), cerebral hemorrhage, cerebrovascular accident, decreased cardiac ejection fraction, Interstitial lung disease, pneumonia

NOTE: 室溫保存

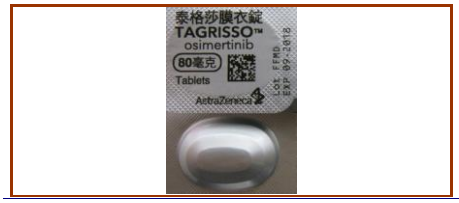
·Swallowed whole, do not crush
·For patients who have difficulty swallowing tablets, it may be dispersed in 50mL of water and drink immediate
·Use effective contraception during treatment and for 6 wks after the final dose for females, 4 mons

after the final dose for males

藥名相似:

外觀相似:

外觀描述: 淺棕色、橢圓形、雙凸面錠劑，一面壓印「AZ 80」字樣



08.12C Protein Kinase Inhibitors

27569 D / Unsafe

Votubia 2.5 mg tablets 愛服妥錠 2.5 毫克

■■急用Everolimus 2.5mg tab

Dosage: 2急用藥 27569

Adult
·Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS) :
0.5m2~1.2m2: 2.5mg qd
1.3m2~2.1m2: 5mg qd
≧2.2m2: 7.5mg qd

Pediatric (≧3 yrs or BSA > 0.58 m2)
·Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS) : Same as adult

Dosing adjustments in hepatic impairment:

Moderate hepatic impairment (Child-Pugh Class B): 50% dose reduction
Severe hepatic impairment (Child-Pugh Class C): Not recommended

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 5mg(27579,急用)(27979,專案捐贈), 2.5mg(27569,急用)

ADR:

COMMON
Hypertension, peripheral edema, infection of skin and/or subcutaneous tissue, rash, decreased phosphate level, dyslipidemia, hyperlipidemia, increased glucose level, serum cholesterol raised, serum triglycerides raised, constipation, diarrhea, loss of appetite, nausea, oropharyngeal mucositis, stomatitis, ulcer of mouth, vomiting, anemia, decreased hemoglobin, decreased lymphocyte count, decreased platelet count, ALT/SGPT level raised, AST/SGOT level raised, surgical wound finding, asthenia, otitis media, serum creatinine raised, urinary tract infectious disease, cough, dyspnea, sinusitis, upper respiratory infection, fatigue, fever
SERIOUS
Decreased hemoglobin (grade 4), decreased lymphocyte count (grade 4), hemorrhage, leukopenia, thrombotic microangiopathy, thrombotic thrombocytopenic purpura, infectious disease, seizure, hemolytic uremic syndrome, thrombosis of renal artery, pleural effusion, noninfectious pneumonitis

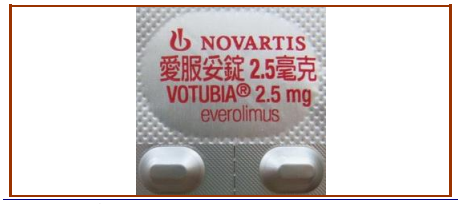
NOTE: 室溫儲存30℃以下

·Swallow whole; do not crush or chew.
·If coadministration with a strong CYP3A4 inducer, consider adjusting everolimus dose upward in 5mg increments up to 20mg daily.
·If miss a dose, use it as soon as possible. If it is more than 6 hours, skip the missed dose and go back to the regular dosing schedule. Do not double doses.
·If dose reduction is required for patients receiving 2.5 mg daily, consider alternate day dosing.

藥名相似:

外觀相似:

外觀描述: 白色至微黃長型錠劑，一面有"LCL"字樣，另一面有" NVR"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=20000021

08.12C Protein Kinase Inhibitors

27572 D / Infant risk can

Nexavar film-coated tablets 200mg 蕾莎瓦膜衣錠 200 毫克

■■Sorafenib 200mg FC tab

Dosage: 1常備品 27572

Adult
· Advanced renal cell carcinoma: PO, 400mg bid ac

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Mild to moderate impairment(Child-Pugh A or B): No dosage adjustment needed
Severe impairment(Child-Pugh C): Not studied

Dosing adjustments in renal impairment:

NDA

P: Tab: 200mg(27572)

ADR:

COMMON
Hypertension, alopecia, dry skin, hand-foot syndrome due to cytotoxic therapy, pruritus, rash, hypophosphatemia, weight loss, abdominal pain, constipation, diarrhea, increased amylase level, increased lipase level, loss of appetite, nausea, vomiting, anemia, lymphocytopenia, neutropenia, thrombocytopenia, arthralgia, myalgia, headache, sensory neuropathy, depression, fatigue
SERIOUS
Heart failure, hypertensive crisis, ischemic heart disease, acute, myocardial infarction, erythema multiforme, hemorrhage, all body sites, thromboembolic disorder, acute renal failure

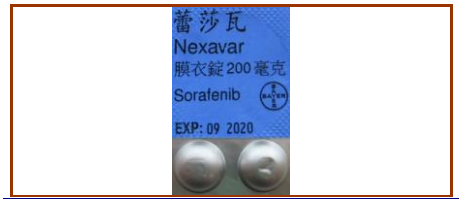
NOTE: 室溫儲存30℃以下

· If dosage reduction is required in the management of adverse reactions, the recommended reduced dose is 400mg qd; may reduce further to 400mg qod

藥名相似:

外觀相似:

外觀描述: 磚紅色圓扁錠，一面有200字樣，另一面有BAYER字樣



08.12C Protein Kinase Inhibitors

27576 **D /**

Tykerb tablets 250mg 泰嘉錠 250 毫克膜衣錠

■■急用Lapatinib 250mg tab

Dosage: 2急用藥 27576

Adult
· Advanced/metastatic breast cancer: PO, 1250mg once daily on days 1-21 in combination with capecitabine 2000mg/m2/day divided into 2 doses on days 1-14 of each 21-day cycle until disease progression or unacceptable toxicity

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Severe hepatic impairment (Child-Pugh Class C): 750mg daily

Dosing adjustments in renal impairment:

NDA

P: Tab: 250mg(27576)

ADR:

COMMON
Hand-foot syndrome, rash, diarrhea, indigestion, nausea, vomiting, anemia, thrombocytopenia, ALT/SGPT level raised, AST/SGOT level raised, hyperbilirubinemia, backache, pain in limb, insomnia, dyspnea
SERIOUS
Depression of left ventricular systolic function, prolonged QT interval, interstitial lung disease

NOTE: 室溫保存

· Lapatinib daily dosage should not be divided
· Lapatinib should be taken at least 1 hour before or 1 hour after meals. However, capecitabine should be taken with food or within 30 mins after food
· Concomitant use of lapatinib with a potent CYP3A4 inhibitor/inducer should be avoided

藥名相似:

外觀相似:

外觀描述: 米黃色橢圓錠，一面有GS XJG字樣

08.12C Protein Kinase Inhibitors

27579 **D / Unsafe**

Afinitor 5mg tablets 癌伏妥錠5毫克

■■急用Everolimus 5mg tab

Dosage: 2急用藥 27579

Adult
·Advanced renal cell carcinoma after treatment failure with sunitinib or sorafenib: PO, 10mg qd

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Moderate hepatic impairment (Child-Pugh Class B): 5mg qd
Severe hepatic impairment (Child-Pugh Class C): Not recommended

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 5mg(27579)(27979,專案捐贈)

ADR:

COMMON
Hypertension, peripheral edema, infection of skin and/or subcutaneous tissue, rash, decreased phosphate level, dyslipidemia, hyperlipidemia, increased glucose level, serum cholesterol raised, serum triglycerides raised, constipation, diarrhea, loss of appetite, nausea, oropharyngeal mucositis, stomatitis, ulcer of mouth, vomiting, anemia, decreased hemoglobin, decreased lymphocyte count, decreased platelet count, ALT/SGPT level raised, AST/SGOT level raised, surgical wound finding, asthenia, otitis media, serum creatinine raised, urinary tract infectious disease, cough, dyspnea, sinusitis, upper respiratory infection, fatigue, fever
SERIOUS
Decreased hemoglobin (grade 4), decreased lymphocyte count (grade 4), hemorrhage, leukopenia, thrombotic microangiopathy, thrombotic thrombocytopenic purpura, infectious disease, seizure, hemolytic uremic syndrome, thrombosis of renal artery, pleural effusion, noninfectious pneumonitis

NOTE: 室溫儲存

·Swallow whole; do not crush or chew.
·If coadministration with a strong CYP3A4 inducer, consider adjusting everolimus dose upward in 5mg increments up to 20mg daily.
·If miss a dose, use it as soon as possible. If it is more than 6 hours, skip the missed dose and go back to the regular dosing schedule. Do not double doses.

藥名相似:

外觀相似:

外觀描述: 鋁片有黑色" AFINITOR 5MG"字樣;白色長橢圓錠，一面印有5字樣，另一面印有NVR字樣

08.12C Protein Kinase Inhibitors

27580 **D / Unsafe**

Votrient (Pazopanib HCl) film-coated tablets 200mg 福退癌膜衣錠200毫克

■■Pazopanib 200mg tab

Dosage: 1常備品 27580

Adult
·Advanced renal cell carcinoma: PO, ac, 800mg qd; initial dose reduction should be 400mg with additional dose decreases or increases in 200mg increments based on tolerability; Max. 800mg/day

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

· Mild hepatic impairment: No dosage adjustment needed
· Moderate hepatic impairment: 200mg/day
· Severe hepatic impairment(total bilirubin >3X ULN with any ALT level): Not recommended
· ALT 3-8X ULN: Continue pazopanib; monitor liver function weekly until ALT return to grade 1 or baseline
· ALT >8X ULN: Interrupt pazopanib until ALT return to grade 1 or baseline; if benefit outweighs risk, reinitiate pazopanib at a reduced dosage of 400mg or less once daily. Following reinitiation, if ALT greater than 3X ULN recurs, discontinue pazopanib permanently
· ALT >3X ULN and bilirubin >2X ULN: Discontinue pazopanib permanently

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 200mg(27580)

ADR:

COMMON
Hypertension, hair color change, decreased albumin, hypomagnesemia, hyponatremia, hypophosphatemia, increased glucose level, weight decreased, decrease in appetite, diarrhea, loss of appetite, nausea, vomiting, leukopenia, neutropenia, thrombocytopenia, alkaline phosphatase raised, ALT/SGPT level raised, AST/SGOT level raised, increased bilirubin level, lymphocytopenia, musculoskeletal pain, myalgia, headache, dyspnea, cancer pain, fatigue
SERIOUS
Congestive heart failure, hypertension(grade 3/4), hypertensive crisis, left ventricular cardiac dysfunction, myocardial infarction, prolonged QT interval, Torsades de pointes, hypothyroidism, bleeding from anus, bleeding from mouth, gastrointestinal fistula, gastrointestinal perforation, pancreatitis, rectal hemorrhage, hemorrhage, leukopenia(grade 3/4), neutropenia(grade 3/4), thrombocytopenia(grade 3/4), venous thromboembolism, ALT/SGPT level raised(grade 3/4), AST/SGOT level raised(grade 3/4), hepatotoxicity, increased bilirubin level(grade 3/4), infectious disease, lymphocytopenia(grade 3/4), cerebrovascular accident, reversible posterior leukoencephalopathy syndrome, transient ischemic attack, pneumothorax, fatal pulmonary embolism

NOTE: 室溫儲存

·Take on an empty stomach 1 hour before or 2 hours after a meal.
·It should be swallowed whole and should not be crushed; crushing the tablets has been shown to increase the rate of absorption and systemic exposure to the drug.
·Stop pazopanib at least 7 days prior to scheduled surgery and resume after surgery based on clinical judgement of adequate wound healing.

藥名相似:

外觀相似:

外觀描述: 修飾膠囊型之粉紅色錠劑，一面印有GS JT字樣

08.12C Protein Kinase Inhibitors

27582 **ɔt be ruled out / Infant risk can**

XALKORI Capsules 250mg 截剋瘤膠囊250毫克

■■急用Crizotinib 250mg cap

Dosage: 2急用藥 27582

·Metastatic anaplastic lymphoma kinase(ALK)-positive non-small cell lung cancer: PO, 250mg bid until disease progression or intolerance.
·Non-small cell lung cancer, Metastatic, ROS1-positive: PO, 250mg bid until disease progression or intolerance.

Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

·Mild impairment(AST> ULN and total bilirubin? ULN, or any AST and ULN< total bilirubin? 1.5×ULN): No adjustment required.
·Moderate impairment(any AST and 1.5×ULN< total bilirubin? 3×ULN): PO, 200 mg BID.
·Severe impairment(any AST and total bilirubin> 3×ULN): PO, 250 mg QD.
·Dosage reduction during therapy:
(1)Grade 3 or 4 ALT or AST elevation (ALT or AST >5X ULN) with ? grade 1 total bilirubin elevation (bilirubin? 1.5X ULN): Withhold until recovery to baseline or ? grade 1 (? 3X ULN), then resume at 200mg bid; if toxicity recurs, withhold again until recovery to ? grade 1, then resume at 250mg qd; permanently discontinue if unable to tolerate 250mg qd
(2)ALT or AST elevation >3X ULN with total bilirubin > 1.5X ULN (in the absence of cholestasis or

hemolysis): Permanently discontinue

Dosing adjustments in renal impairment:

Moderate impairment (Clcr 30-59 mL/min): No dosage adjustments required.
Severe impairment not requiring dialysis: Initial 250mg qd

P: Cap: 250mg(27582)

ADR:

COMMON
Edema, Constipation, Diarrhea, Nausea, Vomiting, All grades of Lymphocytopenia, All grades of Neutropenia, Disorder of vision.
SERIOUS
Bradyarrhythmia, Prolonged QT interval, Grade 3 or 4 Lymphocytopenia, Grade 3 or 4 Neutropenia, ALT/SGPT level raised, AST/SGOT level raised, Hepatotoxicity, Unexplained visual loss, Dyspnea, Interstitial lung disease, Pneumonia, Pneumonitis, Pulmonary embolism.

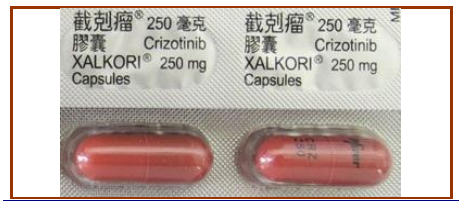
NOTE: 室溫儲存30℃以下

·Swallowed whole; do not crush, dissolve or open it.
·If dose reduction is necessary due to adverse reactions of Grade 3 or 4 severity, reduce dose to 200mg bid; if necessary, further reduce to 250mg qd. If unable to tolerate 250mg qd, permanently discontinue therapy.對於接受250mg QD治療，或曾調降至250mg QD的病人，評估期間停止給藥。
·Severe vision loss has been reported; potentially due to optic atrophy or optic nerve disorder; monitoring recommended and discontinuation required
·1.特殊警語及使用注意事項：增列心衰竭。(如出現心衰竭的症狀，應酌情考慮中斷投藥、減少劑量或停藥)2.不良反應：增列心衰竭。 (仿單內容變更，公文號:2622)(106.03.10)
·2.最初2個月治療期間應每週監測一次肝功能，包括ALT、AST與總膽紅素，之後每月監測一次肝功能，臨床上出現第2、3或第4級升高的情況時，應更為頻繁地重複檢測。

藥名相似:

外觀相似:

外觀描述: 粉紅色膠囊，有Pfizer及CRZ 250字樣



08.12C Protein Kinase Inhibitors

27583 **D / Unsafe**

Giotrif Film-Coated Tablets 30 mg 妥復克膜衣錠30毫克

■■Afatinib 30mg tab

Dosage: 1常備品 27583

Adult
·Metastatic nonsmall cell lung cancer (NSCLC) with EGFR-TK mutations: PO, 40 mg qd at least 1 hr before or 2-3 hrs after a meal; continue until disease progression or no longer tolerated

Pediatric
· Safety and effectiveness have not been established in pediatric patients

Dosing adjustments in hepatic impairment:

· Mild to moderate impairment (Child Pugh class A or B): No dosage adjustment necessary
· Severe (Child-Pugh C) impairment: Not recommended

Dosing adjustments in renal impairment:

· Mild to moderate impairment: No dosage adjustment necessary.
· Severe impairment (Clcr< 30mL/min): Not recommended

P: Tab:30mg(捐贈專案27883), 40mg(捐贈專案27884), 50mg(捐贈專案27882), 40mg(27584), 30mg(27583)

ADR:

COMMON
Acneiform drug eruption, dry skin, paronychia, pruritus, rash, decrease in appetite, diarrhea, stomatitis
SERIOUS
Impaired left ventricular function, bullous eruption, Hand-foot syndrome, grade 3 diarrhea, hepatotoxicity, interstitial lung disease

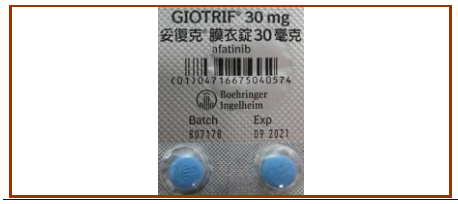
NOTE: 室溫儲存

·A high-fat meal decreased Cmax by 50% and AUC by 39% relative to the fasted condition.
·Afatinib is indicated for metastatic NSCLC whose EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.
·For grade 3 or higher adverse events, withhold treatment until fully resolved, a return to baseline, or improvement to grade 1. Resume therapy at 10mg per day less than previous dose.

藥名相似:

外觀相似:

外觀描述: 深藍色圓形,一面有商標圖樣,另一面有T30字樣



08.12C Protein Kinase Inhibitors

27584 **D / Unsafe**

Giotrif Film-Coated Tablets 40 mg 妥復克膜衣錠40毫克

■■Afatinib 40mg tab

Dosage: 1常備品 27584

ADULT
·Metastatic nonsmall cell lung cancer (NSCLC) with EGFR-TK mutations: PO, 40 mg qd at least 1 hr before or 2-3 hrs after a meal; continue until disease progression or no longer tolerated

PEDIATRIC
· Safety and effectiveness have not been established in pediatric patients

Dosing adjustments in hepatic impairment:

· Mild to moderate impairment (Child Pugh class A or B): No dosage adjustment necessary
· Severe (Child-Pugh C) impairment: Not recommended

Dosing adjustments in renal impairment:

· Mild to moderate impairment: No dosage adjustment necessary.
· Severe impairment (Clcr< 30mL/min): Not recommended

P: Tab:30mg(捐贈專案27883), 40mg(捐贈專案27884), 50mg(捐贈專案27882), 40mg(急用27584)

ADR:

COMMON
Acneiform drug eruption, dry skin, paronychia, pruritus, rash, decrease in appetite, diarrhea, stomatitis
SERIOUS
Impaired left ventricular function, bullous eruption, Hand-foot syndrome, grade 3 diarrhea, hepatotoxicity, interstitial lung disease

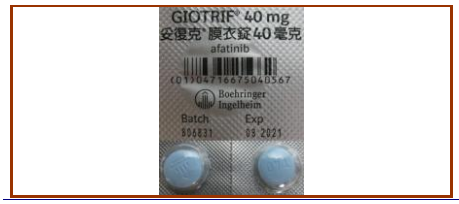
NOTE: 室溫儲存

·A high-fat meal decreased Cmax by 50% and AUC by 39% relative to the fasted condition.
·Afatinib is indicated for metastatic NSCLC whose EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.

藥名相似:

外觀相似:

外觀描述: 淺藍色圓形,一面有商標圖樣,另一面有T40字樣



08.12C Protein Kinase Inhibitors

27588 **C / Unsafe**

JAKAVI 5mg tablet 捷可衛錠 5毫克

■■急用Ruxolitinib 5mg tab

Dosage: 2急用藥 27588

Adult
· Myelofibrosis: PO,
Platelets >200,000/mm(3): 20 mg bid
Platelets 100,000-200,000/mm(3):15 mg bid
Platelets 50,000-100,000/mm(3): initial dose should not exceed 5 mg bid; titrate dose cautiously
Max. 25mg bid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Platelets 100,000-200,000/mm(3): 10mg bid
Platelets <100,000/mm(3): Avoid use

Dosing adjustments in renal impairment:

Clcr 15-59mL/min, platelets 100,000-150,000/mm(3): 10mg bid
Clcr 15-59mL/min, platelets <100,000/mm(3): Avoid use
Clcr <15mL/min: Avoid use

P: Tab: 5mg(27588)

ADR:

COMMON
Contusion, anemia, neutropenia, thrombocytopenia, dizziness, headache
SERIOUS
Anemia(grade 3/4), neutropenia(grade 3/4), thrombocytopenia(grade 3/4)

NOTE: 室溫儲存

· Dosage should not be increased during the first 4 weeks of therapy or more frequently than every 2 weeks.
· It should be interrupted in patients with platelet counts< 50,000/mm(3).
·NG tube administration: Suspend 1 tablet in ~40mL water and stir for ~10 mins and administer within 6 hrs after dispersion with appropriate syringe; rinse NG tube with ~75mL water.

藥名相似:

外觀相似:

外觀描述: 白色圓錠，一面印有NVR字樣，另一面印有L5字樣

08.12C Protein Kinase Inhibitors

27589 **C / Unsafe**

JAKAVI* 15mg tablet 捷可衛錠 15毫克

■■急用Ruxolitinib 15mg tab

Dosage: 2急用藥 27589

Adult
· Myelofibrosis: PO,
Platelets >200,000/mm(3): 20 mg bid
Platelets 100,000-200,000/mm(3):15 mg bid
Platelets 50,000-100,000/mm(3): initial dose should not exceed 5 mg bid; titrate dose cautiously
Max. 25mg bid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Platelets 100,000-200,000/mm(3): 10mg bid
Platelets <100,000/mm(3): Avoid use

Dosing adjustments in renal impairment:

Clcr 15-59mL/min, platelets 100,000-150,000/mm(3): 10mg bid
Clcr 15-59mL/min, platelets <100,000/mm(3): Avoid use
Clcr <15mL/min: Avoid use

P: Tab: 5mg(27588), 15mg(27589)

ADR:

COMMON
Contusion, anemia, neutropenia,

thrombocytopenia, dizziness, headache
SERIOUS
Anemia(grade 3/4), neutropenia(grade 3/4), thrombocytopenia(grade 3/4)

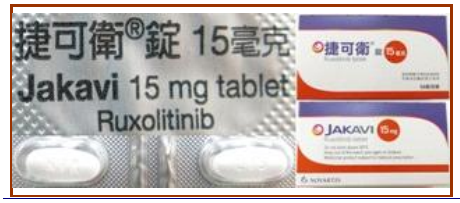
NOTE: 室溫儲存

· Dosage should not be increased during the first 4 weeks of therapy or more frequently than every 2 weeks.
· It should be interrupted in patients with platelet counts< 50,000/mm(3).
·NG tube administration: Suspend 1 tablet in ~40mL water and stir for ~10 mins and administer within 6 hrs after dispersion with appropriate syringe; rinse NG tube with ~75mL water.

藥名相似:

外觀相似:

外觀描述: 白色橢圓形錠劑，一面印有NVR字樣，另一面印有L15字樣



08.12C Protein Kinase Inhibitors

27590 **D / Infant risk can**

INLYTA* FILM-COATED TABLETS 1 MG 抑癌特膜衣錠 1 毫克

■■急用Axitinib 1mg tab

Dosage: 2急用藥 27590

Adult
·Metastatic renal cell carcinoma, First-line therapy: PO, 5 mg twice daily;increases at 2-week intervals to 7 mg twice daily, then 10 mg twice daily.
·Renal cell carcinoma, Advanced, after failure of 1 prior systemic therapy: PO, Initial 5 mg orally every 12 hours, may increase to 7 mg orally every 12 hours after 2 consecutive weeks, may increase further to 10 mg orally every 12 hours after 2 consecutive weeks .(based on safety and tolerability criteria)

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

·mild hepatic impairment (Child-Pugh class A): no adjustment required in patients with hepatic impairment. ·moderate hepatic impairment (Child-Pugh class B): The starting dose should be reduced by half .
·severe hepatic impairment (Child-Pugh class C): has not been studied in this population.

Dosing adjustments in renal impairment:

No dosage adjustment needed

P:

ADR:

COMMON
Hypertension, Hand-foot syndrome due to cytotoxic therapy, Rash, Hypothyroidism, Weight decreased, Abdominal pain, Constipation, Diarrhea, Inflammatory disease of mucous membrane, Loss of appetite, Nausea, Stomatitis, Vomiting, ALT/SGPT level raised, AST/SGOT level raised, Musculoskeletal pain, Neurologic: Asthenia, Dysphonia, Headache, Cough, Dyspnea, Fatigue.
SERIOUS
Cardiac arrest, Heart failure, Hypertensive crisis, Myocardial infarction, Myocarditis, Fatal, Sudden cardiac death, Gastric hemorrhage, Fatal, Gastrointestinal fistula, Gastrointestinal perforation, Arterial thrombosis, Deep venous thrombosis, Hemorrhage, Venous thrombosis, Hepatotoxicity, Cerebrovascular accident, Posterior reversible encephalopathy syndrome, Transient ischemic attack, Thrombosis of retinal vein, Proteinuria, Pulmonary embolism.

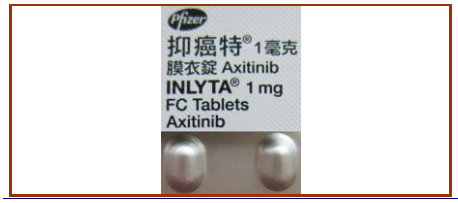
NOTE: 室溫儲存

·《Contraindications》Specific contraindications have not been determined.

藥名相似:

外觀相似:

外觀描述: 紅色橢圓形膜衣錠，有pfizer及1 XNB字樣



08.12C Protein Kinase Inhibitors

27591 **D / Infant risk can**

INLYTA* Film-Coated Tablets 5 mg 抑癌特膜衣錠 5 毫克

■■急用Axitinib 5mg tab

Dosage: 2急用藥 27591

Adult
·Metastatic renal cell carcinoma, First-line therapy: PO, 5 mg twice daily;increases at 2-week intervals to 7 mg twice daily, then 10 mg twice daily.
·Renal cell carcinoma, Advanced, after failure of 1 prior systemic therapy: PO, Initial 5 mg orally every 12 hours, may increase to 7 mg orally every 12 hours after 2 consecutive weeks, may increase further to 10 mg orally every 12 hours after 2 consecutive weeks .(based on safety and tolerability criteria)

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

·mild hepatic impairment (Child-Pugh class A): no adjustment required in patients with hepatic impairment. ·moderate hepatic impairment (Child-Pugh class B): The starting dose should be reduced by half .
·severe hepatic impairment (Child-Pugh class C): has not been studied in this population.

Dosing adjustments in renal impairment:

No dosage adjustment needed

P:

ADR:

COMMON
Hypertension, Hand-foot syndrome due to cytotoxic therapy, Rash, Hypothyroidism, Weight decreased, Abdominal pain, Constipation, Diarrhea, Inflammatory disease of mucous membrane, Loss of appetite, Nausea, Stomatitis, Vomiting, ALT/SGPT level raised, AST/SGOT level raised, Musculoskeletal pain, Neurologic: Asthenia, Dysphonia, Headache, Cough, Dyspnea, Fatigue.
SERIOUS
Cardiac arrest, Heart failure, Hypertensive crisis, Myocardial infarction, Myocarditis, Fatal, Sudden cardiac death, Gastric hemorrhage, Fatal, Gastrointestinal fistula, Gastrointestinal perforation, Arterial thrombosis, Deep venous thrombosis, Hemorrhage, Venous thrombosis, Hepatotoxicity, Cerebrovascular accident, Posterior reversible encephalopathy syndrome, Transient ischemic attack, Thrombosis of retinal vein, Proteinuria, Pulmonary embolism.

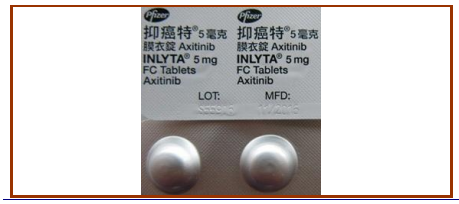
NOTE: 室溫儲存

·《Contraindications》Specific contraindications have not been determined；

藥名相似:

外觀相似:

外觀描述: 紅色三角形膜衣錠，有pfizer及5 XNB字樣



08.12C Protein Kinase Inhibitors

27592 /

ZYKADIA* capsules 150 mg 立克癌 膠囊 150 毫克

■■急用Ceritinib 150mg cap

Dosage: 2急用藥 27592

Adult
·Anaplastic lymphoma kinase positive non-small cell lung cancer, Metastatic: PO, 750mg qd until disease progression or unacceptable toxicity

Pediatric
·Safety and efficacy in pediatric patients have not been established

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Cap: 150mg(27592)

ADR:

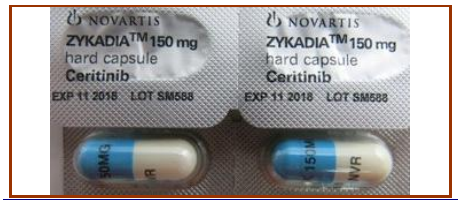
COMMON
Constipation, Decrease in appetite, Decreased hemoglobin, ALT/SGPT level raised, AST/SGOT level raised, Fatigue
SERIOUS
Bradyarrhythmia, Cardiac tamponade, Prolonged QT interval, Hyperglycemia, Abdominal pain, Diarrhea, Gastric hemorrhage, Nausea, Vomiting, Hepatotoxicity, Seizure, Dyspnea, Interstitial lung disease, Pneumonia, Pneumonitis, Pneumothorax, Pulmonary tuberculosis, Respiratory failure, Cachexia, Dehydration, Sepsis

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 藍/白色膠囊，有LDK 150 MG及NVR字樣



08.12C Protein Kinase Inhibitors

27593 C / Unsafe

JAKAVI* 20mg tablet 捷可衛錠 20毫克

■■急用Ruxolitinib 20mg tab

Dosage: 2急用藥 27593

Adult
· Myelofibrosis: PO,
Platelets >200,000/mm(3): 20 mg bid
Platelets 100,000-200,000/mm(3):15 mg bid
Platelets 50,000-100,000/mm(3): initial dose should not exceed 5 mg bid; titrate dose cautiously
Max. 25mg bid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Platelets 100,000-200,000/mm(3): 10mg bid
Platelets <100,000/mm(3): Avoid use

Dosing adjustments in renal impairment:

Clcr 15-59mL/min, platelets 100,000-150,000/mm(3): 10mg bid
Clcr 15-59mL/min, platelets <100,000/mm(3): Avoid use
Clcr <15mL/min: Avoid use

P: Tab: 5mg(27588), 15mg(27589), 20mg(27593)

ADR:

COMMON
Contusion, anemia, neutropenia, thrombocytopenia, dizziness, headache
SERIOUS
Anemia(grade 3/4), neutropenia(grade 3/4), thrombocytopenia(grade 3/4)

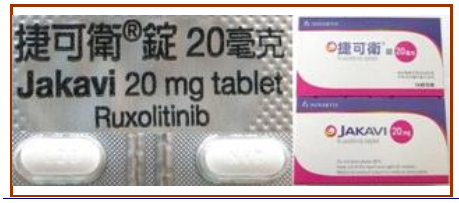
NOTE: 室溫儲存

· Dosage should not be increased during the first 4 weeks of therapy or more frequently than every 2 weeks.
· It should be interrupted in patients with platelet counts< 50,000/mm(3).
·NG tube administration: Suspend 1 tablet in ~40mL water and stir for ~10 mins and administer within 6 hrs after dispersion with appropriate syringe; rinse NG tube with ~75mL water.

藥名相似:

外觀相似:

外觀描述: 白色膠囊形錠劑，一面印有NVR字樣，另一面印有L20字樣



08.12C Protein Kinase Inhibitors

27594 X / Infant risk can

ALECENSA* 150mg capsules 安立適膠囊150毫克

■■急用Alectinib 150mg cap

Dosage: 2急用藥 27594

Adult
·Anaplastic lymphoma kinase positive non-small cell lung cancer, Metastatic: PO, 600mg bid with food until disease progression or unacceptable toxicity

Pediatric
·Safety and efficacy in pediatric patients have not been established

Dosing adjustments in hepatic impairment:

·Hepatic impairment (Mild to moderate): No adjustment required.
·Severe Hepatic impairment(Child-Pugh C): PO, 450mg BID.
·ALT or AST elevations greater than 5 times ULN with total bilirubin less than or equal to 2 time ULN: Withhold treatment temporarily until resolution to baseline or to less than or equal to 3 times ULN then resume at next reduced dose level (first reduction, 450 mg twice daily; second reduction 300 mg twice daily; discontinue if 300 mg twice daily dosage not tolerated.
·ALT or AST elevation greater than 3 times ULN with total bilirubin elevation greater than 2 times ULN without cholestasis or hemolysis: Permanently discontinue treatment.

Dosing adjustments in renal impairment:

·Renal impairment (Mild to moderate): No adjustment required.
·Renal toxicity (Grade 3 impairment): Withhold temporarily until serum creatinine recovers to less than or equal to 1.5 times ULN then resume at next reduced dose level (first reduction, 450 mg twice daily; second reduction 300 mg twice daily; discontinue if 300 mg twice daily dosage not tolerated)
·Renal toxicity (Grade 4 impairment): Permanently discontinue treatment.

P: Cap: 150mg(27594)

ADR:

COMMON
Edema, constipation, anemia, lymphocytopenia, ALT/SGPT level raised, AST/SGOT level raised, hyperbilirubinemia, myalgia, dyspnea, fatigue
SERIOUS
Bradyarrhythmia, fatal endocarditis, fatal perforation of intestine, grade 3 or 4 anemia, fatal hemorrhage, grade 3 or 4 lymphocytopenia, grade 3 or 4 ALT/SGPT level raised, grade 3 or 4 AST/SGOT level raised, grade 3 or 4 hyperbilirubinemia, increased creatine kinase level, renal impairment, interstitial lung disease, pneumonitis, Pulmonary embolis.

NOTE: 儲存30℃以下

·《Contraindications》Specific contraindications have not been determined；
·《仿單警語》診斷出非感染性肺炎(pneumonitis)，應立即停止治療。如未發現任何其他可能的引發非感染性肺炎的導因，應永久停用本藥。

藥名相似:

外觀相似:

外觀描述: 白色膠囊，有"ALE"及"150mg"字樣

08.12C Protein Kinase Inhibitors

27595 ɔt be ruled out / Infant risk can

IBRANCE* Capsules 125 mg 愛乳適 膠囊125毫克

■■急用Palbociclib 125mg cap

Dosage: 2急用藥 27595

Adult
·Breast cancer, Advanced or metastatic, HER2-negative, hormone receptor-positive disease; in combination with fulvestrant for progression following endocrine therapy: PO, 125 mg once daily with food at the same time each day for 21 consecutive days, followed by 7 days off treatment for a 28-day cycle; give with fulvestrant 500 mg IM on days 1, 15, and 29, then once a month thereafter.
·Breast cancer, Advanced or metastatic, HER2-negative, hormone receptor-positive disease in postmenopausal women; initial therapy in combination with an aromatase inhibitor: PO, 125 mg once daily with food at the same time each day for 21 consecutive days, followed by 7 days off treatment of a 28-day cycle; administer concurrent aromatase inhibitor at usual dosage.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

·Mild to moderate hepatic impairment (Child Pugh A and B): No dosage adjustment needed.
·Severe hepatic impairment (Child Pugh C): 75 mg once daily with food at the same time each day for 21 consecutive days, followed by 7 days off treatment for a 28-day cycle.

Dosing adjustments in renal impairment:

Severe : Use with caution

P: P Cap: 急用125mg(27595), 100mg(27612), 75mg(27613)；捐贈125mg(27871), 100mg(27872), 75mg(27873)

ADR:

COMMON
Alopecia, Rash, Constipation, Decrease in appetite, Diarrhea, Nausea, Stomatitis, Vomiting, All Grades Anemia, All Grades Leukopenia, All Grades Neutropenia, All Grades Thrombocytopenia, Infectious disease, Asthenia, Headache, Peripheral neuropathy, Bleeding from nose, Upper respiratory infection, Asthenia, Fatigue, Fever.
SERIOUS
Grade 3 or 4 Anemia, Febrile neutropenia, Grade 3 or 4 Leukopenia, Grade 3 or 4 Neutropenia, Grade 3 or 4 Thrombocytopenia.

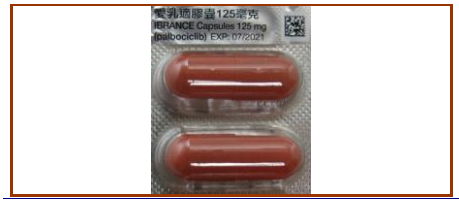
NOTE: 室溫儲存30°C以下

·《Contraindications》Specific contraindications have not been determined；
·Swallow capsules whole; do not crush, chew, or open. Do not ingest any capsule that is cracked or not intact.
·.Missed dose or vomiting: Do not give an additional dose that day.
·治療的婦女或其男性伴侶在治療期間應採取適當的避孕措施(如雙重阻隔避孕法)，且女性與男性在治療結束後分別應繼續避孕至少3週與14週.

藥名相似:

外觀相似:

外觀描述: 淡褐色膠囊，印有 Pfizer 及 PBC 125 字樣



08.12C Protein Kinase Inhibitors

27597 ɔt be ruled out / Infant risk can

KISQALI* 200mg Film-Coated Tablets 擊癌利200毫克膜衣錠

■■Ribociclib 200mg tab

Dosage: 1常備品 27597

Adult
· Breast cancer, Metastatic or advanced, HER-2 negative, hormone receptor-positive, postmenopausal women, in combination with an aromatase inhibitor for initial endocrine-based treatment: PO, 600 mg (3 tablets of 200 mg) qd for 21 consecutive days followed by 7 days off treatment for a 28 day cycle.

Pediatric
· Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Moderate or severe impairment (Child-Pugh class B or C): Reduce starting dosage to 400 mg orally daily for 21 days of 28-day cycle. [1]
· Hepatobiliary toxicity
Elevations in AST and ALT have been reported; monitoring recommended and dosage interruption, reduction, or discontinuation may be required. [1]

Dosing adjustments in renal impairment:

Specific guidelines for dosage adjustments in renalimpairment are not available; it appears that no dosage adjustments are needed.

P: P Tab:200mg(27597)

ADR:

Common
Alopecia, Constipation, Diarrhea, Nausea, Vomiting, Leukopenia(All Grades), Neutropenia(All Grades), Backache, Headache, Fatigue.

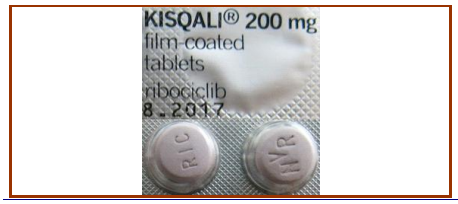
Serious
Prolonged QT interval, Sudden cardiac death, Syncope, Anemia(Grade 3 or 4), Febrile neutropenia, Leukopenia(Grade 4), Lymphocytopenia(Grade 3 or 4), Neutropenia(Grade 4).

NOTE: 室溫儲存30°C 以下

藥名相似: 急用Palbociclib 125mg cap

外觀相似:

外觀描述: 粉紫色圓扁錠，一面有"NYR"字樣，另一面有"RIC"字樣



08.12C Protein Kinase Inhibitors

27612 ɔt be ruled out / Infant risk can

IBRANCE* Capsules 100 mg 愛乳適 膠囊100毫克

■■急用Palbociclib 100mg cap

Dosage: 2急用藥 27612

Adult
·Breast cancer, Advanced or metastatic, HER2-negative, hormone receptor-positive disease; in combination with fulvestrant for progression following endocrine therapy: PO, 125 mg once daily with food at the same time each day for 21 consecutive days, followed by 7 days off treatment for a 28-day cycle; give with fulvestrant 500 mg IM on days 1, 15, and 29, then once a month thereafter.
·Breast cancer, Advanced or metastatic, HER2-negative, hormone receptor-positive disease in postmenopausal women; initial therapy in combination with an aromatase inhibitor: PO, 125 mg once daily with food at the same time each day for 21 consecutive days, followed by 7 days off treatment of a 28-day cycle; administer concurrent aromatase inhibitor at usual dosage.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

·Mild to moderate hepatic impairment (Child Pugh A and B): No dosage adjustment needed.
·Severe hepatic impairment (Child Pugh C): 75 mg once daily with food at the same time each day for 21 consecutive days, followed by 7 days off treatment for a 28-day cycle.

Dosing adjustments in renal impairment:

Severe : Use with caution

P: P Cap: 急用125mg(27595), 100mg(27612), 75mg(27613)；捐贈125mg(27871), 100mg(27872), 75mg(27873)

ADR:

COMMON
Alopecia, Rash, Constipation, Decrease in appetite, Diarrhea, Nausea, Stomatitis, Vomiting, All Grades Anemia, All Grades Leukopenia, All Grades Neutropenia, All Grades Thrombocytopenia, Infectious disease, Asthenia, Headache, Peripheral neuropathy, Bleeding from nose, Upper respiratory infection, Asthenia, Fatigue, Fever.
SERIOUS
Grade 3 or 4 Anemia, Febrile neutropenia, Grade 3 or 4 Leukopenia, Grade 3 or 4 Neutropenia, Grade 3 or 4 Thrombocytopenia.

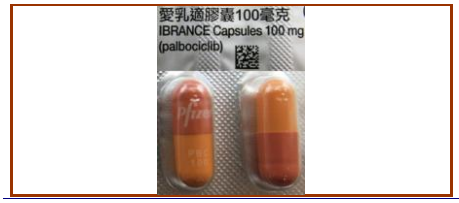
NOTE: 室溫儲存

·《Contraindications》Specific contraindications have not been determined；
·Swallow capsules whole; do not crush, chew, or open. Do not ingest any capsule that is cracked or not intact.
·Missed dose or vomiting: Do not give an additional dose that day.
·治療的婦女或其男性伴侶在治療期間應採取適當的避孕措施(如雙重阻隔避孕法)，且女性與男性在治療結束後分別應繼續避孕至少3週與14週.

藥名相似:

外觀相似:

外觀描述: 淡褐色/淡橙色膠囊，印有 Pfizer 及 PBC 100 字樣



08.12C Protein Kinase Inhibitors

27613 ɔt be ruled out / Infant risk can

IBRANCE Capsules 75 mg 愛乳適 膠囊75毫克

■■急用Palbociclib 75mg cap

Dosage: 2急用藥 27613

Adult
·Breast cancer, Advanced or metastatic, HER2-negative, hormone receptor-positive disease; in combination with fulvestrant for progression following endocrine therapy: PO, 125 mg once daily with food at the same time each day for 21 consecutive days, followed by 7 days off treatment for a 28-day cycle; give with fulvestrant 500 mg IM on days 1, 15, and 29, then once a month thereafter.
·Breast cancer, Advanced or metastatic, HER2-negative, hormone receptor-positive disease in postmenopausal women; initial therapy in combination with an aromatase inhibitor: PO, 125 mg once daily with food at the same time each day for 21 consecutive days, followed by 7 days off treatment of a 28-day cycle; administer concurrent aromatase inhibitor at usual dosage.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

·Mild to moderate hepatic impairment (Child Pugh A and B): No dosage adjustment needed.
·Severe hepatic impairment (Child Pugh C): 75 mg once daily with food at the same time each day for 21 consecutive days, followed by 7 days off treatment for a 28-day cycle.

Dosing adjustments in renal impairment:

Severe : Use with caution

P: P Cap: 急用125mg(27595), 100mg(27612), 75mg(27613)；捐贈125mg(27871), 100mg(27872), 75mg(27873)

ADR:

COMMON
Alopecia, Rash, Constipation, Decrease in appetite, Diarrhea, Nausea, Stomatitis, Vomiting, All Grades Anemia, All Grades Leukopenia, All Grades Neutropenia, All Grades Thrombocytopenia, Infectious disease, Asthenia, Headache, Peripheral neuropathy, Bleeding from nose, Upper respiratory infection, Asthenia, Fatigue, Fever.
SERIOUS
Grade 3 or 4 Anemia, Febrile neutropenia, Grade 3 or 4 Leukopenia, Grade 3 or 4 Neutropenia, Grade 3 or 4 Thrombocytopenia.

NOTE: 室溫儲存

·《Contraindications》Specific contraindications have not been determined；
·Swallow capsules whole; do not crush, chew, or open. Do not ingest any capsule that is cracked or not intact.
·Missed dose or vomiting: Do not give an additional dose that day.
·治療的婦女或其男性伴侶在治療期間應採取適當的避孕措施(如雙重阻隔避孕法)，且女性與男性在治療結束後分別應繼續避孕至少3週與14週.

藥名相似:

外觀相似:

外觀描述: 淡橙色膠囊，印有 Pfizer 及 PBC 75 字樣

08.12C Protein Kinase Inhibitors

27615 ɔt be ruled out / Infant risk can

LENVIMA* Capsules 10 mg 樂衛瑪膠囊10毫克

■■急用Lenvatinib 10mg cap

Dosage: 2急用藥 27615

Adult
· Advanced renal cell carcinoma, in combination with everolimus, after 1 prior anti-angiogenic therapy : PO, 18 mg (one 10 mg capsule and two 4 mg capsules) in combination with everolimus 5 mg orally once daily with or without food until disease

progression or unacceptable toxicity.
· Thyroid cancer, Differentiated, locally recurrent or metastatic, progressive, refractory to radioactive iodine : PO, 24 mg (two 10-mg capsules and one 4-mg capsule) orally once daily with or without food; continue until disease progression or unacceptable toxicity.
· Liver carcinoma, Unresectable, first-line therapy: PO, 8 mg(< 60 kg) or 12 mg(> 60 kg) orally once daily with or without food; continue until disease progression or unacceptable toxicity.

Pedatric
·Safety and effectiveness not established in pediatric patients.

Dosing adjustments in hepatic impairment:

Mild or moderate impairment (Child-Pugh A or B): No dosage adjustment is necessary.
Severe hepatic impairment (Child-Pugh C): Reduce dose to 14 mg/day in patients with differentiated thyroid cancer or to 10 mg/day in patients with renal cell carcinoma.

Dosing adjustments in renal impairment:

Mild or moderate impairment: No dosage adjustment is necessary.
Severe impairment (CrCl less than 30 mL/min; using actual body weight): Reduce dose to 14 mg/day in patients with differentiated thyroid cancer or to 10 mg/day in patients with renal cell carcinoma.
Patients with end-stage renal disease have not been studied

P: P Cap: 10mg(27615)

ADR:

COMMON
·Hypertension, peripheral edema, hand-foot syndrome due to cytotoxic therapy, impaired wound healing, rash, abdominal pain, decrease in appetite, nausea, stomatitis, weight decreased, arthralgia, myalgia, headache, proteinuria, cough, difficulty speaking, fatigue.
SERIOUS
·Myocardial dysfunction, prolonged QT interval, diarrhea, vomiting, anemia, arterial thrombosis, thrombocytopenia, hepatic encephalopathy, hepatitis, hepatorenal syndrome, liver failure, renal failure, renal impairment, dyspnea, dehydration.

NOTE: 室溫儲存

·可能發生傷口癒合併發症，包括廔管形成或傷口裂開，預定手術前須至少停藥6天。
·服藥期間至停藥後30天，均須採取避孕措施。服藥期間至停藥後1周，均須停止哺乳。

藥名相似:

外觀相似:

外觀描述: 紅/黃色膠囊，紅色膠囊蓋印有"E"字樣，黃色膠囊體印有黑色"LENV 10 mg"字樣

08.12C Protein Kinase Inhibitors

27616 ɔt be ruled out / Infant risk can

Lenvima Capsules 4 mg 樂衛瑪膠囊4毫克

■■急用Lenvatinib 4mg cap

Dosage: 2急用藥 27616

Adult
· Endometrial carcinoma, advanced: PO, 20mg QD (in combination with pembrolizumab) until disease progression or unacceptable toxicity
· Liver carcinoma, unresectable, first-line therapy: PO, 8mg (<60kg) or 12mg (≧60 kg) QD continue until disease progression or unacceptable toxicity
· Renal cell carcinoma, advanced: PO, 18mg QD (in combination with everolimus) continue until disease progression or unacceptable toxicity
· Thyroid cancer, differentiated: PO, 24mg QD continue until disease progression or unacceptable toxicity

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild or moderate (Child-Pugh A or B): No dosage adjustment needed
Severe (Child-Pugh C): Reduce dose to 14 mg/day in patients with differentiated thyroid cancer or to 10 mg/day in patients with endometrial or renal cell carcinoma

Dosing adjustments in renal impairment:

Mild or moderate: No dosage adjustment needed
Severe (CrCl < 30 mL/min): Reduce dose to 14 mg/day in patients with differentiated thyroid cancer or to 10 mg/day in patients with endometrial or renal cell carcinoma.
ESRD: NDA

P: P Cap: 4mg(27616), 10mg(27615)

ADR:

COMMON
Hypertension, peripheral edema, hand-foot syndrome due to cytotoxic therapy, impaired wound healing, rash, hypomagnesemia, hypothyroidism, abdominal pain, constipation, decrease in appetite, nausea, stomatitis, vomiting, weight decreased, hemorrhage, arthralgia, myalgia, headache, proteinuria, urinary tract infectious disease, cough, dyspnea, difficulty speaking, fatigue
SERIOUS
Myocardial dysfunction, prolonged QT interval, diarrhea, anemia, arterial thrombosis, thrombocytopenia, hepatic encephalopathy, hepatitis, hepatorenal syndrome, liver failure, cerebral hemorrhage, posterior reversible encephalopathy syndrome, renal failure, renal impairment, dehydration

NOTE: 室溫儲存

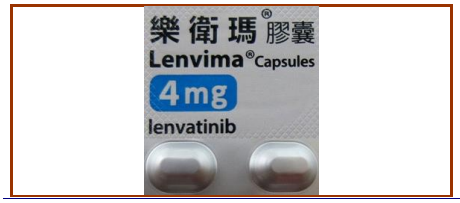
·可能發生傷口癒合併發症，包括廔管形成或傷口裂開，預定手術前須至少停藥6天。
·服藥期間至停藥後30天，均須採取避孕措施。服藥期間至停藥後1周，均須停止哺乳。

藥名相似:

外觀相似:

外觀描述: 紅/黃色膠囊，紅色膠囊蓋印有"E"字樣，黃色膠

囊體印有黑色"LENV 4mg"字樣



面刻 HMJ 字樣

08.12C Protein Kinase Inhibitors

27617 ɔt be ruled out / Infant risk can

MEKINIST* Film-Coated Tablets 2mg 麥欣霓膜衣錠2毫克

■■急用Trametinib 2mg tab

Dosage: 2急用藥 27617

Adult

· Malignant melanoma(with BRAF V600E or V600K mutation), monotherapy or combination with dabrafenib : PO, 2mg once daily take at least 1 hour before or 2 hours after a meal, until disease progression or unacceptable toxicity.

· Non-small cell lung cancer (with BRAF V600E mutation), in combination with dabrafenib : PO, 2mg once daily take at least 1 hour before or 2 hours after a meal, until disease progression or unacceptable toxicity.

Pedatric

·Safety and effectiveness not established in pediatric patients.

Dosing adjustments in hepatic impairment:

Mild or moderate impairment (Child-Pugh A or B): No dosage adjustment is necessary.
Severe hepatic impairment (Child-Pugh C): Appropriate dosage has not been established.

Dosing adjustments in renal impairment:

Mild or moderate impairment: No dosage adjustment is necessary.
Severe impairment: Appropriate dosage has not been established.

P: P Tab: 2mg(27617)

ADR:

COMMON

·Peripheral edema, rash, abdominal pain, decrease in appetite, diarrhea, nausea, vomiting, cough, dyspnea, fatigue, fever, shivering.

SERIOUS

·Cardiomyopathy, basal cell carcinoma, dermatologic toxicity, malignant melanoma, squamous cell carcinoma of skin, colitis, gastrointestinal hemorrhage, gastrointestinal perforation, hemorrhage, venous thromboembolism, rhabdomyolysis, intracranial hemorrhage, retinal pigment epithelial detachment, thrombosis of retinal vein, interstitial lung disease, pneumonitis, pulmonary embolism.

NOTE: 冰箱冷藏 2-8℃，不可冷凍

藥名相似:

外觀相似:

外觀描述: 粉紅色圓形雙凸膜衣錠，一面刻 GS 字樣，另一

08.12C Protein Kinase Inhibitors

27625 ɔt be ruled out / Infant risk can

VERZENIO film-coated tablet 150mg 捷癌寧膜衣錠150毫克

■■急用Abemaciclib 150mg tab

Dosage: 2急用藥 27625

Adult

· Breast cancer, Advanced or metastatic, HER2-negative, hormone receptor-positive disease, in combination with an aromatase inhibitor for initial endocrine therapy: PO, 150 mg BID until disease progression or unacceptable toxicity

· Breast cancer, Advanced or metastatic, HER2-negative, hormone receptor-positive disease, in combination with fulvestrant for progression following endocrine therapy: PO, 150 mg BID in combination with fulvestrant 500 mg IM on day 1,15, and 29 and once monthly thereafter until disease progression or unacceptable toxicity; administer goserelin for at least 4 weeks prior to and for the duration of treatment

Pediatric

·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild or moderate (Child-Pugh A or B): No dosage adjustment needed
Severe(Child-Pugh C): Reduce dosing frequency to QD

Dosing adjustments in renal impairment:

Mild or moderate (CrCl 30-89 mL/min): No dosage adjustment needed
Severe or ESRD, (CrCl < 30 mL/min): The effect on pharmacokinetics of abemaciclib is unknown

P: P Tab: 150mg(27625 急用), 150mg(27826 捐贈急用), 200mg(27624 急用), 50mg(27614 捐贈專案)

ADR:

COMMON

Abdominal pain, decrease in appetite, all Grades diarrhea, nausea, vomiting, all Grades anemia, all Grades leukopenia, all Grades neutropenia, infectious disease, headache, fatigue

SERIOUS

Grade 3 diarrhea, febrile neutropenia, Grade 3 or 4 neutropenia, neutropenic sepsis, venous thromboembolism, ALT/SGPT level raised, AST/SGOT level raised, cerebral infarction, interstitial lung disease, pneumonitis

NOTE: 室溫儲存

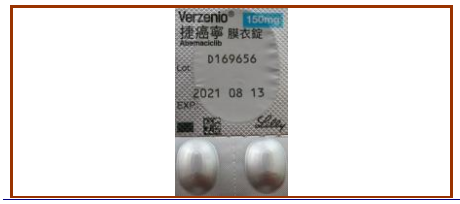
1.Swallow capsules whole; do not crush, chew, or open. Do not ingest any capsule that is cracked or not intact.
2.Missed dose or vomiting: Do not give an

additional dose that day.
3.治療的婦女或其男性伴侶在治療期間應採取適當的避孕措施(如雙重阻隔避孕法)，且女性與男性在治療結束後分別應繼續避孕至少3週與14週.

藥名相似:

外觀相似:

外觀描述: 黃色橢圓形錠，一面有"Lilly"，另一面有"150"字樣



08.12C Protein Kinase Inhibitors

27680 ɔt be ruled out / Infant risk can

Lorbrena* Film-Coated Tablets 25mg(美國包裝) 瘤利剋膜衣錠25毫克

■■急用 Lorlatinib 25mg Film-Coated Tablets

Dosage: 2急用藥 27680

Adult
·Anaplastic lymphoma kinase positive non-small cell lung cancer, Metastatic, progressed on alectinib or ceritinib as first ALK inhibitor therapy or crizotinib and a least 1 other ALK inhibitor for metastatic disease: PO, 100mg qd with or without food until disease progression or unacceptable toxicity

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

·Mild (total bilirubin <= ULN with AST > ULN or total bilirubin >1 to 1.5 times ULN with any AST): No dosage adjustment needed
·Moderate or severe: NDA

Dosing adjustments in renal impairment:

·Mild or moderate (CrCl 30~89 mL/min): No dosage adjustment needed
·Severe (CrCl < 30mL/min): NDA

P: P Tab: 25mg(27680)

ADR:

COMMON
Weight gain, diarrhea, arthralgia, peripheral nerve disease, dyspnea, fatigue
SERIOUS
Atrioventricular block, prolonged PR interval, hepatotoxicity, dyssomnia, seizure, speech problem, hallucinations, mood swings, interstitial lung disease, pneumonitis

NOTE: 室溫儲存

Dosing adjustment for toxicity:
·Usual initial dose: 100 mg qd
·First dose reduction level: 75 mg qd
·Second dose reduction level: 50 mg qd
·Discontinue permanently if unable to tolerate 50 mg qd

藥名相似:

外觀相似:

外觀描述: 褐色圓形膜衣錠，有25 LLN及Pfizer字樣

08.12C Protein Kinase Inhibitors

27870 ɔt be ruled out / Infant risk can

KISQALI* 200mg Film-Coated Tablets 擊癌利200毫克膜衣錠

■■捐贈急用Ribociclib 200mg tab

Dosage: 2急用藥 27870

Adult
· Breast cancer, Metastatic or advanced, HER-2 negative, hormone receptor-positive, postmenopausal women, in combination with an aromatase inhibitor for initial endocrine-based treatment: PO, 600 mg (3 tablets of 200 mg) qd for 21 consecutive days followed by 7 days off treatment for a 28 day cycle.

Pediatric
· Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Moderate or severe impairment (Child-Pugh class B or C): Reduce starting dosage to 400 mg orally daily for 21 days of 28-day cycle. [1]
· Hepatobiliary toxicity
Elevations in AST and ALT have been reported; monitoring recommended and dosage interruption, reduction, or discontinuation may be required. [1]

Dosing adjustments in renal impairment:

Specific guidelines for dosage adjustments in renalimpairment are not available; it appears that no dosage adjustments are needed.

P: P Tab:200mg(27597,急用; 27870,捐贈急用)

ADR:

Common
Alopecia, Constipation, Diarrhea, Nausea, Vomiting, Leukopenia(All Grades), Neutropenia(All Grades), Backache, Headache, Fatigue.

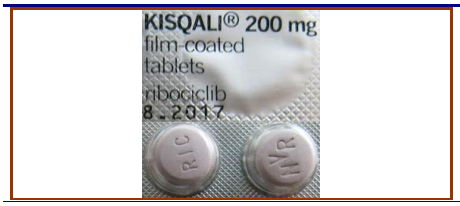
Serious
Prolonged QT interval, Sudden cardiac death, Syncope, Anemia(Grade 3 or 4), Febrile neutropenia, Leukopenia(Grade 4), Lymphocytopenia(Grade 3 or 4), Neutropenia(Grade 4).

NOTE: 室溫儲存

藥名相似: 急用Palbociclib 125mg cap

外觀相似:

外觀描述:



08.12C Protein Kinase Inhibitors

27871 **ɔt be ruled out / Infant risk can**

IBRANCE* Capsules 125 mg (捐贈急用)愛乳適 膠囊125毫克

■■捐贈急用Palbociclib 125mg cap

Dosage: 2急用藥 27871

Adult

·Breast cancer, Advanced or metastatic, HER2-negative, hormone receptor-positive disease; in combination with fulvestrant for progression following endocrine therapy: PO, 125 mg once daily with food at the same time each day for 21 consecutive days, followed by 7 days off treatment for a 28-day cycle; give with fulvestrant 500 mg IM on days 1, 15, and 29, then once a month thereafter.
·Breast cancer, Advanced or metastatic, HER2-negative, hormone receptor-positive disease in postmenopausal women; initial therapy in combination with an aromatase inhibitor: PO, 125 mg once daily with food at the same time each day for 21 consecutive days, followed by 7 days off treatment of a 28-day cycle; administer concurrent aromatase inhibitor at usual dosage.

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

·Mild to moderate hepatic impairment (Child Pugh A and B): No dosage adjustment needed.
·Severe hepatic impairment (Child Pugh C): 75 mg once daily with food at the same time each day for 21 consecutive days, followed by 7 days off treatment for a 28-day cycle.

Dosing adjustments in renal impairment:

Severe : Use with caution

P: P Cap: 急用125mg(27595), 100mg(27612), 75mg(27613)；捐贈125mg(27871), 100mg(27872), 75mg(27873)

ADR:

COMMON

Alopecia, Rash, Constipation, Decrease in appetite, Diarrhea, Nausea, Stomatitis, Vomiting, All Grades Anemia, All Grades Leukopenia, All Grades Neutropenia, All Grades Thrombocytopenia, Infectious disease, Asthenia, Headache, Peripheral neuropathy, Bleeding from nose, Upper respiratory infection, Asthenia, Fatigue, Fever.

SERIOUS

Grade 3 or 4 Anemia, Febrile neutropenia, Grade 3 or 4 Leukopenia, Grade 3 or 4 Neutropenia, Grade 3 or 4 Thrombocytopenia.

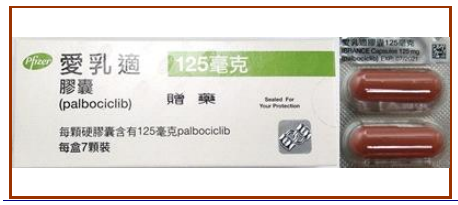
NOTE: 室溫儲存30°C以下

·《Contraindications》Specific contraindications have not been determined；
·Swallow capsules whole; do not crush, chew, or open. Do not ingest any capsule that is cracked or not intact.
·Missed dose or vomiting: Do not give an additional dose that day.
·治療的婦女或其男性伴侶在治療期間應採取適當的避孕措施(如雙重阻隔避孕法)，且女性與男性在治療結束後分別應繼續避孕至少3週與14週.

藥名相似:

外觀相似:

外觀描述: 淡褐色膠囊，印有 Pfizer 及 PBC 125 字樣



08.12C Protein Kinase Inhibitors

27872 **ɔt be ruled out / Infant risk can**

IBRANCE* Capsules 100 mg (捐贈急用)愛乳適 膠囊100毫克

■■捐贈急用Palbociclib 125mg cap

Dosage: 2急用藥 27872

Adult

·Breast cancer, Advanced or metastatic, HER2-negative, hormone receptor-positive disease; in combination with fulvestrant for progression following endocrine therapy: PO, 125 mg once daily with food at the same time each day for 21 consecutive days, followed by 7 days off treatment for a 28-day cycle; give with fulvestrant 500 mg IM on days 1, 15, and 29, then once a month thereafter.
·Breast cancer, Advanced or metastatic, HER2-negative, hormone receptor-positive disease in postmenopausal women; initial therapy in combination with an aromatase inhibitor: PO, 125 mg once daily with food at the same time each day for 21 consecutive days, followed by 7 days off treatment of a 28-day cycle; administer concurrent aromatase inhibitor at usual dosage.

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

·Mild to moderate hepatic impairment (Child Pugh A and B): No dosage adjustment needed.
·Severe hepatic impairment (Child Pugh C): 75 mg once daily with food at the same time each day for 21 consecutive days, followed by 7 days off treatment for a 28-day cycle.

Dosing adjustments in renal impairment:

Severe : Use with caution

P: P Cap: 急用125mg(27595), 100mg(27612), 75mg(27613)；捐贈125mg(27871), 100mg(27872), 75mg(27873)

ADR:

COMMON

Alopecia, Rash, Constipation, Decrease in appetite, Diarrhea, Nausea, Stomatitis, Vomiting, All Grades Anemia, All Grades Leukopenia, All Grades

Neutropenia, All Grades Thrombocytopenia, Infectious disease, Asthenia, Headache, Peripheral neuropathy, Bleeding from nose, Upper respiratory infection, Asthenia, Fatigue, Fever.
SERIOUS
Grade 3 or 4 Anemia, Febrile neutropenia, Grade 3 or 4 Leukopenia, Grade 3 or 4 Neutropenia, Grade 3 or 4 Thrombocytopenia.

NOTE:

·《Contraindications》Specific contraindications have not been determined；
·Swallow capsules whole; do not crush, chew, or open. Do not ingest any capsule that is cracked or not intact.
·Missed dose or vomiting: Do not give an additional dose that day.
·治療的婦女或其男性伴侶在治療期間應採取適當的避孕措施(如雙重阻隔避孕法)，且女性與男性在治療結束後分別應繼續避孕至少3週與14週.

藥名相似:

外觀相似:

外觀描述: 淡褐色/淡橙色膠囊，印有 Pfizer 及 PBC 100 字樣

08.12C Protein Kinase Inhibitors

27886 D / Unsafe

Stivarga Film-Coated Tablets 40mg 癌瑞格膜衣錠40毫克

■■Regorafenib 40mg tab

Dosage: 1常備品 27886

Adult
· Metastatic colorectal cancer, Gastrointestinal stromal tumor, Liver carcinoma: PO, 160 mg qd on days 1 through 21 of every 28-day cycle until disease progression or unacceptable toxicity.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Mild or moderate hepatic impairment (Child-Pugh A or B): No dosage adjustment needed
Severe hepatic impairment (Child-Pugh C): Use is not recommended
Hepatotoxicity during treatment:
1.Grade 3 AST and/or ALT elevation: Withhold dose until recovery. Resume at a reduced dose of 120 mg daily only if potential benefit outweighs the risk of hepatoxicity
2.AST or ALT >20X ULN: Discontinue permanently
3.AST or ALT >3X ULN and bilirubin >2X ULN: Discontinue permanently
4.Recurrence of AST or ALT >5X ULN despite dose reduction to 120 mg: Discontinue permanently

Dosing adjustments in renal impairment:

Clcr >15mL/min:No dosage adjustment needed
Severe renal impairment or ESRD: NDA

P: Tab: 40mg(27886)

ADR:

COMMON
Hypertension, acral erythema, hypocalcemia, hyponatremia, hypophosphatemia, weight loss, decrease in appetite, diarrhea, inflammatory disease of mucous membrane, nausea, vomiting, anemia, lymphocytopenia, thrombocytopenia, ALT/SGPT level raised, AST/SGOT level raised, hyperbilirubinemia, increased serum lipase level, asthenia, difficulty speaking, proteinuria, fatigue, fever, infectious disease, pain
SERIOUS
Hypertension(grade3 or 4), hypertensive crisis, myocardial infarction, myocardial ischemia, acral erythema(grade3 or 4), erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, gastrointestinal fistula, gastrointestinal perforation, hemorrhage, ALT/SGPT level raised(grade3/4), AST/SGOT level raised(grade3/4), hepatotoxicity, liver failure

NOTE: 室溫儲存

· Swallow tablets whole and take it with a low-fat breakfast that contains less than 30% fat.
· Discard any unused tablets 7 weeks after opening the original container.

藥名相似:

外觀相似:

外觀描述: 淺粉紅色橢圓錠，一面印有BAYER字樣，另一面印有40字樣

08.12C Protein Kinase Inhibitors

27901 D / Unsafe

Zelboraf film-coated tablets 240mg (vemurafenib) 日沛樂膜衣錠240毫克

■■急用Vemurafenib 240mg tab

Dosage: 2急用藥 27901

Adult
·Melanoma, metastatic or unresectable (with BRAF V600E mutation): PO, 960 mg bid

Pediatric (< 18 yrs)
·Safety and efficacy have not been established in patients less than 18 years old

Dosing adjustments in hepatic impairment:

Mild and moderate impairment: No dosage adjustment needed

Dosing adjustments in renal impairment:

Mild and moderate impairment: No dosage adjustment needed

P: Tab: 240mg tab(27901)

ADR:

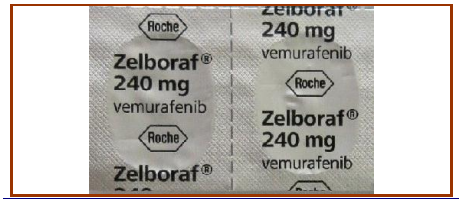
COMMON
Alopecia, papilloma of skin, photosensitivity, pruritus, rash, nausea, arthralgia, fatigue, papilloma of skin
SERIOUS
Prolonged QT interval, hand-foot syndrome due to cytotoxic therapy, keratoacanthoma, malignant melanoma, squamous cell carcinoma of skin, Stevens-Johnson syndrome, Toxic epidermal necrolysis, hypersensitivity reaction, renal failure, keratoacanthoma, malignant melanoma, squamous cell carcinoma of skin

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 淺粉紅色橢圓形錠，有VEM字樣



08.12C Protein Kinase Inhibitors

37798 **D / Unsafe**

Torisel Concentrate and diluent for solution for infusion 特癌適濃縮注射劑

■■急用Temsirolimus 30mg/1.2mL vial with 1.8mL diluent

Dosage: 2急用藥 37798

Adult
·Advanced renal cell carcinoma: IV infusion over 30-60mins, 25mg qw
·Mantle cell lymphoma: IV infusion 30-60mins, 175mg qw for 3 weeks, followed by 75mg qw thereafter

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Mild hepatic impairment (bilirubin 1-1.5 x ULN or AST >ULN with bilirubin ?ULN): Reduce to 15mg qw
Moderate-to-severe hepatic impairment (bilirubin >1.5 x ULN): Use is contraindicated

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 30mg/1.2mL vial with 1.8mL diluent(37798)

ADR:

COMMON
Edema, rash, hyperglycemia, hyperlipidemia, hypertriglyceridemia, hypophosphatemia, serum cholesterol raised, inflammatory disease of mucous membrane, loss of appetite, nausea, decreased hemoglobin, decreased lymphocyte count , decreased platelet count, leukopenia, quantitative disorder of neutrophils, alkaline phosphatase raised, AST/SGOT level raised, asthenia, serum creatinine raised
SERIOUS
Stevens-Johnson syndrome, bowel perforation, hypersensitivity reaction, renal failure, interstitial lung disease, pneumonia, angioedema

NOTE: 冰箱儲存

· Do not use DEHP-containing(PVC) containers or administration sets.
·An inline polyethersulfone filter with a pore size not exceeding 5 mm should be used.
·It should be protected from excessive room light and sunlight during handling and preparation.

藥名相似:

外觀相似:

外觀描述:

08.12E Other Antineoplastic Agents

21595 **D / Unsafe**

HYCAMTIN CAPSULES 0.25MG 癌康定膠囊0.25毫克

■■急用Topotecan 0.25mg cap

Dosage: 2急用藥 21595

Adult
· Relapsed small-cell lung cancer: PO, 2.3mg/m(2) qd for 5 days, repeat every 21 days

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 30-49mL/min: 1.8mg/m(2)/day
Clcr<30mL/min: NDA

P: Cap: 0.25mg(21595,急用藥);1mg(21597,急用藥); Inj: 4mg Vial(31238)

ADR:

COMMON
Alopecia, rash, abdominal pain, constipation, diarrhea, nausea, vomiting, stomatitis, anemia, leukopenia, neutropenia, thrombocytopenia, asthenia, headache, pain, cough, dyspnea, fatigue, fever
SERIOUS
Diarrhea(grade 3/4), anemia(grade 3/4), febrile neutropenia, leukopenia(grade 3/4), neutropenia(grade 3/4), neutropenic colitis, thrombocytopenia(grade 3/4), interstitial lung disease

NOTE: 避光冷藏

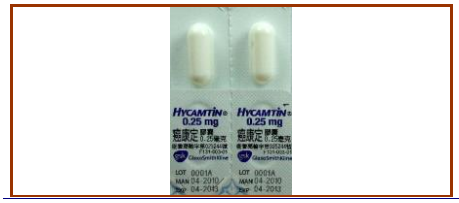
· Swallow whole, do not open, crush, break or chew it.
· If vomiting after taking topotecan, a replacement dose should not be administered.
· It should only be administered to patients with a baseline neutrophil count of ≧1500 cells/mm3 and a

platelet count of ≧100,000 cells/mm3.

藥名相似:

外觀相似:

外觀描述: 白色到黃白色膠囊，印有HYCAMTIN及0.25mg字樣



08.12E Other Antineoplastic Agents

21597 **D / Unsafe**

HYCAMTIN CAPSULES 1MG 癌康定膠囊1毫克

■■急用Topotecan 1mg cap

Dosage: 2急用藥 21597

Adult

· Relapsed small-cell lung cancer: PO, 2.3mg/m(2) qd for 5 days, repeat every 21 days

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 30-49mL/min: 1.8mg/m(2)/day
Clcr<30mL/min: NDA

P: Cap: 0.25mg(21595,急用藥);1mg(21597,急用藥); Inj: 4mg Vial(31238)

ADR:

COMMON
Alopecia, rash, abdominal pain, constipation, diarrhea, nausea, vomiting, stomatitis, anemia, leukopenia, neutropenia, thrombocytopenia, asthenia, headache, pain, cough, dyspnea, fatigue, fever
SERIOUS
Diarrhea(grade 3/4), anemia(grade 3/4), febrile neutropenia, leukopenia(grade 3/4), neutropenia(grade 3/4), neutropenic colitis, thrombocytopenia(grade 3/4), interstitial lung disease

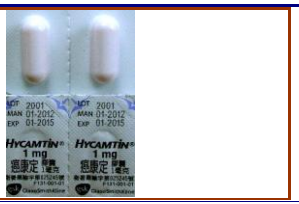
NOTE: 2-8℃避光冷藏

· Swallow whole, do not open, crush, break or chew it.
· If vomiting after taking topotecan, a replacement dose should not be administered.
· It should only be administered to patients with a baseline neutrophil count of ≧1500 cells/mm3 and a platelet count of ≧100,000 cells/mm3.

藥名相似:

外觀相似:

外觀描述: 粉紅色膠囊，印有HYCAMTIN及1mg字樣



08.12E Other Antineoplastic Agents

21619 **D /**

VESANOID SOFT GELATIN CAPSULES 10MG 凡善能軟膠囊10毫克

■■Tretinoin (All-trans retinoic acid, ATRA) 10mg soft gel cap

Dosage: 1常備品 21619

Adult

· Remission induction of acute promyelocytic leukemia: PO, 45mg/m(2)/day (divided twice daily) for 90 days or 30 days past complete remission whichever comes first. After complete remission, a standard course of consolidation chemotherapy should be initiated immediately.

Pediatric: >1 yr, the same as adult

Dosing adjustments in hepatic impairment:

NDA, however, a dose reduction to 25mg/m(2) is recommended as a precautionary measure

Dosing adjustments in renal impairment:

NDA, however, a dose reduction to 25mg/m(2) is recommended as a precautionary measure

P: Cap: 10mg(21619); Cream: 0.05%, 20g/tube (29458)

ADR:

COMMON
Arrhythmias, elevated liver function tests, fatigue, weakness, fever , headache, hypercholesterolemia, hypertriglyceridemia , upper respiratory tract disorders, dyspnea, pleural effusion, pneumonia
SERIOUS
ATRA/RA-APL syndrome (fever, dyspnea, weight gain, pulmonary infiltrates), leukocytosis (oral), pericardial effusions, pleural effusions, retinoid toxicity (headache, N/V, fever, skin dryness, bone pain)

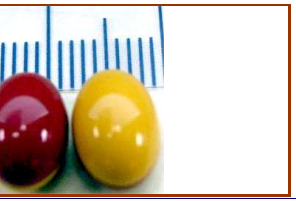
NOTE: 室溫儲存

1. A pregnancy test should be performed within 1 week before starting therapy and monthly there after during therapy

藥名相似:

外觀相似:

外觀描述: 金黃色/紅棕色卵形軟膠囊



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022357

08.12E Other Antineoplastic Agents

21620 D / Unsafe

HYDREA CAPSULES 500MG 愛治膠囊 5 0 0 公絲

■■Hydroxyurea 500mg cap

Dosage: 1常備品 21620

Adult
· Chronic myelogenous leukemia: PO, 20-30mg/kg qd
· Head and neck cancer: PO, 80mg/kg single dose q3d; 20-30mg/kg/day continuous therapy
· Melanoma: PO, 80mg/kg single dose q3d; 20-30mg/kg/day continuous therapy
· Ovarian cancer: PO, 80mg/kg single dose q3d; 20-30mg/kg/day continuous therapy
· Sickle cell disease: PO, 15-35mg/kg qd

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

GFR<10mL/min: Decrease the dose of hydroxyurea by 80%

P: Cap: 500mg(21620)

ADR:

COMMON
Myelosuppression
SERIOUS
Mutagenicity/secondary leukemias (long-term use)

NOTE: 室溫儲存

WBC count < 2500 cell/mm3, or the platelet count < 100,000/mm3, therapy should be stopped for at least 3 days and resumed when values rise toward normal

藥名相似:

外觀相似:

外觀描述: 灰綠色/粉紅色膠囊，有BMS 303字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2020757

08.12E Other Antineoplastic Agents

27602 X /

ROACCUTANE "ROCHE" SOFT GELATIN CAPSULES 20MG "羅氏" 羅可坦軟膠囊 2 0 豪克

■■兒癌Isotretinoin 20mg cap

Dosage: 2兒癌基金用藥 27602

Adult
·BASAL CELL CARCINOMA: PO, 1.5 to 8.2mg/kg/day with the average dose of 4.6mg/kg/day
·ACNE - SEVERE RECALCITRANT NODULAR: PO, initiated with 0.5 to 2mg/kg/day with food in 2 divided doses for 15 to 20 weeks. If the total cyst count has been reduced by more than 70% during this time period, the drug may be discontinued. The dose should be adjusted according to the appearance of clinical side effects and the response of the disease. A second course of therapy may be initiated 2 months after discontinuation, if the patient experiences persistent or recurring severe nodular acne. In patients who have not completed skeletal growth, the optimal interval before retreatment has not been established; caution should be taken as reports of hyperostosis and premature epiphyseal closure are documented (Prod Info Accutane?, 2000).
·HYPERTROPHIC LUPUS ERYTHEMATOSUS: PO, 1mg/kg/day for 3 weeks resulted in dramatic improvement of lesions, with disappearance of erythema, hyperkeratosis and thickness by 9 weeks; the drug was withdrawn after 11 weeks of treatment and the patient had remained free of occurrence for 9 months.
·KERATINIZATION DISORDERS: PO, Average doses of 2.0mg/kg/day (range 0.5 to 8.0mg/kg/day)
·SQUAMOUS CELL CARCINOMA: PO, 1mg/kg/daily in 2 divided doses for at least 4 weeks. Duration of response ranged from 2 to 23 plus months.

Pediatric
·ACNE - SEVERE RECALITRANT NODULAR: PO, 1mg/kg/day has been used in pediatric patients (13 to 17 years) with severe recalcitrant nodular acne. Except for increased incidence of back pain, arthralgia, and myalgia, efficacy and toxicity was similar to those in adults (Anon, 2003).

Dosing adjustments in hepatic impairment:

Empirical dose reductions are indicated in hepatic disease due to extensive metabolism of the drug by the liver.

Dosing adjustments in renal impairment:

P: Soft gelatin cap: 10mg(27500), 20mg (27602, 兒癌用藥)

ADR:

Dry mouth, dry nose, epistaxis, elevated erythrocyte sedimentation rates (ESR), pancreatitis, anemia, bleeding and bruising, leukopenia and neutropenia, agranulocytosis, polycythemia, thrombocytopenia, chest pain, vasculitis, depression, hyperglycemia

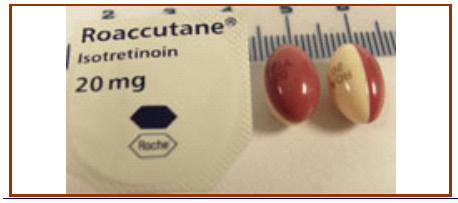
NOTE: 室溫儲存

Contraindications
1.hypersensitivity to isotretinion products or paraben
2.pregnancy and lactation

藥名相似:

外觀相似:

外觀描述: 紫紅色/白色卵形膠囊，有ROA 20字樣



08.12E Other Antineoplastic Agents

27609 ɔt be ruled out / Infant risk can

VENCLEXTA* Film-Coated Tablets 100mg 唯可來膜衣錠

100毫克

■■急用Venetoclax 100mg tab

Dosage: 2急用藥 27609

Adult

· Chronic lymphoid leukemia(CLL): PO, 400mg qd.(20mg qd during week 1; 50mg qd during week 2; 100mg qd during week 3; 200mg qd during week 4, then 400mg qd during week 5)

Pediatric

· Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

·Mild or moderate(Child Pugh A or B): No dosage adjustment necessary.
·Severe(Child Pugh C): Reduce once daily dosage by 50% and closely monitor patients for signs of toxicity.

Dosing adjustments in renal impairment:

·Mild or moderate renal Impairment (CrCl >30 mL/min) : No dosage adjustment is necessary.

P: P Tab: 100mg(27609)

ADR:

COMMON
Edema, Hypotension, Peripheral edema, Rash, Abdominal pain, Constipation, Diarrhea, Nausea, Pain in throat, Vomiting, Anemia, Hemorrhage, Neutropenia, Thrombocytopenia, Backache, Musculoskeletal pain, Myalgia, Dizziness, Cough, Dyspnea, Upper respiratory infection, Fatigue, Fever
SERIOUS
Anemia-Grade 3 or 4, Febrile neutropenia, Hemorrhage-Grade 3 or 4, Neutropenia-Grade 3 or 4, Thrombocytopenia-Grade 3 or 4, Autoimmune hemolytic anemia, Pneumonia, Sepsis, Tumor lysis syndrome

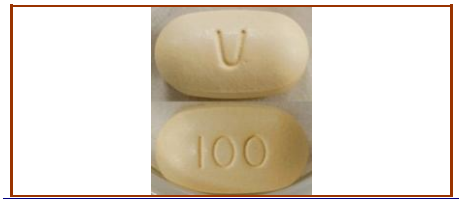
NOTE: 室溫儲存

·考量病人特異性因素，以評估腫瘤溶解症候群(TLS)的風險高低的程度，並在VENCLEXTA第一劑治療前，預防性補充水分及施用降尿酸藥物，以降低腫瘤溶解症候群(TLS)風險

藥名相似:

外觀相似:

外觀描述: 黃色橢圓雙凸錠，一面有 V 字樣，另一面有 100 字樣



08.12E Other Antineoplastic Agents

27619 ɔt be ruled out / Infant risk can

LYNPARZA* Film-coated Tablets 150mg 令癌莎膜衣錠 150毫克

■■Olaparib 150mg tab

Dosage: 1常備品 27619

Adult

·Ovarian cancer, Fallopian tube, or primary peritoneal cancer; recurrent disease after complete or partial response to platinum-based chemotherapy, maintenance therapy: PO, 300 mg orally twice daily, continued until unacceptable toxicity or disease progression.

· Metastatic breast cancer, HER2-negative, germline BRCA-mutated disease with prior chemotherapy in neoadjuvant, adjuvant, or metastatic setting: PO, 300 mg orally twice daily, continued until unacceptable toxicity or disease progression.

Pediatric

·Safety and efficacy not established in pediatric patients

Dosing adjustments in hepatic impairment:

No adjustment to initial dose is required

Dosing adjustments in renal impairment:

Moderate (CrCl 31 to 50 mL/min, estimated with Cockcroft-Gault): Reduce tablet dosage to 200 mg orally twice daily.

P:

P Tab: 150mg(27619)

ADR:

Common
Abdominal pain, constipation, decrease in appetite, diarrhea, indigestion, nausea, stomatitis, taste sense altered, vomiting, anemia, leukopenia, neutropenia, arthralgia, myalgia, dizziness, headache, respiratory tract infection, fatigue
Serious
Venous thromboembolism, anemia, febrile neutropenia, leukopenia, myelodysplastic syndrome, neutropenia, pneumonitis

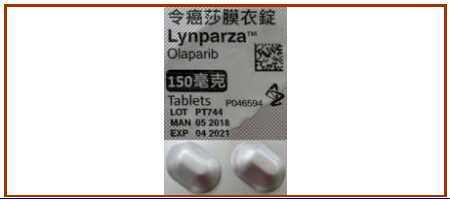
NOTE:

·Do not open, chew, dissolve, or divide capsule or tablet; swallow whole

藥名相似:

外觀相似:

外觀描述: 綠色橢圓雙凸錠，一面有"OP150"字樣



08.12E Other Antineoplastic Agents

31229 D / Unknown(有

IRINO SOLUTION FOR I.V. INFUSION 益立諾靜脈輸注液

■■Irinotecan 100mg/5mL vial

Dosage: 1常備品 31229

Adult

· Colorectal cancer: IV, 125mg/m(2) weekly for 4 wks, followed by 2-wk rest or 150mg/m(2) every 2 wk

Pediatric: NDA

Dosing adjustments in hepatic impairment:

Bilirubin >2 mg/dL: not recommended

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Inj: 100mg/5ml Vial(31229)

ADR:

COMMON
Alopecia
SERIOUS
Diarrhea (early and late), N/V, hepatic dysfunction, neutropenic fever (2.2%; single agent weekly regimen), severe myelosuppression

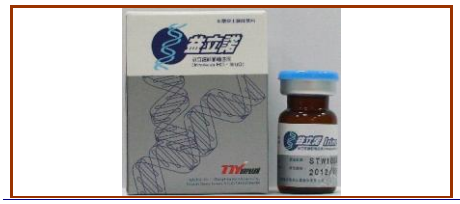
NOTE: 室溫儲存

1.Dilute in 250-500 mL D5W or NS, IV infusion over 90 mins
2.Premedicate with antiemetic
3.Sequence of administration- irinotecan, leucovorin, and 5-fluorouracil
4.Atropine 0.25-1mg IV or SC to prevent early diarrhea and loperamide for late diarrhea.

藥名相似:

外觀相似:

外觀描述:



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1047170

08.12E Other Antineoplastic Agents

31234 **UK / Unknown(有**

PICIBANIL 5KE 必醫你舒 5 K E 注射劑

■■Streptococcus Pyogenes 5KE pow in vial

Dosage: 1常備品 31234

Adult
· IM, SC, 0.2-0.5KE at first then gradually increased stepwise to 2-5KE over 2-3wk; MD 1-5KE 1-3 times weekly;
· Intraperitoneal, intratumor, 5-10KE, 1-2 times/wk

Pediatric
NDA

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 5KE with 2ml NS diluent Vial(31234) (contain Potassium Benzyl penicillin 13470U)

ADR:

Leukocytosis, hemolytic anemia, chest pain, headache, nausea, abdominal distension, dull abdominal pain, vomiting, abscess, pain on injection, drug fever

NOTE: 冰箱保存

1.When reconstituted become tubid suspension
2.It is advisable to perform skin tests before administration because Benzyl penicilline is included
3.Unit conversion: The strength of PICIBANIL preparations is expressed in KE (Klinische Einheit) units, with 1 KE corresponding to approximately 0.1 milligram of lyophilized preparation

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2019924

08.12E Other Antineoplastic Agents

31238 **D / Unknown(有**

Topotecan Sandoz 1mg/mL Concentrate for Solution for Infusion 托普迪肯 "山德士" 1毫克/毫升注射劑

■■Topotecan HCl inj 4mg/4mL vial

Dosage: 1常備品 31238

Adult
· Ovarian neoplasms and small cell lung cancer: 1.5mg/m(2) for 5 days, repeat every 21 days. A minimum of 4 courses is recommended. In the event of severe neutropenia during any course, reduce the dose by 0.25mg/m2 for subsequent courses.
· Cervical cancer, stageIVB: 0.75 mg/m(2) for 3 days (followed by cisplatin 50 mg/m(2) on D!)

Pediatric: NDA

Dosing adjustments in hepatic impairment:

Bilirubin 1.5-10 mg/dL: no adjustment necessary

Dosing adjustments in renal impairment:

Moderate impairment (Clcr 20-39mL/min): Decrease dose to 0.75mg/m(2)

P: Inj: 4mg Vial(31238)(39953, 兒癌用藥)

ADR:

COMMON
Alopecia, rash, abdominal pain, constipation, diarrhea, nausea, vomiting, stomatitis, asthenia, headache, pain, cough, dyspnea, fatigue, fever
SERIOUS
Anemia(grade 3/4), febrile neutropenia, neutropenia(grade 4), thrombocytopenia(grade 4)

NOTE: 冰箱冷藏，不可冷凍

1.Prior to administration of the first course of topotecan, patients must have a baseline neutrophil count of > 1500 cells/mm3 and a platelet count of > 100,000 cells/mm3

藥名相似:

外觀相似:

外觀描述: 淡黃色注射液、『紫』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025791

08.12E Other Antineoplastic Agents

31246 D / Unsafe

ASADIN INJECTION 1MG/ML (ARSENIC TRIOXIDE) 伸定注射劑1公絲/公撮

■■Arsenic trioxide 10mg/10mL vial

Dosage: 1常備品 31246

Adult

· Leukemia, acute promyelocytic- induction: IV, 0.15mg/kg IV over 1-2 hours daily until bone marrow remission or Max. 60 doses

· Leukemia, acute promyelocytic- consolidation: IV, 0.15mg/kg IV over 1-2 hours daily for 25 doses over a period up to 5 weeks; beginning 3-6 weeks after completing induction

Pediatric

safety and effectiveness in children less than 5 years-old have not been studied

· Leukemia, acute promyelocytic- induction: IV, 0.15mg/kg IV over 1-2 hours daily until bone marrow remission or Max. 60 doses

· Leukemia, acute promyelocytic- consolidation: IV, 0.15mg/kg IV over 1-2 hours daily for 25 doses over a period up to 5 weeks; beginning 3-6 weeks after completing induction

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 10mg/10ml Vial(31246)

ADR:

COMMON

Chest pain, Edema, Hypotension, Dermatitis, Pruritus, Hyperglycemia, Hypokalemia, Hypomagnesemia, Abdominal pain, Constipation, Diarrhea, Loss of appetite, Nausea, Pain in throat, Vomiting, All grades Hyperleukocytosis, Arthralgia, Bone pain, Myalgia, Dizziness, Headache, Insomnia, Paresthesia, Anxiety, Bleeding from nose, Cough, Dyspnea , Hypoxia, Fatigue, Fever, Rigor.

SERIOUS

Complete atrioventricular block, Prolonged QT interval, Torsades de pointes, Typhlitis, Grade 3 or 4 Anemia, Grade 3 or 4 Disseminated intravascular coagulation, All grades Febrile neutropenia, Grade 3 or 4 Febrile neutropenia, Grade 3 or 4 Hyperleukocytosis, Grade 3 or 4 Neutropenia, Grade 3 or 4 Thrombocytopenia, Hepatotoxicity, Serum bilirubin raised, Hypersensitivity reaction, Infectious disease, Sepsis, Coma, Encephalopathy, Seizure, Wernicke' s disease, Renal failure, Renal impairment, Pleural effusion, Pneumonia, Pulmonary edema, Differentiation syndrome due to and following chemotherapy co-occurrent with acute promyelocytic leukemia.

NOTE: 室溫避光

1.Dilute with 100-250mL D5W or NS and infuse over 1-2 hours; extend infusion duration up to 4 hours if acute vasomotor reactions are observed

2.Initiate dexamethasone 10mg IV twice daily at first sign of acute promyelocytic leukemia differentiation syndrome

藥名相似:

外觀相似:

外觀描述: 10mL透明注射液『白』蓋透明玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=21000005

08.12E Other Antineoplastic Agents

31257 C / Unknown(有

LEUNASE INJECTION (10,000 K.U.) 樂拿舒注射劑 10,000 K.U.

■■L-Asparaginase 5000KU(int unit) pow in vial

Dosage: 1常備品 31257

Adult

· Leukemia, acute lymphocytic: IV, 200units/kg/day for 28 days

· Leukemia, acute lymphocytic: IV, 5000-10,000units/m(2)/day for 7 days, every 3 weeks, or 10,000-40,000units every 2 to 3 weeks

Pediatric

· Leukemia, acute lymphocytic: IV, IM, 6000units/m(2), 3 times/week

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 10000KU (IU) Vial(31257)

ADR:

COMMON

Agitation, coma, confusion, depression, fatigue, arthralgia, hallucinations, somnolence, angioneurotic edema, azotemia, anorexia, abdominal cramps, N/V

hepatotoxicity, skin rashes, urticaria

SERIOUS

Acute renal failure, respiratory distress, anaphylaxis, bone marrow suppression, hyperfibrinogenemia (factors V, VIII), hyperglycemia, hyperthermia, pancreatitis

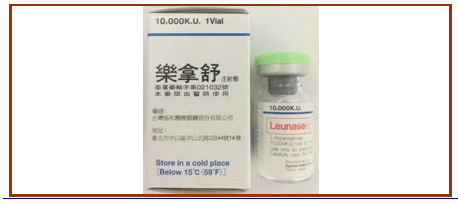
NOTE: 冰箱保存，不可冷凍。

Intradermal skin testing recommended prior to administration

藥名相似:

外觀相似:

外觀描述: 白色粉末，透明白色玻璃瓶，綠蓋



08.12E Other Antineoplastic Agents

37634 ɔt be ruled out / Infant risk can

ONIVYDE* (irinotecan liposome injection) 50mg/10mL 安能得微脂體注射劑

■■急用Irinotecan HCl, liposome 50mg/10ml vial

Dosage: 2急用藥 37634

Adult

· Adenocarcinoma of pancreas, Metastatic progressive disease following gemcitabine-based therapy; In combination with fluorouracil and leucovorin: IV infusion over 90 minutes, 80mg/m(2) every 2 wk.administer prior to leucovorin and fluorouracil and premedicate with a corticosteroid in combination with an anti-emetic 30 minutes prior to infusion.

Pediatric: NDA

Dosing adjustments in hepatic impairment:

Bilirubin >ULN: NDA

Dosing adjustments in renal impairment:

CrCl <30 mL/minute: NDA, Avoid use.

P: Inj: 50mg/10mL vial(liposome, 37634)

ADR:

COMMON

Hypoalbuminemia, Hypocalcemia, Hypokalemia, Hypomagnesemia, Decrease in appetite, All grades Diarrhea, Nausea, Stomatitis, Vomiting, All grades Anemia, All grades Lymphocytopenia, All grades Neutropenia, All grades Thrombocytopenia, ALT/SGPT level raised, Asthenia, Fatigue, Fever.

SERIOUS

Grade 3 or 4 Diarrhea, Febrile neutropenia, All grades Or sepsis, Febrile neutropenia, Grade 3 or 4 Or sepsis, Grade 3 or 4 Lymphocytopenia, Grade 3 or 4 Neutropenia, Neutropenic sepsis, Fatal, Hypersensitivity reaction, Severe, Sepsis, Septic shock, Acute renal failure, Interstitial lung disease, Pneumonia.

NOTE: 冰箱冷藏，不可冷凍。

1.Irinotecan liposome injection (Onivyde(R)) cannot be substituted for other drugs containing irinotecan hydrochloride

· 請勿以ONIVYDE取代其他含有irinotecan HCl的藥物

· 絕對嗜中性白血球計數低於1,500/mm3或有嗜中性白血球減少合併發燒時，則應暫緩使用。治療期間定期監測血球計數。

· 腹瀉嚴重度為第2-4級時，則暫緩使用。

藥名相似:

外觀相似:

外觀描述: 10mL不透明非均質微脂體，『綠/』蓋玻璃小瓶，白底綠/黑字標籤，有綠色區塊

08.12E Other Antineoplastic Agents

37717 ɔt be ruled out / Infant risk can

KYPROLIS* for injection 凱博斯凍晶注射劑

■■捐贈急用Carfilzomib inj 60mg pow in vial

Dosage: 2急用藥 37717

· Multiple myeloma, Relapsed or refractory,
1. Combination with Lenalidomide and Dexamethasone : Cycle 1, administer carfilzomib on 2 consecutive days each week for the first 3 weeks of a 4 week cycle; initial dose, 20 mg/m(2) IV on days 1 and 2; if tolerated, increase to 27 mg/m(2) IV for subsequent doses for 18 cycles 2.Combination with Dexamethasone : Cycle 1, administer carfilzomib on 2 consecutive days each week for the first 3 weeks of a 4 week cycle. Initial dose, 20 mg/m(2) IV , and if tolerated, increase to 56 mg/m(2) for subsequent doses

· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild or moderate impairment : Reduce dose by 25%

Dosing adjustments in renal impairment:

· Dosage Adjustment During Dialysis: Administer dose after dialysis sessions.

· Renal toxicity attributable to carfilzomib :Withhold carfilzomib until renal function has recovered to within 25% of baseline; restart with dose reduced by 1 level (For 27 mg/m(2) dose, first reduction is to 20 mg/m(2) and second reduction is to 15 mg/m(2); discontinue if toxicity persists after second dose reduction. For 56 mg/m(2) dose, the first reduction is to 45 mg/m(2), the second reduction is to 36 mg/m(2), and the third reduction is to 27 mg/m(2); discontinue if toxicity persists after third dose reduction)

· Renal toxicity not attributable to carfilzomib: Withhold carfilzomib, continue renal function monitoring, and resume dosing at prescriber's discretion

P: Carfilzomib 60mg pow in vial

ADR:

COMMON

Peripheral edema, hypokalemia, constipation , diarrhea , nausea , vomiting , anemia, lymphocytopenia , Neutropenia, thrombocytopenia, backache , headache, bronchitis , cough , upper respiratory infection ,fatigue , fever

SERIOUS

Cardiac arrest , congestive heart failure , heart failure , myocardial infarction , myocardial ischemia , restrictive cardiomyopathy, venous thrombosis , gastrointestinal hemorrhage , hemorrhage , neutropenia, , thrombocytopenia, thrombotic microangiopathy, liver failure intracranial hemorrhage , peripheral neuropathy , acute renal failure , renal failure , acute respiratory distress syndrome , acute respiratory failure , dyspnea , infectious disease of lung , pulmonary edema, pulmonary hemorrhage , pulmonary hypertension , pulmonary infiltrate, acute diffuse infiltrative disease , tumor lysis syndrome

NOTE: 避光冷藏 2~8℃

1.如您有使用以下可能會影響Carfilzomib藥效之藥品: melphalan 或 prednisone，請告知醫師
2.服用期間避免懷孕及哺乳
3.本藥可能會增加進行性多發性腦白質病變(PML)與B型肝炎病毒再活化的風險。

藥名相似:

外觀相似:

外觀描述: 白色凍晶粉末，『褐』蓋透明玻璃小瓶，白底褐/黑字標籤

08.12E Other Antineoplastic Agents

37780 D / Unsafe

VELCADE* Powder for Solution for Injection "法國"萬科靜脈凍晶注射劑

■■急用Bortezomib 3.5mg pow in vial

Dosage: 2急用藥 37780

Adult
· Multiple myeloma, mantle cell lymphoma: IV bolus over 3 to 5 seconds or SC, 1.3 mg/m2/dose twice weekly for 2 weeks (days 1, 4, 8 and 11) followed by a 10-day rest period. If an extended therapy of more than 8 cycles is required, it may be administered on the standard schedule or on on a maintenance schedule of once weekly for 4 weeks (days 1, 8, 15 and 22) followed by a 13-day rest period

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P: Inj: 3.5mg Vial (37780)

ADR:

COMMON
hypotension, rash, constipation, diarrhea, loss of appetite, nausea, vomiting, all grades of anemia, all grades of leukopenia,all grades of lymphocytopenia, all grades of neutropenia, all grades of thrombocytopenia, arthralgia, bone pain, cramp, myalgia, asthenia, dizziness, dysesthesia, headache, neuralgia, paresthesia, peripheral neuropathy, cough, dyspnea, lower respiratory tract infection, fatigue, fever.
SERIOUS
heart disease, heart failure, Stevens-Johnson syndrome, Toxic epidermal necrolysis, grade 3 or greater of anemia, grade 3 or greater of febrile neutropenia, grade 3 or greater of leukopenia, grade 3 or greater of lymphocytopenia, grade 3 or greater of neutropenia, grade 3 or greater of thrombocytopenia, hepatic failure, acute ,angioedema, posterior reversible encephalopathy syndrome, postherpetic neuralgia, progressive multifocal leukoencephalopathy, transient ischemic attack, acute respiratory distress syndrome, interstitial pneumonia, pneumonia, pneumonitis, acute, tumor lysis syndrome.

NOTE: 室溫避光儲存

· Consecutive doses should be separated by at least 72 hours
· Dose modifications are necessary in cases of neuropathic and/or peripheral sensory or motor neuropathy.

藥名相似:

外觀相似:

外觀描述: 白色乾粉，藍蓋透明玻璃小瓶

08.12E Other Antineoplastic Agents

37984 D / Unsafe

Halaven 0.5mg/ml Solution for injection 賀樂維 0.5毫克/毫升注射液

■■Eribulin mesylate inj 1mg/2mL vial

Dosage: 1常備品 37984

Adult
· Metastatic breast cancer in patients previously treated with at least 2 chemotherapy regimens: IV over 2-5 mins, 1.4 mg/m(2) on days 1 and 8 of a 21-day cycle
· Liposarcoma, Unresectable or metastatic, after a prior anthracycline-containing regimen: IV over 2-5 mins, 1.4 mg/m(2) on days 1 and 8 of a 21-day cycle.

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild hepatic impairment (Child-Pugh Class A): 1.1mg/m(2)
Moderate hepatic impairment (Child-Pugh Class B): 0.7mg/m(2)
Severe hepatic impairment (Child-Pugh class C): Use has not been studied

Dosing adjustments in renal impairment:

Clcr 15-49 mL/min: Reduce dose to 1.1 mgm(2) IV over 2 to 5 minutes on days 1 and 8 of a 21st cycle.

P: Inj: 1mg/2mL vial(37984, 急用藥)(37779, 捐贈)

ADR:

COMMON
Alopecia, weight loss, constipation, loss of appetite, nausea, anemia, neutropenia, ALT/SGPT level raised, arthralgia, myalgia, asthenia, headache, peripheral neuropathy, fatigue, fever
SERIOUS
Prolonged QT interval, anemia (Grade 3 or greater), febrile neutropenia, neutropenia (Grade 3 or greater), thrombocytopenia (Grade 3 or greater),

peripheral motor neuropathy, peripheral neuropathy (Grade 3 or greater)

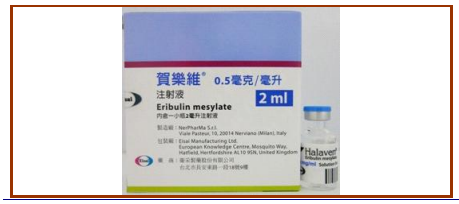
NOTE: 室溫儲存

·It should not be diluted or administered with dextrose solutions.

藥名相似:

外觀相似:

外觀描述: 2mL透明注射液『藍』蓋透明玻璃小瓶



08.12E Other Antineoplastic Agents

37987 **D / Caution**

Mozobil solution for injection 總動原注射劑

■■急用Plerixafor inj 24mg/1.2mL vial

Dosage: 2急用藥 37987

Adult

·Peripheral blood progenitor cell (PBPC) transplantation in non-Hodgkin lymphoma and multiple myeloma: SC, in the evening (approximately 11 hrs prior to initiation of apheresis) for up to 4 consecutive days
≦83 kg: 20-mg fixed dose or 0.24 mg/kg (actual body weight) once daily
> 83 kg: 0.24 mg/kg (actual body weight) once daily; Max. 40 mg/day

Administer granulocyte-colony stimulating factor (G-CSF) 10 mcg/kg subQ bolus or continuous infusion once daily in the morning for 4 days prior to the first evening dose of plerixafor, and on each day prior to apheresis

Pediatric

·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

CrCl >50 mL/min: No dosage adjustment needed
CrCl ?50 mL/min:
?83 kg: 13 mg fixed dose or 0.16 mg/kg once daily
>83 kg and <160 kg: 0.16 mg/kg once daily; Max: 27 mg daily

P: 24mg/1.2mL vial(37987, 急用藥)

ADR:

COMMON
Injection site reaction, diarrhea, nausea, vomiting, arthralgia, dizziness, headache, fatigue.
SERIOUS
Anaphylaxis, hypersensitivity reaction

NOTE: 室溫儲存

·For single use only, any unused drug remaining after injection must be discarded

藥名相似:

外觀相似:

外觀描述:

10.02A Reversible Acetylcholinesterase Inhibitor

22029 B /

EXELON CAPSULES 1.5MG 憶思能膠囊1.5毫克

Rivastigmine 1.5mg cap

Dosage: 1常備品 22029

Adult
·Mild to moderate Alzheimer's dementia: PO, initial 1.5mg bid with meals; if tolerated, increase dose after a minimum of 2 wks to 3mg bid; subsequent increases to 4.5mg bid and then 6mg bid should be attempted after a minimum of 2 wks of treatment at the previous dose. Max. 6mg bid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: 1.5mg (22029), 4.5mg (22030)

ADR:

COMMON
Weight loss, indigestion, loss of appetite, nausea, vomiting, dizziness
SERIOUS
Cardiac arrrest (infrequent), supraventricular tachycardia (infrequent), tachyarrhythmia (infrequent), gastrointtetinal hemorrhage(infrequent), bronchospasm (infrequent)

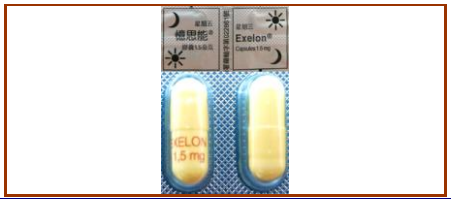
NOTE: 室溫儲存

1. Swallow the capsule whole. Do not crush, break, or chew it
2. If treatment is interrupted for longer than several days, treatment should be reinitiated with the lowest daily dose and titrated back to maintenance dose

藥名相似:

外觀相似:

外觀描述: 黃色膠囊，有EXELON 1,5mg字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022861

10.02A Reversible Acetylcholinesterase Inhibitor

22030 B /

EXELON CAPSULES 4.5MG 憶思能膠囊4.5毫克

Rivastigmine 4.5mg cap

Dosage: 1常備品 22030

Adult
·Mild to moderate Alzheimer's dementia: PO, initial 1.5mg bid with meals; if tolerated, increase dose after a minimum of 2 wks to 3mg bid; subsequent increases to 4.5mg bid and then 6mg bid should be attempted after a minimum of 2 wks of treatment at the previous dose. Max. 6mg bid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Cap: 1.5mg (22029), 4.5mg (22030)

ADR:

COMMON
weight loss, indigestion, loss of appetite, nausea, vomiting, dizziness
SERIOUS
Cardiac arrrest (infrequent), supraventricular tachycardia (infrequent), tachyarrhythmia (infrequent), gastrointtetinal hemorrhage(infrequent), bronchospasm (infrequent)

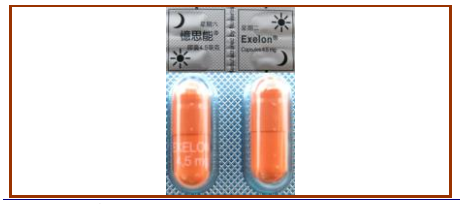
NOTE: 室溫儲存

1. Swallow the capsule whole. Do not crush, break, or chew it
2. If treatment is interrupted for longer than several days, treatment should be reinitiated with the lowest daily dose and titrated back to maintenance dose

藥名相似:

外觀相似:

外觀描述: 紅褐色膠囊，有EXELON 4.5mg字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022863

10.02A Reversible Acetylcholinesterase Inhibitor

27542 C / Unsafe

ARICEPT F.C. TABLETS 10MG 愛憶欣膜衣錠10毫克

Donepezil HCl 10mg FC tab

Dosage: 1常備品 27542

Adult
·Alzheimer’ s disease (mild-to-moderate): PO, initial 5 mg QD at bedtime, may increase to 10 mg QD at bedtime after 4-6 wks
·Alzheimer’ s disease (moderate-to-severe): PO, initial 5 mg QD at bedtime, may increase to 10 mg QD at bedtime after 4-6 wks; if suboptimal clinical response, may increase dose to Max. 23 mg once daily after 3 months

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Tab: 5mg(22033), 10mg(27542)

ADR:

COMMON
Hypertension, diarrhea, loss of appetite, nausea, vomiting, cramp, insomnia, fatigue
SERIOUS
Atrioventricular block, Torsades de pointes, gastrointestinal hemorrhage

NOTE: 室溫儲存

1. Adverse events most often occur during dose initiation or escalation; frequency of adverse events may be affected by the rate of dosage titration
2. Adverse events occurr more frequently in female patients and with advancing age.

藥名相似:

外觀相似:

外觀描述: 黃色圓扁錠，一面印有ARICEPT字樣，另一面印有10字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046989

10.02A Reversible Acetylcholinesterase Inhibitor

28300 **ɔt be ruled out / Infant risk can**

Rivast Oral Solution "Center" "晟德" 理曼提內服液劑

Rivastigmine 2mg/mL, 120mL/Bot

Dosage: 1常備品 28300

Adult
·Mild to moderate Alzheimer's dementia: PO, initial 1.5mg bid with meals; if tolerated, increase dose after a minimum of 2 wks to 3mg bid; subsequent increases to 4.5mg bid and then 6mg bid should be attempted after a minimum of 2 wks of treatment at the previous dose. Max. 6mg bid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: 1.5mg (22029), 4.5mg (22030); Patch: ; Oral soln: 2mg/mL, 120mL/bot (28300)

ADR:

COMMON
Weight loss, Abdominal pain, Diarrhea, Indigestion, Loss of appetite, Nausea, Vomiting, Neurologic: Asthenia, Dizziness, Headache , Tremor.
SERIOUS
Atrial fibrillation, Atrioventricular block, Myocardial infarction, Peripheral ischemia, Sick sinus syndrome, Hypokalemia, Hyponatremia, Gastrointestinal hemorrhage, Hematemesis, Melena, Pancreatitis, Rectal hemorrhage, Rupture of esophagus, Gamma-glutamyl transferase raised, Hepatitis, Liver function tests abnormal, Cerebrovascular accident, Intracranial hemorrhage, Seizure, Transient ischemic attack, Glaucoma, Suicidal behavior, Acute renal failure, Bronchospasm.

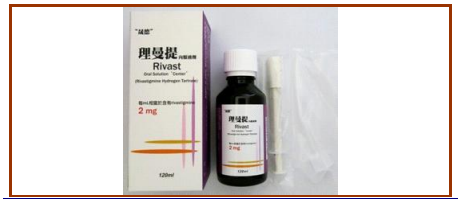
NOTE: 室溫儲存

· If treatment is interrupted for longer than several days, treatment should be reinitiated with the lowest daily dose and titrated back to maintenance dose
· 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 白色上蓋，內附劑量管[含底座]及內塞吸管一支，120mL棕色塑膠瓶



10.02A Reversible Acetylcholinesterase Inhibitor

29831 **B / Unsafe**

EXELON PATCH 5 憶思能穿皮貼片5

Rivastigmine patch 4.6mg/24hrs

Dosage: 1常備品 29831

Adult
·Mild to moderate Alzheimer's dementia: Transdermal, 1 patch qd

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: 1.5mg(22029), 4.5mg(22030); Patch: 4.6mg/24hr(29831)

ADR:

COMMON
Diarrhea, nausea, vomiting

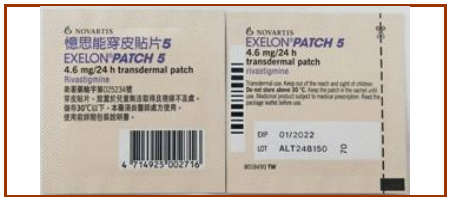
NOTE: 室溫儲存30℃以下

·Do not apply a new patch in the same place for at least 14 days.
·If interrupted for more than several days, reinitiate with the lowest dose of oral rivastigmineat at (i.e., 1.5 mg bid)
·Patient who is on a total daily dose of 6mg of oral rivastigmine can be switched to rivastigmine patch 4.6mg/24hrs

藥名相似:

外觀相似:

外觀描述: 粉橘色外袋，內有5平方公分貼片，背層為米色印有"AMCX"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025234

10.02A Reversible Acetylcholinesterase Inhibitor

29832 B / Caution

EXELON* PATCH 10 憶思能穿皮貼片10

Rivastigmine patch 9.5mg/24hrs

Dosage: 1常備品 29832

Adult
·Mild to moderate Alzheimer's dementia: Transdermal, 1 patch qd

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap:1.5mg(22029), 4.5mg(22030), Oral soln: 2mg/mL, 120mL/bot (28300)
Patch: 4.6mg/24hr(29831), 9.5mg/24hr(29832)

ADR:

COMMON
Decrease in apetite,Diarrhea,Nausea,Vomiting,UTI,Falls
SERIOUS
Seizure,Dehydration

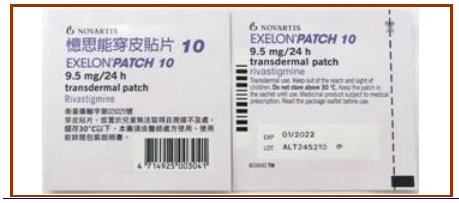
NOTE: 室溫儲存30℃以下

1.Switch from oral to patch: for total daily doses of 6 mg of oral rivastigmine, switch to 4.6 mg/24 hours patch; for a total daily dose of 12 mg of oral rivastigmine, switch to 9.5 mg/24 hours patch; apply the first patch on the day following the last oral dose
2.Do not apply a new patch in the same place for at least 14 days.

藥名相似:

外觀相似:

外觀描述: 粉紫色外袋，內有10平方公分貼片，背層為米色印有"BHDI"字樣



10.02B Anticholinesterase Agents

22002 C / Infant risk is

Antilon F.C. Tablets "Y.C." "元宙" 肌立健膜衣錠

Pyridostigmine bromide 60mg tab

Dosage: 1常備品 22002

Adult
·Myasthenia gravis: PO, initial 60 mg tid, MD 60-1500 mg/day, average 600 mg/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 60mg (22002)

ADR:

COMMON
Diaphoresis, diarrhea, excessive salivation, increased peristalsis, nausea and vomiting, stomach cramps, muscle cramps, muscle fasciculation, asthenia, miosis, excessive bronchial secretion
SERIOUS
Bradyarrhythmia, cholinergic crisis

NOTE: 室溫儲存

Contraindications: mechanical intestinal obstruction, urinary obstruction

藥名相似:

外觀相似:

外觀描述: 橘色圓扁錠，一面有刻痕，另一面有"PR"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048908

10.02B Anticholinesterase Agents

31601 C / Unsafe

NEOSTIGMINE METHYLSULFATE* INJECTION "TAI YU" 甲硫酸新斯狄格明注射液

Neostigmine methylsulfate inj 0.5mg/1mL amp

Dosage: 1常備品 31601

Adult
·Myasthenia gravis, diagnosis: IM, 0.02 mg/kg as a single dose
·Myasthenia gravis, treatment (when oral therapy is impractical): IV, IM, SC, initial 0.5mg; subsequent doses based on patient response
·Reversal of nondepolarizing neuromuscular blockade after surgery: IV, 0.5-2.5mg; total dose not to exceed 5mg; must administer atropine several minutes prior to neostigmine
·Post-OP distension and urinary retention, prevention: IM, SC, 0.25mg post-OP, repeat Q4-6H for 2-3 days
·Post-OP distension, treatment: IM, SC, 0.5mg as required
·Post-OP urinary retention, treatment: IM, SC, 0.5mg; if no response after 1hr, catheterize patient and continue 0.5mg/dose for 5 doses

Pediatrc
·Myasthenia gravis, diagnosis: IM 0.025-0.04 mg/kg as a single dose
·Myasthenia gravis, treatment): IV, IM, SC 0.01-0.04 mg/kg q2-4 hrs
·Reversal of nondepolarizing neuromuscular blockade after surgery in conjunction with atropine or glycopyrrolate: I.V. Infants: 0.025-0.1 mg/kg/dose ;Children: 0.025-0.08 mg/kg/dose

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

Clcr 10-50 mL/min: 50% of normal dose
Clcr <10 mL/min: 25% of normal dose

P: Inj: 0.5mg/1mL Amp (31601); Oph Soln: 0.01%, 10mL/B (29221)

ADR:

COMMON
Excessive salivation, muscle fasciculation
SERIOUS
Atrial fibrillation, AV block, bradyarrhythmia, cardiac arrest, cardiac dysrhythmia, loss of consciousness, seizure, bronchospasm, respiratory arrest, respiratory depression

NOTE: 室溫儲存

Contraindications: mechanical intestinal or urinary obstruction, peritonitis

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液，透明玻璃安瓿頸部有藍點，白底黑字標籤有淺藍色區塊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1014361

10.02C Muscarinic Agonists

22004 C / Infant risk can

BETHANECHOL TABLETS 25MG "JOHNSON" "強生" 脈酯膽生僉錠 2 5 毫克

Bethanechol chloride 25mg tab

Dosage: 1常備品 22004

Adult
·Urinary retention: PO, 10-50mg tid-qid
Pediatric
·Urinary retention: PO, 0.6 mg/kg/day divided in 3 or 4 doses

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Tab: 25mg (22004)

ADR:

COMMON
Flushing, Abdominal cramps, Diarrhea, Urgent desire to urinate.
SERIOUS
Seizure, Acute exacerbation of asthma.

NOTE: 室溫儲存

Contraindications: asthma, bradycardia, hypotension/vasomotor instability/vagotonia, compromised integrity of gastrointestinal or bladder wall, coronary artery disease, epilepsy, gastrointestinal inflammation/spasms/peritonitis, gastrointestinal or bladder surgery/resection/obstruction, hyperthyroidism, Parkinsonism, peptic ulcer

藥名相似:

外觀相似: Isoniazide* 100mg Tab (21133)

外觀描述: 黃色三角扁錠,中間有刻痕)

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044254

10.02C Muscarinic Agonists

22005 C /

SALICRET* F.C. TABLETS 5MG 液泌快膜衣錠5毫克

Pilocarpine HCl 5mg tab

Dosage: 1常備品 22005

Adult
·Mucositis following chemotherapy, prophylaxis: PO, 5mg 1 hr before chemotherapy, then 5mg QD for next 7 days
·Xerostomia: PO, 5-10mg tid
·Sjogren' s syndrome: PO, 5mg qid
Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild hepatic insufficiency: No dosage adjustment
Moderate hepatic insufficiency: initial 5mg bid
Severe hepatic insufficiency: Not recommended

Dosing adjustments in renal impairment:

No data available

P: Tab: 5mg (22005); Oph soln: 2% 15mL/B (29232)

ADR:

Flushing, sweating symptom, shivering, nausea, dizziness, increased frequency of urination, rhinitis

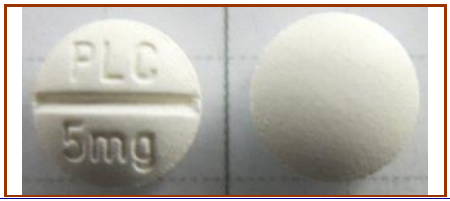
NOTE: 室溫儲存

1. Decreased rate and extent of absorption with high fat meal. Avoid administering with high fat meal
2. Contraindications: acute iritis or glaucoma after cataract extraction, narrow-angle (angle-closure) glaucoma, uncontrolled asthma

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有"PLC | 5mg"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1056778

10.02C Muscarinic Agonists

22006 C /

Evoxac (cevimeline HCl) Capsules 30mg 台灣第一三共愛我津膠囊30毫克

Cevimeline 30mg cap

Dosage: 1常備品 22006

Adult
·Sj?gren's syndrome: PO, 30mg tid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: 30mg(22006)

ADR:

COMMON
Sweating symptom, diarrhea, excessive salivation, indigestion, nausea, vomiting, urinary tract infectious disease, bronchitis, cough, rhinitis, sinusitis, upper respiratory infection
SERIOUS
Chest pain, edema, palpitations, eye/vision finding

NOTE: 室溫儲存

· Contrainidcations: uncontrolled asthma, acute iritis/narrow-angle (angle-closure) glaucoma

藥名相似:

外觀相似:

外觀描述: 白色膠囊，有"EVO"及"30"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1057883

10.04A Antiparkinsonian Agents

22032 C / Caution

BIPERIN TABLETS 2MG (BIPERIDEN) "UNION" "聯邦" 帕金寧錠 2 毫克(比培立汀)

Biperiden HCl 2mg tab

Dosage: 1常備品 22032

Adult
·Parkinsonism: PO, 2 mg tid-qid, Max. 16 mg/day
·Drug-induced extrapyramidal reactions: 2 mg qd-tid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data availble

P: Tab: 2mg (22032); Inj: 5mg/1mL Amp (31631)

ADR:

COMMON
Constipation, xerostomia, somnolence, blurred vision, urinary retention
SERIOUS
Anticholinergic agent toxicity, abnormal behavior, confusion

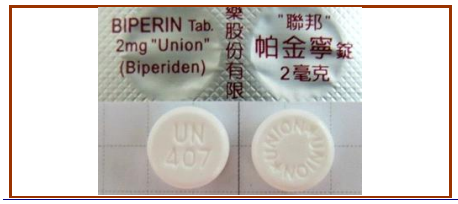
NOTE: 室溫儲存

Contraindications: bowel obstruction, megacolon, narrow angle glaucoma

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有"UN 407"，另一面有"UNION*UNION*"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1037441

10.04A Antiparkinsonian Agents

22904 C / Caution

SWITANE TABLET 2MG (TRIHEXYPHENIDYL) "SWISS" "瑞士"瑞丹錠 2 毫克（崇和費定）

Trihexyphenidyl HCl 2mg tab

Dosage: 1常備品 22904

Adult
·Parkinson's disease: PO, initial 1mg/day on first day, then increase in 2mg increments at 3-5 day intervals to 6-10mg/day according to response (div. tid-qid)
·Drug-induced extrapyramidal disorder: PO, 5-15mg/day div. tid-qid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 2mg(22904), 5mg(22905)

ADR:

COMMON
Nausea, xerostomia, dizziness, blurred vision, feeling nervous
SERIOUS
Angle-closure glaucoma, raised intraocular pressure, disorientated

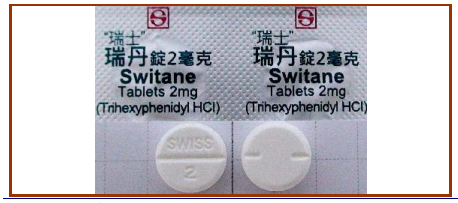
NOTE: 室溫儲存

Contraindications: narrow-angle glaucoma, under 3 years of age, tardive dyskinesias

藥名相似:

外觀相似: Rivotril* Clonazepam 2mg (22870)

外觀描述: 白色圓扁錠，有SWISS及2字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1039597

10.04A Antiparkinsonian Agents

22905 C / Caution

B.H.L. TABLET 5MG 顫立靜錠5毫克

Trihexyphenidyl HCl 5mg tab

Dosage: 1常備品 22905

Adult
·Parkinson’ s disease: PO, initial 1mg/day on first day, then increase in 2mg increments at 3-5 day intervals to 6-10mg/day according to response (div. tid-qid)
·Drug-induced extrapyramidal disorder: PO, 5-15mg/day div. tid-qid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 2mg(22904), 5mg(22905)

ADR:

COMMON
nausea, xerostomia, dizziness, blurred vision, feeling nervous
SERIOUS
angle-closure glaucoma, raised intraocular pressure, disorientated

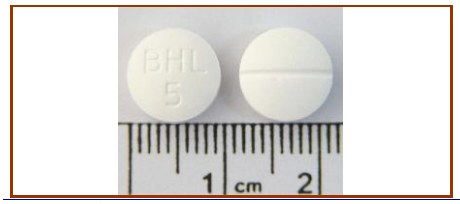
NOTE: 室溫儲存

Contraindications: narrow-angle glaucoma, under 3 years of age, tardive dyskinesias

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，有BHL及5字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046236

10.04A Antiparkinsonian Agents

31631 C / Unknown(有

BIPIDEN INJECTION 美必定注射液

Biperiden lactate 5mg/1mL amp

Dosage: 1常備品 31631

Adult
·Parkinsonism: IM/slow IV 10-20mg/day
·Drug-induced extrapyramidal reactions: IM/slow IV, 2.5-5mg, may repeat Q30min if necessary; Max.10-20mg/day

Pediatric:
·Drug-induced extrapyramidal reactions: <1yr:1mg/dose ; <6yr: 2mg/dose ; <10yr:3mg/dose IM every 30 min if needed, up to 4 doses/day

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Tab: 2mg(22032); Inj: 5mg/1mL Amp(31631)

ADR:

COMMON
Constipation, xerostomia, somnolence, blurred vision, urinary retention
SERIOUS
Anticholinergic agent toxicity, abnormal behavior, confusion

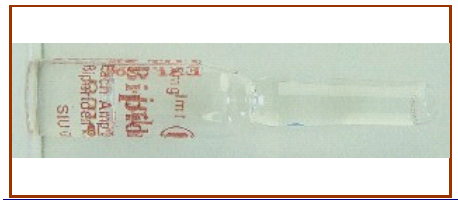
NOTE: 室溫儲存

Contraindications: bowel obstruction, megacolon, narrow angle glaucoma

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液透明安瓿頸部有藍點



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044187

10.04B Antimuscarinics

22026 C / Infant risk can

Vesicare film-coated tablets 5mg 衛喜康 膜衣錠 5毫克

Solifenacin FC 5mg tab

Dosage: 1常備品 22026

Adult
·Overactive bladder, with symptoms of urinary frequency, urgency, or urge incontinence: PO, 5mg qd; if tolerated, may increase to 10mg qd

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Moderate (Child-Pugh class B): Max. 5mg/day
Severe (Child-Pugh class C): Not recommended

Dosing adjustments in renal impairment:

Clcr<30mL/min: Max. 5mg/day

P: Tab:5mg(22026)

ADR:

COMMON
Constipation, indigestion, nausea, xerostomia, blurred vision, urinary retention, urinary tract infectious disease, Abdominal pain, taste disorders, dry nasal cavity and dry skin.
SERIOUS
Prolonged QT interval, Bowel obstruction, Fecal impaction, Obstruction of colon, Anaphylaxis, Confusion, Headache, Somnolence, Hallucinations, Angioedema

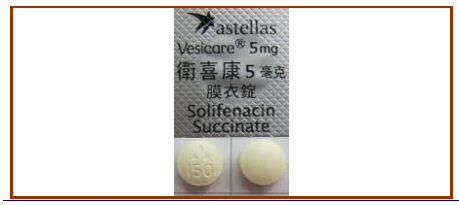
NOTE: 室溫儲存

·Contraindications: urinary retention, gastric retention, uncontrolled narrow-angle glaucoma
·Maximum dose with concomitant CYP3A4 inhibitors: 5mg/day
·Swallow whole. Do not crush, break, or chew it.
·Beers Criteria: Use caution or avoid use as potentially inappropriate in older adults.

藥名相似:

外觀相似: Ciproxin*(20839)

外觀描述: 圓形淡黃色錠劑，有150字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024437

10.04B Antimuscarinics

22031 C /

Terodine F.C. Tablets 2 mg 特洛定膜衣錠 2 毫克

Tolterodine L-tartrate 2mg FC tab

Dosage: 1常備品 22031

Adult
·Overactive bladder, with symptoms of urinary frequency, urgency, or urge incontinence: PO, 2mg bid; may adjust dose to 1mg bid based on tolerability and response

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

1mg bid

Dosing adjustments in renal impairment:

CrCl 10-30 mL/min: 1mg bid

P: Tab: 2mg(22031)

ADR:

COMMON
Constipation, xerostomia, headache
SERIOUS
Anaphylactoid reaction, dementa, memory impairment, angioedema

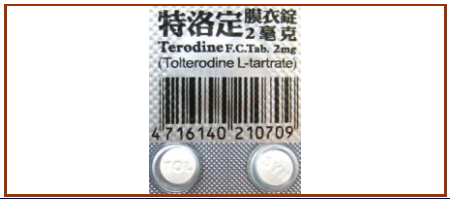
NOTE: 室溫保存

Contraindications: gastric retention, uncontrolled narrow-angle glaucoma, urinary retention

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有"SYN"，另一面有"TOL"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1055408

10.04B Antimuscarinics

22036 UK /

TRANCOLON F.C. TABLETS 7.5MG (MEPENZOLATE BROMIDE) 特良高朗膜衣錠 7．5 公絲（溴玫若雷）

Mepenzolate bromide 7.5mg FC tab

Dosage: 1常備品 22036

Adult
·Irritable bowel syndrome: PO, 15mg tid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Tab: 7.5mg(22036)

ADR:

anticholinergic effects, headache, tachycardia, nausea, vomiting

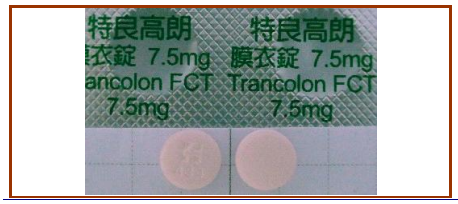
NOTE: 室溫儲存

Contraindications: myasthenia gravis, narrow-angle glaucoma, obstructive gastrointestinal disease, obstructive uropathy, paralytic ileus or intestinal atony, reflux esophagitis, ulcerative colitis or toxic megacolon, unstable cardiovascular status in acute hemorrhage

藥名相似:

外觀相似:

外觀描述: 淡粉紅色圓扁錠，有434字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1000844

10.04B Antimuscarinics

22041 C / Infant risk is

Buscopan Sugar Coated Tablets 10mg 補斯可伴糖衣錠 10毫克

Scopolamine(Hyoscine) butylbromide 10mg tab

Dosage: 1常備品 22041

Adult
·Gastrointestinal/genitourinary spasm: PO,10-20 mg tid-qid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Tab: 10mg(22041); Inj: 20mg/1mL Amp(31634)

ADR:

COMMON
Xerostomia, somnolence, blurred vision
SERIOUS
Transient alteration in heart rate, drug-induced psychosis (rare)

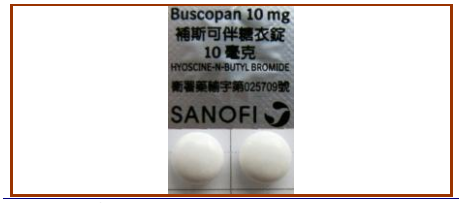
NOTE: 室溫儲存30℃以下

Contraindications: Narrow angle glaucoma, mechanical stenoses of the GI or urinary tract, myasthenia gravis, prostatic hypertrophy with urinary retention

藥名相似:

外觀相似: Dulcolax E.S.C.T* 5mg Tab (24930)

外觀描述: 白色糖衣錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025709

10.04B Antimuscarinics

31634 C / Infant risk is

DESPAS INJECTION 攣怕斯注射液

Hyoscine(scopolamine) butylbromide inj 20mg/1mL amp

Dosage: 1常備品 31634

Adult

·Gastrointestinal/genitourinary spasm: IM, IV, SC, 20mg repeated after 30min if necessary

Pediatric

·Gastrointestinal/genitourinary spasm: 0.3-0.6mg/kg by slow IV,IM,SC if necessary; Max dose: do not exceed 1.5mg/kg daily

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Tab: 10mg(22041); Inj: 20mg/1mL Amp(31634)

ADR:

COMMOM

˙ Dermatologic: Diminished sweating, Injection, Dry skin, Injection

˙ Gastrointestinal: Xerostomia, Injection

˙ Neurologic: Amnesia, Injection, Somnolence, Injection

˙ Ophthalmic: Mydriasis

˙ Other: Irritation symptom, Local

SERIOUS

˙ Cardiovascular: Tachyarrhythmia

˙ Dermatologic: Dry skin, Systemic absorption of ophthalmic formulation

˙ Gastrointestinal: Xerostomia, Systemic absorption of ophthalmic formulation

˙ Neurologic: Confusion, Systemic absorption of ophthalmic formulation, Somnolence, Systemic absorption of ophthalmic formulation

˙ Psychiatric: Hallucinations, Systemic absorption of ophthalmic formulation

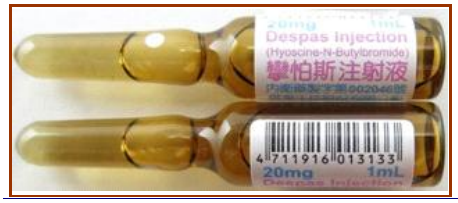
NOTE: 室溫儲存

Contraindications: chronic lung disease; repeated administration may increase the risk of adverse events; glaucoma, primary, or a tendency toward glaucoma (eg, narrow anterior chamber angle); hepatic impairment; hypersensitivity to scopolamine hydrobromide; any component of the product; other belladonna alkaloids, anticholinergic drugs, or barbiturates; narrow-angle (angle-closure) glaucoma; prostatic hypertrophy; pyloric obstruction; renal impairment.

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液,『棕』色玻璃安瓿,頸部有『灰』點,白底粉紅字及淺藍色字標籤



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12002046

10.06A Cardiovascular Drugs

22116 C /

MIDORINE TABLETS "P.L." "培力" 邁妥林錠

Midodrine HCl 2.5mg tab

Dosage: 1常備品 22116

Adult

·Orthostatic hypotension: PO, initial 2.5 mg bid or tid, can be increased in increments of 2.5 mg tid at weekly intervals, Max. 40 mg/day

Pediatric

·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

2.5mg tid; gradually increase as tolerated

P: Tab: 2.5mg(22116)

ADR:

COMMON

Hypertension, piloerection, pruritius, shivering, paresthesia, dysuria, urinary retention, urinary frequency

SERIOUS

Marked elevation of supine systolic blood pressure (200mmHg or above)

NOTE: 室溫儲存

Contraindications: acute renal disease/urinary retention, pheochromocytoma, severe organic heart disease or CHF, persistent and excessive supine hypertension, thyrotoxicosis

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠,有PL及T03字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045334

10.06A Cardiovascular Drugs

29144 C / Caution

Epirenin Solution "H.S." "黃氏" 妙舒安液

Epinephrine (Adrenaline) 0.1% 500mL/bot

Dosage: 1常備品 29144

Adult

· Local vasoconstriction: sprayed or applied with cotton or gauze to the skin, mucous membranes, or other tissues

Pediatric

·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Soln: 0.1%, 500mL/Bot(29144); Inj: 1mg/1mL Amp(31660)

ADR:

COMMON
Anxiety, apprehension, nervousness, dizziness, weakness, tremor, dyspnea, pallor, headache, nausea, vomiting, sweating, tachycardia, palpitations
SERIOUS
Arrhythmias, hypertensive crisis, pulmonary edema

NOTE: 室溫儲存

Epinephrine is light sensitive and should be stored in a light-resistant container.

藥名相似:

外觀相似:

外觀描述: 褐色玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048907

10.06A Cardiovascular Drugs

31656 **C / Unknown(有**

GIPAMINE INJECTION 3MG/ML "N.K." "南光" 吉利命注射液3毫克/毫升

■Dopamine inj 600mg/200mL bag

Dosage: 1常備品 31656

Adult

·Shock and cardiopulmonary resuscitation: IV infusion, initial 1-5 mcg/kg/min, increase by 1-4mcg/kg/min at 10-30min intervals until the optimal response is attained. In severely ill p' t, initial 5mcg/kg/min and gradually increase in increments of 5-10mcg/kg/min, up to 20-50mcg/kg/min.
·Congestive heart failure: IV infusion, initial 0.5-2mcg/kg/min. Most p't respond adequatley to 1-3mcg/kg/min.
·Hemodynamic effects:
Low-dose : IV infusion,1-3mcg/kg/min, increase renal blood flow and urine output.
Intermediate-dose: IV infusion, 3-10mcg/kg/min, increase renal blood flow, heart rate, cardiac contractility, and cardiac output.
High-dose: IV infusion, >10mcg/kg/min, alpha-adrenergic effects begin to predominate, vasoconstriction, increased blood pressure.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 200mg/5mL Vial(31662), 3mg/mL, 200mL/Bag(31656)

ADR:

COMMON
Chest pain, hypertension, palpitations, tachyarrhythmia, injection site reaction, piloerection, nausea, vomiting, headache, mydriasis , anxiety, oliguria , dyspnea
SERIOUS
Ectopic beats, gangrenous disorder, ventricular arrhythmia, wide QRS complex

NOTE: 室溫儲存

·Contraindications: pheochromocytoma, tachyarrhythmias/ventricular fibrillation
·Gipamine contains 5% dextrose.
·軟袋規格改為加藥專用輸液軟袋(SCPT infusion BAG)，軟袋接頭由單孔膠塞式接頭變更為雙孔式安全接頭(加藥孔與藥液輸出孔分開)
(1)使用時再將外袋撕除。
(2)使用時，請辨識"加藥孔"與IV set"輸出孔"，IV set拆入前再撕除"輸出孔"銀色鋁箔紙。

藥名相似:

外觀相似:

外觀描述: 200mL透明注射液，雙孔式安全接頭塑膠軟袋

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046457

10.06A Cardiovascular Drugs

31660 **C / Unknown(有**

EPINEPHRINE INJECTION "VPP" 腎上腺素注射液

■Adrenaline(Epinephrine) 1mg/1mL amp

Dosage: 1常備品 31660

Adult

·Anaphylaxis or asthma: Slow IV, initial 0.1-0.25 mg over 5-10 min and repeated every 5-15 min or followed by IV infusion at a rate of 1-4 mcg/min; IM, SC, 0.1-1 mg repeated at 10-15 min
·Cardiopulmonary resuscitation and cardiac arrhythmias: IV, 0.5-1 mg repeated every 3-5 min

Pediatric

·Anaphylaxis or asthma: SC, 0.01mg/kg or 0.3mg/m2, repeated at 20 min-4hrs, Max. 0.5mg/dose; IV, initial 0.1mg over 5-10min, followed IV infusion 0.1mcg/kg/min, Max.1.5mcg/kg/min
·Cardiopulmonary resuscitation and cardiac arrhythmias: IV, initial 0.01 mg/kg; may be repeated every 3-5 min as needed

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 1mg/1mL Amp(31660); Soln: 0.1%, 500mL/Bot(29144)

ADR:

COMMON
anxiety, apprehension, nervousness, dizziness, weakness, tremor, dyspnea, pallor, headache, nausea, vomiting, sweating, tachycardia, palpitations
SERIOUS
arrhythmias, hypertensive crisis, pulmonary edema

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液『棕』色安瓿頸部有白點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=115514

10.06A Cardiovascular Drugs

31662 **C / Unknown(有**

DOPAMIN (DOPAMINE) INJECTION 40MG/ML "VPP" " 榮民" 得保命注射液 4 0 公絲/公撮 (杜帕明)

■Dopamine 200mg/5mL amp

Dosage: 1常備品 31662

Adult
·Shock and Cardiopulmonary resuscitation: IV infusion, Initial 1-5 mcg/kg/min, increased by 1-4mcg/kg/min at 10-30min intervals until the optimal response is attained. In severely ill p' t, initial 5mcg/kg/min and gradually increased increments of 5-10mcg/kg/min, up to 20-50mcg/kg/min.
·Congestive heart failure: IV infusion, Initial 0.5-2mcg/kg/min. Most p't respond adequatley to dose of 1-3mcg/kg/min.
·Hemodynamic effect :
Low-dose : IV infusion,1-3mcg/kg/min, increased renal blood flow and urine output
Intermediate-dose : IV infusion,3-10mcg/kg/min, increased renal blood flow, heart rate, cardiaccontractility, and cardiac output.
High-dose :IV infusion, >10mcg/kg/min, alph-adrenergic effects begin to predominate, vasoconstriction, increased blood pressure.

Pediatric
·Cardiac arrest - Hypotension, acute: 2- 20 mcg/kg/min IV, titrate to response
·Hypotension, acute: initial, 2-5 mcg/kg/min IV; increase in 5-10 mcg/kg/min increments; MAX 30 mcg/kg/min IV

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Inj: 200mg/5mL Amp(31662), dopamine premix 1.6mg/mL, 250mL/B(31657)

ADR:

COMMON
anxiety,headache,chest pain, hypertension, palpitations, tachycardia, dyspnea, injection site reaction, mydriasis, nausea, vomiting, oliguria, piloerection
SERIOUS
ectopic heartbeats, gangrene of extremities, widened QRS complex, ventricular arrhythmias

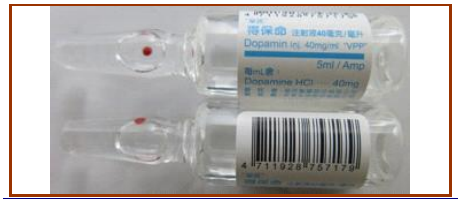
NOTE: 室溫儲存

Contraindications: pheochromocytoma, tachyarrhythmias/ventricular fibrillation

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液，透明安瓿頸部有藍點



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1032704

10.06A Cardiovascular Drugs

31665 **C / Unknown(有**

Proternol-L Injection 普樂他諾注射劑

■L-isoproterenol HCl 0.2mg/1mL amp

Dosage: 1常備品 31665

Adult
·Cardiac arrhythmias and cardiopulmonary resuscition : IV bolus, 0.02-0.06mg, subsequent doses range from 0.01-0.2mg; IV infusion, initial 5mcg/min, generally ranges 2-20mcg/min
·Shock : IV infusion 0.5-5mcg/min
·Bronchospasm : IV, 0.01-0.02mg, may be repeated when necessary

Pediatric
Safety and efficacy have not been established
·Bradyarrhythmias, AV nodal block, or refractory torsade de pointes: Continuous I.V. infusion (Infants and Children): 0.05-2 mcg/kg/minute; titrate to effect

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 0.2mg(200mcg)/1mL Amp(31665)

ADR:

COMMON
confusion, headache, syncope, tachycardia, tremor
SERIOUS
myocardial ischemia

NOTE: 室溫儲存

1.For IV bolus, diluted solutions (0.02mg/mL) are used; these solutions may be prepared by diluting 1mL of 0.2mg/mL to a volume of 10mL with NS or D5W
2.For IV infusion, solutions may be prepared by diluting 1-10mL of 0.2mg/mL with 500mL D5W to provide infusion solutions containing 0.4-4mcg/mL
3.Contraindications: angina pectoris, digitalis-induced tachycardia or heart block, tachyarrhythmias

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液透明安瓿頸部有紅點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=51058806

10.06A Cardiovascular Drugs

31666 **C /**

NOREPINEPHRINE* INJECTION "C.C.P.C." 諾安得理那寧注射劑

■Norepinephrine inj 4mg/ 4mL vial

Dosage: 1常備品 31666

Adult
·Hypotension, shock, cardiopulmonary resuscitation: IV infusion, initial 8-12 mcg(base)/min, MD 2-4 mcg (base)/min, dosage should be titrated according to the response of the patient.

Pediatric
Safety and efficacy have not been established
·Cardiac arrest; Adjunct - Hypotension, Profound: initial, 0.1 to 2 mcg/kg/min IV, titrate to effect
·Hypotension, acute: initial 0.1 mcg/kg/min IV, titrate to desired effect; maintenance 0.05 to 0.3 mcg/kg/min, MAX 6 mcg/min

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 4mg/4mL vial(31666)

ADR:

COMMON
Anxiety, confusion, restlessness, tremor, bradycardia, headache, hypertension, nausea, vomiting, urinary retention, injection site reaction (ie, extravasation leading to necrosis)
SERIOUS
Cardiac arrest, arrhythmias

NOTE: 儲存30℃以下避光

1.1 amp in 1000 ml of D5W or D5S (norepinephrine base 4 mcg/ ml)
2.Sodium chloride soln alone is not recommended as a diluent (dextrose against significant loss of potency due to oxidation)
3.Contraindications: hypotension due to blood volume deficit
4.Norepinephrine bitartrate 8mg/4mL eq. to norepinephrine base 4mg/4ml

藥名相似:

外觀相似:

外觀描述: 4mL注射液，『綠』蓋棕色玻璃小瓶，白/綠底黑/白字標籤，有黃底三角型紅色三角框及驚嘆號圖案

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=51059737

10.06A Cardiovascular Drugs

31668 **B / Unknown(有**

GENDOBU INJECTION 12.5MG/ML (DOBUTAMINE) 健多博注射液１２．５毫克/毫升（多保他命）

■Dobutamine 250mg/ 20mL vial

Dosage: 1常備品 31668

Adult
·Decreased cardiac output, heart failure: IV, initial, 0.5-1 mcg/kg/min, MD 2.5-20 mcg/kg/min ; titrate according to response, Max.40 mcg/kg/min

Pediatric
·Heart failure(post-cardiac arrest care) :IV 2 to 20 mcg/kg/min and titrate to desired response

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 250mg/20mL Vial(31668)

ADR:

COMMON
chest pain, hypertension, palpitations, tachycardia, dyspnea, headache, hypokalemia, injection site reaction, nausea
SERIOUS
arrhythmias, eosinophilic myocarditis, thrombocytopenia

NOTE: 室溫儲存

1.Correct hypovolemia before initiation, monitor ECG and BP
2.Contraindications: idiopathic hypertrophic subaortic stenosis

藥名相似:

外觀相似:

外觀描述: 20mL透明注射液，紅蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1042141

10.06A Cardiovascular Drugs

31670 C / Unknown(有

EPHEDRINE HYDROCHLORIDE INJECTION 鹽酸麻黃素針

■Ephedrine 40mg/1mL amp

Dosage: 1常備品 31670

Adult
·Complication of anesthesia, drug-induced hypotension: IM, SC, 25-50mg; Slow IV, 10-25 mg/dose repeat q5-10 min as needed, Max. 150 mg/day

Pediatric
·Bronchospasm, acute: SC,IV 750 mcg/kg or 25 mg/m2 administered according to patient response

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 40mg/1mL Amp(31670)

ADR:

COMMON
Anxiety, N/V, hypertension, palpitations, tremor

NOTE: 室溫儲存

Contraindications: anesthesia with cyclopropane or halothane,diabetes, hypertension or other cardiovascular disorders, pregnancy with maternal blood pressure above 130/80, thyrotoxicosis

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液透明安瓿頸部有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12008061

10.06B Respiratory Tract Drugs

22062 B / Caution

ASMATIN* TABLETS "SINPHAR" "杏輝" 喘必定錠

Fenoterol HBr 2.5mg tab

Dosage: 1常備品 22062

Adult
PO, 5-10 mg tid

Pediatric
PO, 0.05-0.15mg/kg/day div. 3 dose or
<1yr: PO, 1.25mg bid-tid
1-6yrs: PO,1.25-2.5mg tid
6-14yrs: PO, 2.5mg tid

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Tab: 2.5mg(22062); Berotec* MDI: 100mcg/puff, 200puff/B (29117)

ADR:

Tachycardia, nervousness, palpitations, muscle tremor

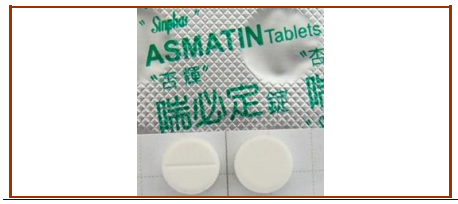
NOTE: 室溫儲存

Contraindications: hyperthyroidism, hypertrophic obstructive cardiomyopathy, tachyarrhythmias

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面中央有刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045733

10.06B Respiratory Tract Drugs

22065 UK / Caution

MECATER TABLETS 25MCG (PROCATEROL HYDROCHLORIDE HEMIHYDRATE) "信東"麥咳喘錠 2 5 微公克

Procaterol HCl hemihydrate 25mcg tab

Dosage: 1常備品 22065

Adult
·Asthma: PO, 50-100mcg bid

Pediatric
·Asthma: PO, 25-50mcg bid

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Tab: 25mcg(22065); Syrup: 60mL/Bot (28687)

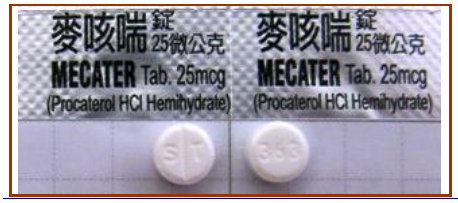
ADR:

NOTE: 室溫儲存

藥名相似: Tab: 25mcg(22065); Syrup: 60mL/Bot (28687)

外觀相似:

外觀描述: 白色圓扁錠，一面中間有刻痕及"S、T"字樣，一面有"363"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045492

10.06B Respiratory Tract Drugs

22068 ɔt be ruled out / Infant risk is

BABUROL TABLETS 10MG "信東"喘平樂錠10毫克

Bambuterol HCl 10mg tab

Dosage: 1常備品 22068

Adult
·Asthma: 10-20mg qhs

Pediatric

·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

Clcr <= 50 mL/min: 5 mg/day

P: Tab: 10mg(22068)

ADR:

Tremor, headache, uneasiness

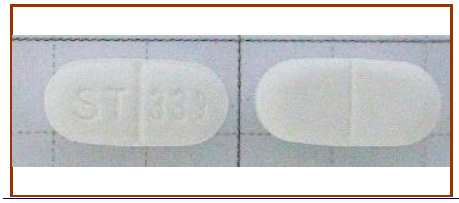
NOTE: 室溫儲存

1.Bambuterol is the prodrug of terbutaline
2.The safety of terbutaline in pregnancy is classified as category "B"

藥名相似:

外觀相似:

外觀描述: 白色長橢圓形扁錠，雙面中央有刻痕，一面有"ST"及"339"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045041

10.06B Respiratory Tract Drugs

28681 **a / Unknown(有**

STROLIN LIQUID 0.5MG/ML "CENTER" 適喘寧液 〝晟德〞

Fenoterol Hydrobromide 0.5mg/mL 60mL/bot

Dosage: 1常備品 28681

Adult
PO, 5-10mL tid

Pediatric
<1yr: PO, 2.5mL bid
1-6yrs: PO, 2.5-5mL tid
6-14yrs: PO, 5mL tid
>14 yrs: same as adults

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 2.5mg(22062); Liq: 0.5mg/mL 60mL/B(28681); Inhalation Aerosol: 100mcg/puff, 200puff/B(29117)

ADR:

Tachycardia, nervousness, palpitation, muscle tremor

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to fenoterol, other product components, or other sympathomimetic amines; Hyperthyroidism; Hypertrophic obstructive cardiomyopathy; Tachyarrhythmia；
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 60mL無色澄清藥水,半透明塑膠瓶,白底綠色區塊標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043189

10.06B Respiratory Tract Drugs

28687 **UK / Unknown(有**

EXDILA LIQUID 5UG/ML "CENTER" "晟德" 喘解液 5 微公克/公撮

Procaterol HCl Hemihydrate soln 5mcg/mL, 60mL/bot

Dosage: 1常備品 28687

Adult
·Asthma: PO, 50-100mcg bid

Pediatric
·Asthma: PO, 25-50mcg bid

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Tab: 25mcg(22065); Syrup: 60mL/Bot (28687)

ADR:

NOTE: 室溫儲存

·《仿單禁忌》1.甲狀腺機能亢進、高血壓、心疾患、糖尿病患者、孕婦宜慎重投與本劑。2.本劑與Epinephrine、Isoproterenol、Catecholamine、併用引起不整脈，應避免併用。3.本劑對Allergen引起的皮膚反應有抑制作用，欲實施皮膚試驗時，須在12小時前停藥；
·It should be taken during or within 20 mins of a full meal or a liquid nutritional supplement in order to enhance absorption.
·香料為葡萄柚香料(成分主為正葵醛，柑橘類易有，不含香草成分)(2018.06.22 晟德 賴藥師提供)
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 白色上蓋，60mL粉紅色塑膠瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044482

10.08A Alpha 1 Adrenergic Blocker

22101 **ɔt be ruled out / Infant risk can**

Naizhu Tablets 2 mg "S.D." "世達" 腦益健 錠 2 毫克

Dihydroergotoxine mesylate 2mg tab

Dosage: 1常備品 22101

Adult
·Symptomatic treatment of age-related dementia: PO, 1mg tid up to 4.5-12mg/day; up to 6 mon of

therapy may be necessary

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Tab: 2mg(22101)

ADR:

COMMON
Flushing, Rash, Nausea and vomiting, Headache, Blurred vision, Congestion of nasal sinus.
SERIOUS
Bradyarrhythmia, Orthostatic hypotension (less frequent or rare)

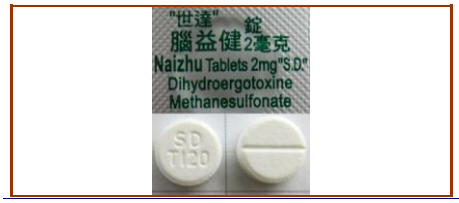
NOTE: 室溫儲存

Contraindications: acute or chronic psychosis

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面印有刻痕，另一面印"SD"及"T120"字樣)



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1050223

10.08A Alpha 1 Adrenergic Blocker

22105 **X / Unsafe**

Lesiton capsules 5mg 樂息痛膠囊5毫克

Dihydroergotamine mesylate 5mg cap

Dosage: 1常備品 22105

Adult
·Migraine: PO, 5mg bid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Contraindicated in severe hepatic disease

Dosing adjustments in renal impairment:

Contraindicated in severe renal impairment

P: Cap: 5mg(22105)

ADR:

COMMON
dizziness, irritation of the nose or throat, nausea/vomiting, paresthesias
SERIOUS
cardiovascular/cerebrovascular or peripheral ischemia, ergotism

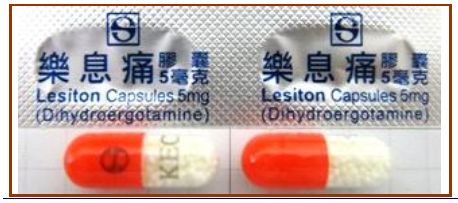
NOTE: 室溫儲存

1.Swallow whole ; do not crush or chew
2.Contraindications: peripheral arterial disease, uncontrolled HTN, ischemic heart disease, angina, hemiplegic/basilar migraine, severely impaired liver/renal function, sepsis, other egot/5HT derivatives last 24hrs, following vascular surgery, pregnancy and lactation

藥名相似:

外觀相似:

外觀描述: 白/橘色膠囊，有"KEC"及"藥商圖案"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1057356

10.08A Alpha 1 Adrenergic Blocker

22120 **B / Caution**

Urief Capsules 4 mg 優列扶膠囊 4 毫克

Silodosin 4mg cap

Dosage: 1常備品 22120

Adult
·Benign prostatic hyperplasia: PO, 4mg bid.or 8mg once daily with a meal

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Child-Pugh scope>=10: contraindicated

Dosing adjustments in renal impairment:

CrCl: 50-80mL/min: No dosage adjustment needed.
CrCl:30-50mL/min: 2mg bid
CrCl<30mL/min: Contraindicated

P: Cap: 4mg(22120)

ADR:

COMMON
Orthostatic hypotension, diarrhea , dizziness, headache , retrograde ejaculation, nasal congestion ,nasopharyngitis

NOTE: 室溫儲存

Contraindications:
1.concomitant use of strong CYP3A4 inhibitors (eg, ketoconazole, clarithromycin, itraconazole, ritonavir). 2. hepatic impairment, severe (Child-Pugh score of 10 or greater) 3.renal impairment, severe (CrCl less than 30 mL/min)

藥名相似:

外觀相似:

外觀描述: 白色膠囊，一端印有"URIEF"及"4"，另一端印有"SYN"字樣

10.08A Alpha 1 Adrenergic Blocker

22493 **B / Infant risk can**

Harnalidge OCAS* prolonged release tablets 0.4 mg 活路利淨OCAS持續性藥效膜衣錠 0.4毫克

Tamsulosin HCl 0.4mg OCAS tab

Dosage: 1常備品 22493

Adult
·Benign prostatic hyperplasia: PO, 0.4mg once daily

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Moderate liver dysfunction(Child-Pugh grade A or B): No dosage adjustment needed
Severe liver dysfunction: Contraindicated

Dosing adjustments in renal impairment:

Clcr>10mL/min: No dosage adjustment needed
Clcr<10mL/min: Not studied

P: Tab: 0.4mg(22493)

ADR:

COMMON
Infectious disease, backache, asthenia, dizziness, headache, insomnia, somnolence, abnormal ejaculation, rhinitis
SERIOUS
Retinal detachment, priapism

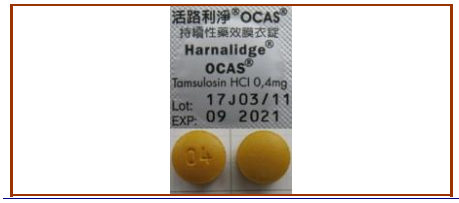
NOTE: 室溫儲存30℃以下

·Swallow whole tablet . Do not crush or chewed

藥名相似:

外觀相似: Lodopin* 50mg tab (22972), Gaster* D 20mg

外觀描述: 土黃色圓扁錠，一面有"04"字樣



10.08A Alpha 1 Adrenergic Blocker

22566 ɔt be ruled out / Unknown(有

SERMION TABLETS 5MG 適脈旺糖衣錠 5 毫克

Nicergoline 5mg tab

Dosage: 1常備品 22566

Adult
·Mental deterioration associated with cerebrovascular insufficiency, peripheral vascular disease : PO, ac, 5-10 mg tid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

SCr>2: dosage adjustment required

P: Tab: 5mg(22566)

ADR:

Gastric disturbance, feeling of heat and flushing, drowsiness, insomnia

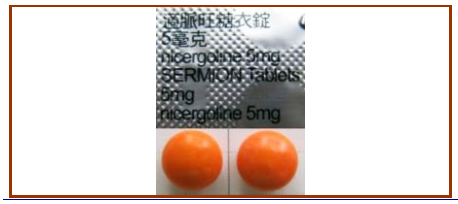
NOTE: 室溫儲存25℃以下

Contraindications: Acute hemorrhage, Arterial hypotension,Hypersensitivity to nicergoline, Recent myocardial infarction, Severe bradycardia
Use with caution: Concurrent use(1)alpha or beta receptor agonists(2)uricosuric agent (3)anticoagulant or antiplatelet agents

藥名相似:

外觀相似: 外盒：Caduet* Tab (22554), Olbetam* (22453

外觀描述: 橙色圓形糖衣錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2014029

10.10A Central Acting Muscle Relaxants

22134 C / Infant risk is

BAFEN* TABLETS 5MG 痛獲平錠 5 毫克

Baclofen 5mg tab

Dosage: 1常備品 22134

Adult
·Spasticity: PO, initial 5 mg tid, MD 40-80 mg/day, Max. 80 mg/day

Pediatric
·Spasticity:PO,
2-7 yrs:10-15 mg/day (2-3 divided doses); may increase by 5-15 mg/day increments every 3 days to a Max. 40 mg/day (3-4 divided doses)
≧8 yrs :10-15 mg/day (2-3 divided doses); may increase by 5-15 mg/day increments every 3 days to a Max.60 mg/day (3-4 divided doses)

Dosing adjustments in hepatic impairment:

No dosage adjustment required

Dosing adjustments in renal impairment:

Dosage adjustment required

P: Tab: 5mg(22134)

ADR:

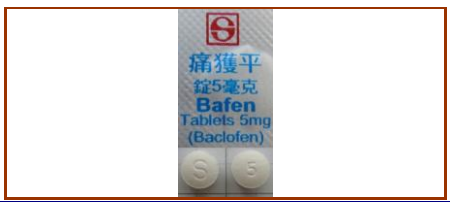
COMMON
Constipation, nausea, vomiting, hypotonia, paresthesia, somnolence, headache, dizziness
SERIOUS
Coma, death, seizures

NOTE: 室溫儲存

藥名相似:

外觀相似: 22910 Seginine* Jumexol

外觀描述: 白色圓扁錠，一面有"S"，另一面有"5"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045383

10.10A Central Acting Muscle Relaxants

22135 UK /

TOPEE F.C. TABLETS 150MG 肌鬆定膜衣錠150公絲

Tolperisone 150mg tab

Dosage: 1常備品 22135

Adult
·Musculoskeletal disorders with hypermyotonia and decreased motility: PO, 150-300mg/day div. 2 or 3 doses, Max. 450mg/day

Pediatric (3mon-14yrs)
·Musculoskeletal disorders with hypermyotonia and decreased motility: PO, 2-5mg/kg/day

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Tab: 150mg(22135)

ADR:

Diarrhea, dizziness, drowsiness, dry mouth, hypotension, headache, rash, muscle weakness, muscle pain

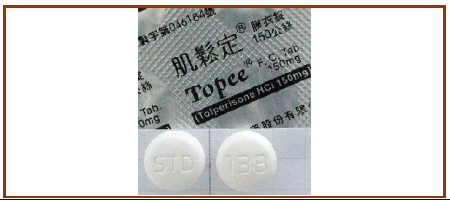
NOTE: 室溫保存

·Contraindications: myasthenia gravis, children under 3 months of age
·仿單內容變更，摘述如下(自第0052批起)
1.適應症變更(反覆發生的疼痛性肌痙攣及腦部血管病變所導致之肌張力異常升高)。
2.用法用量：加註嚴重肝、腎功能不全者不建議服用。
3.警語及注意事項：加註過敏反應之症狀、可能有較高發生過敏反應風險者及具交叉反應之藥品(lidocaine)。
4.交互作用：增列(a)本藥併用CYP2D6作用藥物如dextromethorphan，可能增加其血中濃度。經CYP2D6代謝之藥物包含venlafaxine、atomoxetine、desipramine、dextromethorphan...等。(b)本藥未對CYP2B6、CYP2C8、CYP2C9、CYP2C19、CYP1A2、CYP3A4造成顯著抑制或誘導。?空腹服用本藥會降低生體可用率，故建議服藥與進食間之關係應固定。(d)併用其他NSAID時，需考慮減少NSAID的劑量。
5.使用族群處：加註使用於孩童之安全性及有效性資料尚未建立。
6.不良反應：增列被報告的案件中約50-60%與過敏反應有關。

藥名相似: Tab: 150mg(22135)

外觀相似:

外觀描述: 白色圓扁錠，一面有STD字樣，另一面有138字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046184

10.10A Central Acting Muscle Relaxants

22136 /

MEFNO TABLET 200MG 美舒錠２００毫克

Mephenoxalone 200mg tab

Dosage: 1常備品 22136

Adult
·Muscle spasm: PO, 200-400mg tid

Pediatric
·Muscle spasm: PO, 6-15yr: 0.5tab tid

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Tab: 200mg(22136)

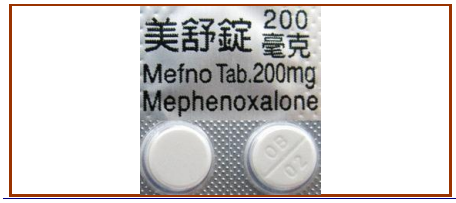
ADR:

NOTE: 室溫儲存

藥名相似: Tab: 200mg(22136)

外觀相似: Ursolic* 100mg Tab (25014),

外觀描述: 白色圓扁錠，一面有中央刻痕及"OB"及"02"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043257

10.10B2 Nondepolarizine Agents

31763 C / Unknown(有

GENSO INJECTION 10MG/ML (ATRACURIUM) 健舒注射液（艾翠克瑞）〝健亞〞

■▼Atracurium besylate inj 25 mg/2.5 mL amp

Dosage: 1常備品 31763

Adult
·Skeletal muscle relaxation: IV, initial 0.4-0.5mg/kg, MD 0.08-0.1mg/kg 20-45min after the initial dose, if necessary repeat every 15-25min; IV infusion, initial 9-10mcg/kg/min, MD 5-9mcg/kg/min

Pediatirc
≧ 2yrs: same as adult

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 25mg/2.5mL(31763)

ADR:

COMMON
Flushing (5%)
SERIOUS
Bradyarrhythmia, edema, hypotension, tachyarrhythmia, erythema, hives, anaphylaxis (rare), immune hypersensitivity reaction (rare), prolonged muscle weakness, prolonged paralysis, bronchospasm (rare), laryngeal spasm

NOTE: 冰箱冷藏，不可冷凍。

藥名相似:

外觀相似:

外觀描述: 2.5mL透明注射液，透明安瓿『藍』色標籤，頸部有一『白』色線條

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1042879

10.10B2 Nondepolarizine Agents

31767 B / Caution

CISATRACURIUM KABI* 2mg/ml solution for injection/infusion "卡比"肌鬆弛注射液2毫克/毫升

■▼Cisatracurium inj 10mg/5mL amp

Dosage: 1常備品 31767

Adult

·Skeletal muscle relaxation: initial, IV bolus 0.15-0.2 mg/kg; MD, IV 0.03 mg/kg or IV infusion rate of 1-3 mcg/kg/min

Pediatric

·Skeletal muscle relaxation: initial, 0.1mg/kg IV bolus over 5-10 sec; MD, initial IV infusion 3 mcg/kg /min; then decrease to 1-2 mcg/kg/min

Dosing adjustments in hepatic impairment:

Dosage reduction may be required in patients with hepatic failure receiving cisatracurium for prolonged periods of time.

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 10mg/5mL amp(31767)

ADR:

SERIOUS
bradycardia (rare), hypotension (rare), bronchospasm (rare)

NOTE: 避光冷藏，不可冷凍。

藥名相似:

外觀相似:

外觀描述: (5mL透明注射液透明安瓿

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=52026541

10.10B3 Toxin

36060 ɔt be ruled out / Infant risk can

Dysport, Powder for Injection 儷緻注射劑

■Botulinum toxin 500 unit pow in vial

Dosage: 1常備品 36060

ADULT

·Upper limb spasticity：IM, total dose of 500/1000U divided among selected muscles(<1mL at any injection site)-
FCR/FCU/FDP/FDS/Brachioradialis/Pronator teres 100-200U; Brachialis/Biceps Brachii 200-400U

·Lower limb spasticity：IM, total dose of 1000/1500U divided among selected muscles-soleus 330-500U in 3 sites per muscle; Gastrocnemius(medial or lateral head) 100-150U in 1 injection site per muscle; Tibialis posterior 200-300U in 2 injection sites per muscle; Flexor digitorum longus 130-200U in 1~2 injection sites per muscle; Flexor hallucis longus 70-200 U in 1 injection site per muscle

·Cervical dystonia:IM,initial 500U divided among 2-3 affected muscles, maintenance, 250~1000 U divided among affected muscles; retreat as needed at least q12w or longer

·Blepharospasm, hemifacial spasm: 40-120 U per eye

·Glabellar lines: IM: Inject 10U into each of 5 sites (2 injections in each corrugator muscle and 1 injection in the procerus muscle) for a total dose of 50 units; do not administer at intervals <3 m

·Cerebral palsy(>2yr): IM , MAX 15U/kg total dose for unilateral injections or 30 U/kg for bilateral injections or 1000 Units, whichever is lower; MAX 0.5 mL in any single injection site

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Inj: 500U Vial(36060)

ADR:

COMMON
Injection site reaction, xerostomia, influenza, muscle weakness, difficulty speaking, headache, visual impairment, cough, nasopharyngitis, pharyngitis, upper respiratory infection, fever
SERIOUS
Dysphagia, hypersensitivity reaction, seizure, dyspnea

NOTE: 冰箱儲存

1.Relative potencies of botulinum A toxin preparations available in the United Kingdom and North America differ significantly
2.Units of biological activity of botulinum toxin type A cannot be compared to nor converted into units of any other botulinum toxin
3.Contraindications: infection at the proposed injection site(s)

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『白』蓋透明玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000870

10.10B3 Toxin

36061 ɔt be ruled out / Infant risk can

BOTOX (BOTULINUM TOXIN TYPE A) PURIFIED NEUROTOXIN COMPLEX "ALLERGAN" 〝愛力根〞保妥適乾粉注射劑

■急用DS檔Botulinum toxin type A 100 unit pow in vial

Dosage: 2急用藥 36061

Adult
·Strabismus: 1.25-5 U (0.05-0.15ml at each site) injected into extraocular muscle
·Blepharospasm: 1.25-2.5 U (0.05-0.1ml at each site) injected into orbicularis oculi muscle.
·Primary axillary hyperhidrosis: Intradermal, 50U/axilla. Injections should be into 10-15 sites, administered in 0.1 to 0.2 mL aliquots, ~1 to 2 cm apart
·Detrusor overactivity associated with neurologic condition: Intradetrusor, 30 injections of 1 mL for a total dose of 200 U/30 mL (maximum: 200 U)
·Overactive bladder: Intradetrusor, 20 injections of 0.5 mL for a total dose of 100 U/10 mL (maximum: 100 U); for the final injection, ~1 mL of sterile NS should be injected to ensure that the remaining medication completely delivered to the bladder; may consider re-treatment with diminishing effect (interval must>12wks)

PEDIATRIC
·Cerebral palsy: 4-6 U/kg injected into the medial and lateral heads of the affected gastrocnemius muscle.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P:

ADR:

COMMON
Injection site pain, sweating symptom, non-axillary, backache, neck pain, pain in limb, headache, dry eyes, ptosis of eyelid, urinary retention, UTI, cough, rhinitis,URI, Fever, Influenza-like symptoms
SERIOUS
Cardiac dysrhythmia, myocardial infarction, dysphagia, anaphylaxis, autonomic dysreflexia, seizure, retrobulbar hemorrhage, respiratory depression

NOTE: 冰箱冷藏

1.Botulinum A toxin should not be given with(or before) aminoglycosides. Interaction may be also occur with other drugs that have neuromuscular blocking activity.
2.For Bladder dysfunction: Prophylactic antibiotic (excluding aminoglycosides) should be administered 1 to 3 days prior to, on the day of, and for 1 to 3 days following botox.Discontinue antiplatelet therapy at least 3 days prior to procedure

藥名相似:

外觀相似:

外觀描述: 白色乾粉，『紫』蓋透明玻璃小瓶

10.10B3 Toxin

36066 ɔt be ruled out / Infant risk can

BOTOX (BOTULINUM TOXIN TYPE A) PURIFIED NEUROTOXIN COMPLEX "ALLERGAN" "愛力根"保妥適乾粉注射劑

■急用Botulinum toxin type A 100 unit pow in vial (Local injection)

Dosage: 2急用藥 36066

Adult
·Strabismus: 1.25-5 U (0.05-0.15ml at each site) injected into extraocular muscle
·Blepharospasm: 1.25-2.5 U (0.05-0.1ml at each site) injected into orbicularis oculi muscle.
·Primary axillary hyperhidrosis: Intradermal, 50U/axilla. Injections should be into 10-15 sites, administered in 0.1 to 0.2 mL aliquots, ~1 to 2 cm apart
·Detrusor overactivity associated with neurologic condition: Intradetrusor, 30 injections of 1 mL for a total dose of 200 U/30 mL (maximum: 200 U)
·Overactive bladder: Intradetrusor, 20 injections of 0.5 mL for a total dose of 100 U/10 mL (maximum: 100 U); for the final injection, ~1 mL of sterile NS should be injected to ensure that the remaining medication completely delivered to the bladder; may consider re-treatment with diminishing effect (interval must>12wks)

PEDIATRIC
·Cerebral palsy: 4-6 U/kg injected into the medial and lateral heads of the affected gastrocnemius muscle.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Inj: 100U(36066), 500U(36060)

ADR:

COMMON
Injection site pain, sweating symptom, non-axillary, backache, neck pain, pain in limb, headache, dry eyes, ptosis of eyelid, urinary retention, UTI, cough, rhinitis,URI, Fever, Influenza-like symptoms
SERIOUS
Cardiac dysrhythmia, myocardial infarction, dysphagia, anaphylaxis, autonomic dysreflexia, seizure, retrobulbar hemorrhage, respiratory depression

NOTE: 冰箱冷藏2-8℃

1.Botulinum A toxin should not be given with(or before) aminoglycosides. Interaction may be also occur with other drugs that have neuromuscular blocking activity.
2.For Bladder dysfunction: Prophylactic antibiotic (excluding aminoglycosides) should be administered 1 to 3 days prior to, on the day of, and for 1 to 3 days following botox.Discontinue antiplatelet therapy at least 3 days prior to procedure

藥名相似:

外觀相似:

外觀描述:

10.12 Smoking Deterrent

27217 ɔt be ruled out / Infant risk can

NICOTINELL* Cool Mint 2mg Chewing Gum 克菸 咀嚼錠(清涼薄荷)2毫克

Nicotine 2mg freshmint mediated Chewing gum (Nicotine-resin complex 10mg)

Dosage: 1常備品 27217

Adult
·Smoking cessation: heavy smokers, 1 piece of 4 mg gum every 1-2 hr for weeks 1-6, 1 piece every 2-4 hr for weeks 7-9, 1 piece of every 4-8 hr for weeks 10-12 ; light smokers, 1 piece of 2 mg gum every 1-2 hr for weeks 1-6, 1 piece every 2-4 hr for weeks 7-9, 1 piece every 4-8 hr for weeks 10-12. Chew 1 piece of gum when urge to smoke, up to 30 pieces/day;most patients require 10-12 pieces of gum/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Patch: 10.4mg/5cm2(29166), 20.8mg/10cm2(29165), 31.2mg/15cm2(29164); Chewing gum: 2mg(27217), 4mg(27230)

ADR:

COMMON
Dyspepsia, diarrhea, mouth irritation
SERIOUS
Irregular heartbeat, palpitations, nicotine overdose

NOTE: 室溫儲存

·《Contraindications》hypersensitivity to nicotine or components ;
·Heavy smokers: smoke 25 or more cigarettes a day
·If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known. (FDA warnings for non-prescription nicotine replacement therapies)
·用量用法(仿單)：不建議服用超過一年。
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 白色四方形咀嚼錠

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024457

10.12 Smoking Deterrent

27230 ɔt be ruled out / Infant risk can

Nicotinell Cool Mint* 4mg Chewing Gum 克菸咀嚼錠(清涼薄荷)4毫克

Nicotine 4mg freshmint mediated chewing gum (Nicotine-resin complex 20mg)

Dosage: 1常備品 27230

Adult
·Smoking cessation: heavy smokers, 1 piece of 4 mg gum every 1-2 hr for weeks 1-6, 1 piece every 2-4 hr for weeks 7-9, 1 piece of every 4-8 hr for weeks 10-12; light smokers, 1 piece of 2 mg gum every 1-2 hr for weeks 1-6, 1 piece every 2-4 hr for weeks 7-9, 1 piece every 4-8 hr for weeks 10-12 . Chew 1 piece of gum when urge to smoke, up to 30 pieces/day;most patients require 10-12 pieces of gum/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Patch: 10.4mg/5cm2(29166), 20.8mg/10cm2(29165), 31.2mg/15cm2(29164); Chewing gum: 2mg(27217), 4mg(27230)

ADR:

COMMON
Dyspepsia, diarrhea, mouth irritation
SERIOUS
Irregular heartbeat, palpitations, nicotine overdose

NOTE: 室溫儲存

·《Contraindications》hypersensitivity to nicotine or components ;
·Heavy smokers: smoke 25 or more cigarettes a day
·If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known. (FDA warnings for non-prescription nicotine replacement therapies)
·用量用法(仿單)：不建議服用超過一年。
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 白色四方形咀嚼錠

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024499

10.12 Smoking Deterrent

27241 ɔt be ruled out / Infant risk can

Champix film coated tablet 0.5 mg 戒必適 膜衣錠 0.5 毫克

Varenicline 0.5mg tab

Dosage: 1常備品 27241

Adult
·Smoking cessation: PO, initial 0.5mg qd on days 1-3, then 0.5mg bid on days 4-7, MD 1mg bid on week 2-12

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr≧30mL/min: No dosage adjustment needed
Clcr<30mL/min: Initial 0.5mg qd, Max. 0.5mg bid
Hemodialysis: Max. 0.5mg qd

P:

ADR:

COMMON
Constipation, flatulence, nausea, vomiting, dream disorder, headache, insomnia
SERIOUS
Angina pectoris, Myocardial infarction, Cerebrovascular accident, Sleep walking disorder, Acquired night blindness, Blurred vision, Retinal vascular disorder, Subcapsular cataract, Transient blindness, Visual disturbance, Abnormal havior, Depression, Hostile behavior, Mood disorder, Suicidal behavior, and/or ideation.

NOTE: 室溫儲存

·Start 1 week before target quit date
·仿單內容變更，摘述如下(版本USPI 201212-3)
1.劑量與用法：新增患者另可以選擇開始服用CHAMPIX*，然後在療程的第8天到第35天之間任選停止吸菸日期。
2.新增「自行選擇停止吸菸日期」的臨床試驗結果。

藥名相似:

外觀相似:

外觀描述: 白色長橢圓形錠，一面有CHX0.5字樣，另一面有pfizer字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024649

10.12 Smoking Deterrent

27242 ɔt be ruled out / Infant risk can

Champix film coated tablet 1.0 mg 戒必適膜衣錠1毫克

Varenicline 1mg F.C. tab

Dosage: 1常備品 27242

Adult
·Smoking cessation: PO, initial 0.5mg qd on days 1-3, then 0.5mg bid on days 4-7, MD 1mg bid on week 2-12

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr≧30mL/min: No dosage adjustment needed
Clcr<30mL/min: Initial 0.5mg qd, Max. 0.5mg bid
Hemodialysis: Max. 0.5mg qd

P:

ADR:

COMMON
Constipation,flatulence,nausea,vomiting,dream disorder,headache,insomnia
SERIOUS
Angina pectoris, Myocardial infarction, Cerebrovascular accident, Sleep walking disorder, Acquired night blindness, Blurred vision, Retinal vascular disorder, Subcapsular cataract, Transient blindness, Visual disturbance, Abnormal havior, Depression, Hostile behavior, Mood disorder, Suicidal behavior, and/or ideation.

NOTE: 室溫儲存

·Start 1 week before target quit date
·仿單內容變更，摘述如下(版本USPI 201302-2)
1.不良反應處更新針對COPD患者、任選戒菸日期、針對穩定型精神分裂症或情感型精神分裂症患者所進行之試驗相關資訊。
·自批號00008309起仿單內容變更，摘述如下(版本USPI 201612-2)(106.7.27)
1.劑量與用法：更新患者確定無法或不願意突然戒除，服用本藥配合逐步戒菸之相關說明。
2.警語和注意事項：增列夢遊並更新神經精神不良事件之相關資訊。
3.更新不良反應、懷孕、授乳、藥物動力學特性、臨床試驗之相關資訊。

藥名相似:

外觀相似:

外觀描述: 淡藍色長橢圓形錠，一面有CHX1.0字樣，另一面有pfizer字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024648

10.12 Smoking Deterrent

29164 D / Caution

Nicotine 31.2mg/15cm2 (no.15)

Dosage: 1常備品 29164

Adult
·Smoking cessation: Transdermal, 1 patch qd, titrate to lower dose, then off

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Patch: 10.4mg/5cm2(29166), 20.8mg/10cm2(29165), 31.2mg/15cm2(29164); Chewing gum: 2mg(27217), 4mg(27230)

ADR:

COMMON
Nicotine withdrawal (dizziness, headache, insomnia), skin irritation
SERIOUS
Fast or irregular heartbeat, hypertension

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 紙盒白底，有綠色花紋及禁菸標誌

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1038646

10.12 Smoking Deterrent

29165 D / Caution

SMOKFREE NICOTINE TDDS 2.08MG/CM 2 (NICOTINE) "S.T." 淨菸經皮吸收戒菸貼片２．０８公絲／平方公分(尼古丁)

Nicotine 20.8mg/10cm2 (no.10)

Dosage: 1常備品 29165

Adult
·Smoking cessation: Transdermal, 1 patch qd, titrate to lower dose, then off

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Patch: 10.4mg/5cm2(29166), 20.8mg/10cm2(29165), 31.2mg/15cm2(29164); Chewing gum: 2mg(27217), 4mg(27230)

ADR:

COMMON
Nicotine withdrawal (dizziness, headache, insomnia), skin irritation
SERIOUS
Fast or irregular heartbeat, hypertension

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 紙盒白底，有綠色花紋及禁菸標誌

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1038646

10.12 Smoking Deterrent

29166 D / Caution

SMOKFREE NICOTINE TDDS 2.08MG/CM 2 (NICOTINE) "S.T." 淨菸經皮吸收戒菸貼片２．０８公絲／平方公分(尼古丁)

Nicotine 10.4mg/5cm2 (no.5)

Dosage: 1常備品 29166

Adult
·Smoking cessation: Transdermal, 1 patch qd, titrate to lower dose, then off

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Patch: 10.4mg/5cm2(29166), 20.8mg/10cm2(29165), 31.2mg/15cm2(29164); Chewing gum: 2mg(27217), 4mg(27230)

ADR:

COMMON
Nicotine withdrawal (dizziness, headache, insomnia), skin irritation
SERIOUS
Fast or irregular heartbeat, hypertension

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 紙盒白底，有綠色花紋及禁菸標誌

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1038646

10.12 Smoking Deterrent

29168 ɔt be ruled out / Infant risk can

NICOTINELL TTS 30 克菸貼片３０

Nicotine TTS 52.5mg/30cm2

Dosage: 1常備品 29168

Adult
·Smoking cessation: Transdermal, 1 patch qd, titrate to lower dose, then off

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Patch: 52.5mg/30cm2 (29168) 10.4mg/5cm2(29166), 20.8mg/10cm2(29165), 31.2mg/15cm2(29164); Chewing gum: 2mg(27217), 4mg(27230)

ADR:

COMMON
Nicotine withdrawal (dizziness, headache, insomnia), skin irritation
SERIOUS
Cardiac dysrhythmia , hypertension , tachyarrhythmia , hypersensitivity reaction

NOTE: 室溫儲存

1.《Contraindications》Hypersensitivity to nicotine or any component of the product；
2. 用量用法(仿單)：治療期間不可超過三個月。

藥名相似:

外觀相似:

外觀描述: 外用貼片，每片鋁箔包裝為白底藍色字樣

12.02A Digoxin

22141 ɔt be ruled out / Infant risk is

LANOXIN DIGOXIN TABLETS 0.25MG B.P. 隆我心錠

■◆Digoxin 0.25mg tab

Dosage: 1常備品 22141

Adult
·Rapid digitalization: PO, initial 0.5-0.75 mg (approx. one-half of total LD); additional 0.125-0.375 mg given cautiously at 6-8 hr intervals until clinical response. Total LD, 10 mcg/kg of lean body weight (range 8 to 12 mcg/kg) or 0.75-1.25 mg
·Maintenance dosing: PO, initial 0.25 mg qd in pts <70 yrs with good renal function; 0.125 mg qd in pts >70 yrs with impaired renal function; 0.0625 mg qd (0.125 mg qod) in pts with marked renal impairment; titrate dose every 2 wks. Usual MD, 0.125-0.5 mg qd

Pediatric
·Rapid digitalization: PO, 1/2 TDD, then 1/4 TDD q8-18h x 2 doses
·Maintenance dosing: PO
<10 yrs: give MD div. bid
>= 10 yrs: give MD qd

Age	TDD	MD
Premature	20	5
Full term	30	8-10
<2 yrs	40-50	10-12
2-10 yrs	30-40	8-10
>10 yrs	10-15	2.5-5

* PO total digitalizing dose (TDD) and maintenance dose (MD) in mcg/kg/day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

The dosage of digoxin must be reduced in renal insufficiency:
1. GFR 10-50 mL/min: increase dosing interval to q36h or give 25%-75% of usual dose at normal dosing interval
2. GFR <10 mL/min: increase dosing interval to q48h or give 10%-25% of usual dose at normal dosing interval

P: Tab: 0.25mg (22141) Inj: 0.5mg/2mL (32009) Elix: 0.05mg/mL, 60mL/B (28511)

ADR:

COMMON
Nausea and vomiting, Dizziness, Headache, Mental disorder.
SERIOUS
Cardiac dysrhythmia, Ischemia, Sinoatrial block, Sinus bradycardia, Vasoconstriction, Thrombocytopenia.

NOTE: 室溫儲存

1. Total LD is administered in div. fractions of 50%, 25% and 25%.
2. 禁忌
- 間歇性完全心阻斷或二級房室阻斷，尤其是曾有Stokes-Adams發作病史病人。
- 因強心配醣體中毒引起之心律不整。
- 伴有副房室路徑之上心室性心律不整，例如Wolff-Parkinson-White症候群，除非曾評估過該副路徑之電生理特性及digoxin對這類特性可能造成之有害作用。若已知或懷疑存在副路徑而無上心室性心律不整病史，同樣也禁用Lanoxin。
- 心室性心搏過速或心室性纖維顫動。
- 肥厚性阻塞心肌病變，除非同時有心房纖維顫動及心衰竭，但即使如此若要使用Lanoxin仍要特別小心。
- 已知對digoxin、其他Digitalis配醣體或其任何成分過敏的病人。
3. 用藥過量
- 在濃度高於2.0 nanograms/mL (2.56 nanomol/L)較常出現，因不同個體有差異。判斷症狀是否因Digoxin所引起，臨床狀況加上血清電解質濃度和甲狀腺功能都是重要因素。
- 心臟徵狀：一般用藥過量後3至6小時達高峰，可能持續24小時或更久。可能導致任何類型心律不整。常見出現多種心律不整。
- 非心臟徵狀：胃腸症狀極為常見，通常在過量初期出現，如食慾不振、噁心及嘔吐等；神經方面徵狀：頭暈、多種中樞神經系統障礙、疲勞與身體不適等；視力障礙為視野色差，主要呈現黃綠色；其他非特定症狀，如：身體不適與無力。

藥名相似:

外觀相似: Roumin* 5mg tab (22969), Eltroxin* (T4) 100

外觀描述: 白色圓扁錠，一面中間有刻痕，有"D025"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2009554

12.02A Digoxin

28511 C / Infant risk is

CARDIACIN ELIXIR 50MCG/ML "CENTER" "晟德" 地高新酏劑 50 微公絲/公撮

■◆Digoxin elixir 3mg/60mL bot

Dosage: 1常備品 28511

Adult
·Rapid digitalization: PO, initial 0.5-0.75 mg (approx. one-half of total LD); additional 0.125-0.375 mg given cautiously at 6-8 hr intervals until clinical response. Total LD, 10 mcg/kg of lean body weight (range 8 to 12 mcg/kg) or 0.75-1.25 mg
·Maintenance dosing: PO, initial 0.25 mg qd in pts <70 yrs with good renal function; 0.125 mg qd in pts >70 yrs with impaired renal function; 0.0625 mg qd (0.125 mg qod) in pts with marked renal impairment; titrate dose every 2 wks. Usual MD, 0.125-0.5 mg qd

Pediatric
·Rapid digitalization: PO, 1/2 TDD, then 1/4 TDD q8-18h x 2 doses
·Maintenance dosing: PO
<10 yrs: give MD div. bid
>= 10 yrs: give MD qd

Age	TDD	MD
Premature	20	5
Full term	30	8-10

<2 yrs	40-50	10-12
2-10 yrs	30-40	8-10
>10 yrs	10-15	2.5-5

* PO total digitalizing dose (TDD) and maintenance dose (MD) in mcg/kg/day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

The dosage of digoxin must be reduced in renal insufficiency:
1. GFR 10-50 mL/min: increase dosing interval to q36h or give 25%-75% of usual dose at normal dosing interval
2. GFR <10 mL/min: increase dosing interval to q48h or give 10%-25% of usual dose at normal dosing interval

P: Tab: 0.25mg (22141) Inj: 0.5mg/2mL (32009) Elix: 0.05mg/mL, 30mL/B (28511)

ADR:

COMMON
anorexia, diarrhea, headache, nausea/vomiting, visual disturbances
SERIOUS
arrhythmias

NOTE: 避光保存

· 《Contraindications》Hypersensitivity to digoxin or other digitalis preparations; Ventricular fibrillation ;
· Total LD is administered in div. fractions of 50%, 25% and 25%.
· Contraindications: ventricular fibrillation
· 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 褐色避光瓶上有白色說明標籤,內為淡黃色藥液

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1047126

12.02A Digoxin

32009 C / Infant risk is

LANOXIN DIGOXIN INJECTION 0.5MG B.P. 隆我心注射劑

■◆Digoxin 0.5mg/2mL amp

Dosage: 1常備品 32009

Adult
·Rapid digitalization: IV, initial 0.4-0.6 mg (approx. one-half of total LD); additional 0.1-0.3 mg given cautiously at 6-8 hr intervals until clinical response. Total LD, 10 mcg/kg of lean body weight (range 8 to 12 mcg/kg) or 0.6 to 1 mg
·Maintenance dosing: IV, 0.075-0.35 mg/day

Pediatric
·Rapid digitalization: IV, 1/2 TDD, then 1/4 TDD q8-18h x 2 doses
·Maintenance dosing: IV
<10 yrs: give MD div. bid
>= 10 yrs: give MD qd

Age	TDD	MD
Premature	15	3-4
Full term	20	6-8
<2 yrs	30-40	7.5-9
2-10 yrs	20-30	6-8
>10 yrs	8-12	2-3

* IV total digitalizing dose (TDD) and maintenance dose (MD) in mcg/kg/day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

The dosage of digoxin must be reduced in renal insufficiency:
1. GFR 10-50 mL/min: increase dosing interval to q36h or give 25%-75% of usual dose at normal dosing interval
2. GFR <10 mL/min: increase dosing interval to q48h or give 10%-25% of usual dose at normal dosing interval

P: Tab: 0.25mg (22141) Inj: 0.5mg/2mL Amp (32009) Elix: 0.05mg/mL, 60mL/B (28511)

ADR:

COMMON
anorexia, diarrhea, headache, nausea/vomiting, visual disturbances
SERIOUS
arrhythmias

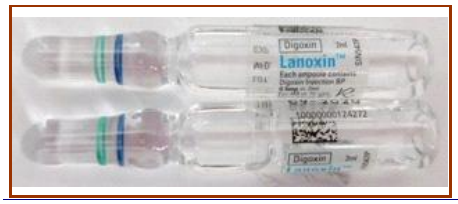
NOTE: 室溫儲存

1. Total LD is administered in div. fractions of 50%, 25% and 25%.
2. Precipitation occurs unless diluted with a 4-fold or greater volume of NS, D5W, SWI or LR.
3.Contraindication: ventricular fibrillation

藥名相似:

外觀相似:

外觀描述: 2mL透明注射液透明安瓿頸部有1條綠色及1條藍色線條



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2009714

12.02B PDE Inhibitors

32102 C / Unknown(有

PRIMACOR I.V. INJECTION 派明克注射劑

■Milrinone lactate inj 10mg/10mL amp

Dosage: 1常備品 32102

Adult
·Congestive heart failure: IV infusion, initial LD 50 mcg/kg IV over 10min; MD 0.375-0.75 mcg/kg/min; Max. 1.13 mg/kg/day

Pediatric (limited data)
Initial LD 50 mcg/kg IV over 15 min; MD 0.5-1 mcg/kg/min

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 50mL/min: 0.43 mcg/kg/min
Clcr 40mL/min: 0.38 mcg/kg/min
Clcr 30mL/min: 0.33 mcg/kg/min
Clcr 20mL/min: 0.28 mcg/kg/min
Clcr 10mL/min: 0.23 mcg/kg/min
Clcr 5mL/min: 0.2 mcg/kg/min

P: Inj: 10mg/10mL (32102)

ADR:

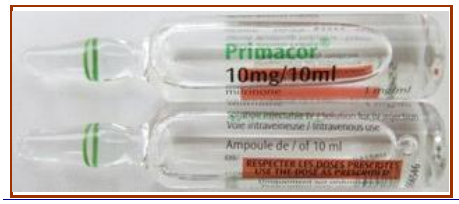
COMMON
chest pain, hypotension, headache
SERIOUS
hepatotoxicity, proarrhythmic events, thrombocytopenia

NOTE: 室溫儲存30℃以下

藥名相似:

外觀相似:

外觀描述: 10mL透明注射液玻璃安瓿，頸部有白點及1條綠色線條



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021128

12.02D Calcium Sensitizer

32020 **UK / Unknown(有**

Simdax 2.5mg/ml Concentrate for Solution for Infusion 心得適濃縮注射劑

■Levosimendan inj 12.5mg/5mL vial

Dosage: 1常備品 32020

Adult
·CHF: IV, Loading dose：6-12mcg/kg over 10mins follow by a continuous infusion of 0.05-0.2mcg/kg/min, adjust according to response.

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Severe hepatic impairment : Use is contraindicated

Dosing adjustments in renal impairment:

Clcr <30mL/min: Use is contraindicated

P: Inj: 12.5mg/5mL vial(32020)

ADR:

>10%: ventricular tachycardia, hypotension, headache
1~10%: atrial fibrillation, ventricular extrasystoles ,hypokalemia, insomnia, dizziness, GI discomfort, anemia

NOTE: 冰箱冷藏，不可冷凍

Contraindications:
1.Hypersensitivity to levosimendan or to any of the excipients.
2.Severe hypotension and tachycardia.
3.Significant mechanical obstructions affecting ventricular filling or outflow
4.Severe renal or hepatic impairment.
5.History of Torsades de Pointes.

藥名相似:

外觀相似:

外觀描述: 5mL淡黃色透明注射液，『白』蓋透明玻璃小瓶

12.04A1 Sodium Channel Blocker(Ia)

22405 **C / Infant risk is**

QUINIDINE SULFATE* TABLETS 200MG "U-LIANG" "優良"硫酸奎尼丁錠200毫克

Quinidine sulfate 200mg tab

Dosage: 1常備品 22405

Adult
·Conversion of atrial fibrillation: PO, 300-400 mg q6h
·Atrial fibrillation (chronic): PO, 200-400 mg tid-qid
·PSVT: PO, 400-600mg q2-3h
·Atrial and ventricular premature contractions: PO, 200-300mg tid-qid
·Malaria: PO, 300-600 mg or 10 mg/kg q8h for 5-7 days

Pediatric
·Safety and efficacy have not been established for antiarrhythmic in children
·Atrial fibrillation and flutter, Chronic therapy to reduce recurrence:PO, 3~ 5 mg/kg/dose q3h for 3 doses, then 15~ 60 mg/kg/24 hours or 900 mg/m(2)/24 hours in 3 to 5 divided doses
·Treatment of uncomplicated P. falciparum malaria: following IV quinidine gluconate for loading dose (24 mg/kg quinidine gluconate IV), PO 7.5 mg/kg quinidine base (approximately 9 mg/kg quinidine sulfate) q8h ; total duration of maintenance therapy is 7 days

Dosing adjustments in hepatic impairment:

Due to the increased volume of distribution, a larger loading dose may be indicated, however, maintenance doses may need to be decreased by 50%

Dosing adjustments in renal impairment:

Clcr ?10 mL/minute: No adjustment required.
Clcr <10 mL/minute: Administer 75% of normal dose.
Hemodialysis: Administer dose following hemodialysis session.
Peritoneal dialysis: Supplemental dose is not necessary.

P: Tab/Cap: 200mg (22405)

ADR:

COMMON
hypotension, ECG changes, syncope, anorexia, cinchonism, diarrhea, nausea, vomiting, dermatitis, photosensitivity reactions, rash
SERIOUS
myelosuppression, hepatotoxicity, nephropathy, proarrhythmic events, SLE, torsade de pointes

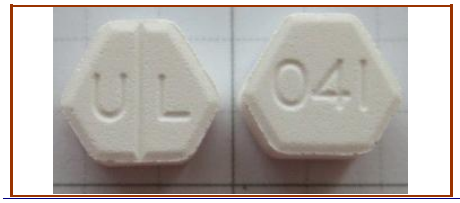
NOTE: 室溫儲存

1. In the treatment of any cardiac arrhythmia, total adult dosage of quinidine sulfate should not exceed 3-4g/day.
2. Contraindications: aberrant impulses and abnormal rhythms due to escape or mechanisms, absence of atrial activity, complete AV block in the absence of an artificial pacemaker, complete AV dissociation, digitalis intoxication (AV conduction disorders), intraventricular conduction defects, myasthenia gravis

藥名相似:

外觀相似:

外觀描述: 白色膠囊，有Nysco及Q01字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1027172

12.04A2 Sodium Channel Blocker(Ib)

22403 **C / Infant risk is**

MELETIN CAPSULES 100MG "S.T." (MEXILETINE) 脈律循膠囊１００公絲〝信東〞

Mexiletine HCl 100mg cap

Dosage: 1常備品 22403

Adult
·Ventricular arrhythmias (rapid control): PO, LD 400mg followed by 200mg in 8 hrs
·Ventricular arrhythmias (maintenance): PO, initial 200mg q8h; MD 200-300mg q8h; Max. 1200mg/day

Pediatirc
·Ventricular arrhythmias : 1.4-5 mg/kg/dose (mean: 3.3 mg/kg/dose) given every 8 hours; start with lower initial dose and titrate if needed

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed if Clcr>10 mL/min

P: Cap: 100mg (22403)

ADR:

COMMON
hypotension, palpitations, ataxia, confusion, coordination difficulties, depression, dizziness, fatigue, headache, lightheadedness, nervousness, paresthesia, tinnitus, tremors, constipation, diarrhea, dyspepsia, dysphagia, nausea, unpleasant taste, vomiting, elevated liver enzymes, blurred vision, diplopia, nystagmus, dyspnea, skin rash, arthralgias
SERIOUS
angina, bradycardia, chest pain, heart failure, blood dyscrasias, proarrhythmic events, seizures, systemic lupus erythematosus

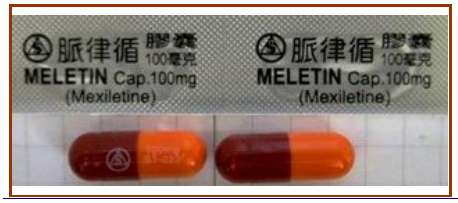
NOTE: 室溫儲存

Contraindications: cardiogenic shock, second- or third-degree AV block

藥名相似: Cap: 100mg (22403)

外觀相似: Ixel* 50mg (23018)

外觀描述: 橘色/咖啡色膠囊，有廠商商標、100mg及ST-022字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043632

12.04A2 Sodium Channel Blocker(Ib)

32012 **B / Infant risk is**

Lidocaine HCl 2% for I.V. Injection "LITA" "利達"利多卡因靜脈注射液 2 %

■Lidocaine inj 2% 100mg/5mL amp

Dosage: 1常備品 32012

Adult
·Ventricular arrhythmias : IV,1-1.5mg/kg as bolus dose at a rate 25-50mg/min, repeat bolus of 0.5-0.75mg/kg every 5-10 min up to total Max. 3mg/kg, followed with 20-50 mcg/kg/min as IV infusion (in D5W)

Pediatric
·Ventricular fibrillation: bolus, 1 mg/kg IV/intraosseous (maximum dose 100 mg); infusion, 20 to 50 mcg/kg/min

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj (local anesthesia): 1% 5mL(37208), 2% 20mL(37202), 2%+epinephrine 1:50000 20mL(37206); Inj (IV): 2% 5mL(32012); Soln(surfance anesthesia): 4% 30mL(29104); Jelly: 2% 30g (29101); Cream: EMLA (29103), EMLA兒癌(29902)

ADR:

COMMON
confusion, dizziness, drowsiness, headache, constipation, nausea, vomiting, hypotension, injection site pain, tremors, paresthesias,
SERIOUS
arrhythmias, cardiac arrest, methemoglobinemia, seizures

NOTE: 室溫儲存

藥庫發固定數code: 37208, 37202, 37209, 29101, 38816

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液透明安瓿，頸部有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1010914

12.04A3 Sodium Channel Blocker(Ic)

22476 C / Caution

RYTMONORM 150MG FILM COATED TABLETS 心利正膜衣錠150毫克

Propafenone HCl 150mg FC tab

Dosage: 1常備品 22476

Adult
·Supraventricular arrhythmias: PO, initial 150 mg q8h; may be increased at intervals of 3-4 days up to Max. 300 mg tid
·Life-threatening ventricular arrhythmias: PO, initial 150 mg q8h; may be increased at intervals of 3-4 days up to Max. 300 mg tid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

20-30% normal dose (70-80% reduction in dosage)

Dosing adjustments in renal impairment:

Use with caution

P: Tab: 150mg (22476)

ADR:

Arrhythmias, palpitations, dizziness, headache, N/V

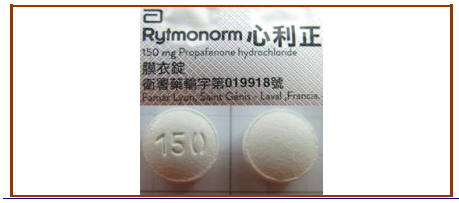
NOTE: 室溫儲存

1. Half-life after chronic dosing ranges up to 32 hrs
2. Contraindications: bradycardia, bronchospastic disorders, cardiogenic shock, electrolyte imbalances, uncontrolled congestive heart failure, severe hypotension, sinoatrial, atrioventricular, and intraventricular disorders of impulse generation and/or conduction (eg, sick sinus syndrome, AV block) in the absence of an artificial pacemaker

藥名相似:

外觀相似: Captolin* Tab(22469)

外觀描述: 白色圓扁錠，有150字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2019918

12.04B Beta-Adrenergic Blocker(II)

22103 C / Unsafe

CARDIOLOL TABLETS 10MG (PROPRANOLOL) "優良"心律整錠10毫克（普潘奈）

Propranolol HCl 10mg tab

Dosage: 1常備品 22103

Adult
·Hypertension: PO, initial 40 mg bid; MD 120-240 mg/day div. bid-tid; Max. 640 mg/day
·Angina pectoris: PO, 80-320 mg/day div. bid-qid
·Cardiac arrhythmias: PO, 10-30 mg tid-qid
·Idiopathic hypertrophic subaortic stenosis: PO, 20-40 mg tid-qid
·Pheochromocytoma:
Inoperable tumor: PO, 30 mg/day in div. doses
Operable tumor: PO, 60 mg/day for 3 days prior to surgery, with alpha-adrenergic blocker
·Migraine: PO, 80 mg/day in div. doses; titrate to MD 80-240 mg/day
·Postmyocardial infarction syndrome: PO, 180-240 mg/day div. bid-qid for at least 3 yrs
·Essential tremor: PO, initial 40 mg bid; MD 60-320 mg/day in div. doses
·Thyroid storm: PO, initial 10 mg qid; MD 40-80 mg q6h; Max. 120 mg qid

Pediatric
·Hypertension: PO, initial 0.5-1 mg/kg/day div. q6-12 h, may increase dose q3-5 days prn; Max. 8 mg/kg/day
·Cardiac arrhythmias: PO, initial 0.5-1 mg/kg/day div. q6-8h, increase dosage q3-5 days prn; usual dosage range: 2-4 mg/kg/day div. q6-8h; Max. 60 mg/day or 16 mg/kg/day
·Thyroid storm:
Neonates: PO, 2 mg/kg/day div. q6-12h
Adolescent: PO, 10-40 mg q6h

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 10mg (22103), 40mg (22107)

ADR:

COMMON
bradycardia, AV block, cognitive dysfunction, cold extremities, depression, hypersomnolence,insomnia, paresthesias, psychosis,anorexia, nausea, vomiting, dyspnea, wheezing, dermatitis, pruritus, urticaria
SERIOUS
bronchospasm (rare)

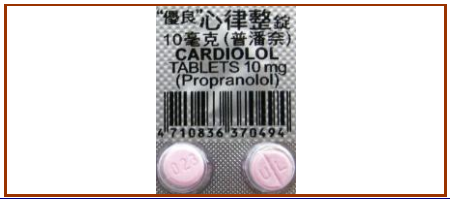
NOTE: 室溫儲存

Contraindications: bronchial asthma or chronic obstructive pulmonary disease, cardiogenic shock, overt cardiac failure, second and third degree AV block, severe sinus bradycardia

藥名相似: Tab: 10mg (22103), 40mg (22107)

外觀相似: Solantin* 25mg Tab 心耐糖衣錠(22533),

外觀描述: 粉紅色圓扁錠，一面有023字樣，另一面中央有刻痕及UL字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1018251

12.04B Beta-Adrenergic Blocker(II)

22107 C / Unsafe

CARDOLOL TABLETS 40MG (PROPRANOLOL) "V.P.P." "榮民" 心康樂錠 4 0 公絲 (健心寧)

Propranolol HCl 40mg tab

Dosage: 1常備品 22107

Adult
·Hypertension: PO, initial 40 mg bid; MD 120-240 mg/day div. bid-tid; Max. 640 mg/day
·Angina pectoris: PO, 80-320 mg/day div. bid-qid
·Cardiac arrhythmias: PO, 10-30 mg tid-qid
·Idiopathic hypertrophic subaortic stenosis: PO, 20-40 mg tid-qid
·Pheochromocytoma:
Inoperable tumor: PO, 30 mg/day in div. doses
Operable tumor: PO, 60 mg/day for 3 days prior to surgery, with alpha-adrenergic blocker
·Migraine: PO, 80 mg/day in div. doses; titrate to MD 80-240 mg/day
·Postmyocardial infarction syndrome: PO, 180-240 mg/day div. bid-qid for at least 3 yrs
·Essential tremor: PO, initial 40 mg bid; MD 60-320 mg/day in div. doses
·Thyroid storm: PO, initial 10 mg qid; MD 40-80 mg q6h; Max. 120 mg qid

Pediatric
·Hypertension: PO, initial 0.5-1 mg/kg/day div. q6-12 h, may increase dose q3-5 days prn; Max. 8 mg/kg/day
·Cardiac arrhythmias: PO, initial 0.5-1 mg/kg/day div. q6-8h, increase dosage q3-5 days prn; usual dosage range: 2-4 mg/kg/day div. q6-8h; Max. 60 mg/day or 16 mg/kg/day
·Thyroid storm:
Neonates: PO, 2 mg/kg/day div. q6-12h
Adolescent: PO, 10-40 mg q6h

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 10mg (22103), 40mg (22107)

ADR:

COMMON
bradycardia, AV block, cognitive dysfunction, cold extremities, depression, hypersomnolence,insomnia, paresthesias, psychosis,anorexia, nausea, vomiting, dyspnea, wheezing, dermatitis, pruritus, urticaria
SERIOUS
bronchospasm (rare)

NOTE: 室溫儲存

Contraindications: bronchial asthma or chronic obstructive pulmonary disease, cardiogenic shock, overt cardiac failure, second and third degree AV block, severe sinus bradycardia

藥名相似: Tab: 10mg (22103), 40mg (22107)

外觀相似:

外觀描述: 粉紅色圓扁錠，有一面有商標,另一面"309"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1019875

12.04B Beta-Adrenergic Blocker(II)

31704 C / Unknown(有

Esmolol HCl INJECTION 10mg/ml "Unipharma" 律平注射液 10 毫克/毫升

■Esmolol HCl 100mg/10mL vial

Dosage: 1常備品 31704

Adult
·Supraventricular tachyarrhythmias (SVT): IV infusion, LD 500 mcg/kg/min for 1 min, followed by 50 mcg/kg/min for 4 min. If a suitable response is not obtained within 5 min, repeat the loading dose and the maintenance infusion may be increased by increments of 50 mcg/kg/min, up to 200 mcg/kg/min
·Intra-OP and post-OP tachycardia and hypertension: IV, LD 80 mg over 30 sec, followed by IV infusion 150 mcg/kg/min, Max. 300 mcg/kg/min

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 100mg/10mL (31704)

ADR:

COMMON
bradycardia, chest pain, hypotension, agitation, dizziness, confusion, fatigue, headache, somnolence, dyspepsia, constipation, nausea, vomiting, dyspnea, nasal congestion, wheezing, pain at injection site
SERIOUS
bronchospasm, pulmonary edema, seizures

NOTE: 室溫儲存

Contraindications: cardiogenic shock, overt cardiac failure, second and third degree AV block, severe sinus bradycardia

藥名相似:

外觀相似:

外觀描述: 10mL透明注射液『白』蓋透明玻璃小瓶，蓋上有FLIP及OFF字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049015

12.04C Potassium Channel Blocker(III)

22406 D / Unsafe

AMIORONE* TAB. 200MG (AMIODARONE) "信東 " 艾歐隆錠２００毫克（艾米達隆）

Amiodarone HCl 200mg tab

Dosage: 1常備品 22406

Adult
·Ventricular arrhythmias: PO, initial 800-1600 mg/day for 1-3 wks, then titrate down to 600-800 mg/day for 1 mon; MD 400-600 mg qd or div. bid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

consider decreasing the dose or discontinuing amiodarone

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 200mg (22406) Inj: 150mg/3mL (32005)

ADR:

COMMON
bradycardia, hypotension, malaise, fatigue, nausea, vomiting, constipation, anorexia, peripheral neuropathy, photosensitivity, poor coordination and gait, tremor and involuntary movements, corneal deposits, visual disturbances
SERIOUS
arrhythmias, congestive heart failure, hepatotoxicity, pulmonary toxicities, shock, Stevens-Johnson syndrome, thrombocytopenia, thyroid abnormalities

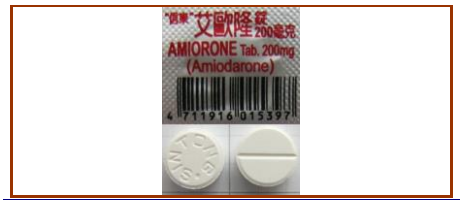
NOTE: 室溫儲存

Contraindications: cardiogenic shock, second or third degree AV block, severe sinus bradycardia, severe sinus node dysfunction

藥名相似: Tab: 200mg (22406) Inj: 150mg/3mL (32005)

外觀相似:

外觀描述: 白色圓扁錠，一面中央有刻痕，另一面有"SINTONG· "環狀字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1028041

12.04C Potassium Channel Blocker(III)

22412 X / Caution

Multaq 400mg film-coated tablets 脈泰克膜衣錠400毫克

Dronedarone HCl 426mg(dronedarone 400mg) tab

Dosage: 1常備品 22412

Adult
Atrial fibrillation / Atrial flutter (Paroxysmal or Persistent) : PO 400 mg bid with meals

Pediatric
Safety and efficacy have not been established in patients <18 yrs old

Dosing adjustments in hepatic impairment:

Contraindicated with severe hepatic impairment

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 400mg (22412)

ADR:

COMMON
Prolonged QT interval,Abdominal pain , Diarrhea , Indigestion,N/V,Asthenia,Serum creatinine raised
SERIOUS
Heart failure,Liver failure

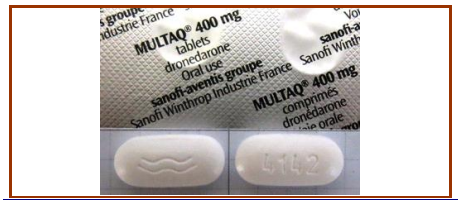
NOTE: 室溫儲存

Contraindication
■Bradycardia (< 50 beats/min)
■Concomitant use Class I and III antiarrhythmics and strong CYP3A inhibitors
■Heart failure, NYHA Class II or III, with recent decompensation requiring hospitalization or specialized heart failure clinic referral or Class IV
■Severe hepatic impairment
■Pregnancy or nursing

藥名相似:

外觀相似:

外觀描述: 白色橢圓形膜衣錠，一面刻有雙波浪狀記號，另一面則刻有數字"4142"



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025224

12.04C Potassium Channel Blocker(III)

32005 D / Unsafe

CORDARONE INJECTION 臟得樂注射液

■Amiodarone HCl 150mg/3mL amp

Dosage: 1常備品 32005

Adult
·Ventricular arrhythmias: IV infusion, rapid loading infusion of 150 mg administered at a rate of 15 mg/min (over 10 min), followed by 1 mg/min for 6 hrs (360 mg), then 0.5 mg/min for 18 hrs (540 mg). After the first 24 hrs, the maintenance infusion rate of 0.5 mg/min (720 mg over 24 hrs) should be continued and the infusion rate may be increased to achieve effective arrhythmia suppression.

Pediatric
safety and efficacy have not been established
·Advanced cardiac life support: pulseless ventricular tachycardia/fibrillation, 5 mg/kg by rapid IV bolus or INTRAOSSEOUS injection; may repeat up to 15 mg/kg; MAX single dose 300 mg
·Ventricular arrhythmia, Life-threatening; Treatment and Prophylaxis: perfusing tachycardias, 5 mg/kg IV or INTRAOSSEOUSLY over 20~60 mins, may repeat; MAX: 15 mg/kg/day or 300 mg/dose

Dosing adjustments in hepatic impairment:

consider decreasing the dose or discontinuing amiodarone

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 200mg (22406) Inj: 150mg/3mL (32005)

ADR:

COMMON
bradycardia, hypotension, malaise, fatigue, nausea, vomiting, constipation, anorexia, peripheral neuropathy, photosensitivity, poor coordination and gait, tremor and involuntary movements, corneal deposits, visual disturbances
SERIOUS
arrhythmias, congestive heart failure, hepatotoxicity, pulmonary toxicities, shock, Stevens-Johnson syndrome, thrombocytopenia, thyroid abnormalities

NOTE: 室溫儲存

Contraindications: cardiogenic shock, second or third degree AV block, severe sinus bradycardia, severe sinus node dysfunction

藥名相似:

外觀相似:

外觀描述: 3mL透明注射液透明安瓿黑色字體，頸部有一圈黃色環

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2014861

12.04D Calcium Channel Blocker(IV)

22540 ɔt be ruled out / Infant risk can

CINTSU SUGAR COATED TABLETS 40MG (VERAPAMIL)"YUNG SHIN" 心舒糖衣錠 4 0 毫克（唯律脈必利）

Verapamil HCl 40mg SC tab

Dosage: 1常備品 22540

Adult
·Hypertension: PO, initial 40mg bid to 80mg tid; Max. 320mg/day
·Angina: PO, initial 80mg q6-8h; MD 320-480 mg/day div. tid-qid
·PSVT, prophylaxis (nondigitalized): PO, 240-480mg/day div 3-4 doses
·Chronic atrial fibrillation (digitalized): PO, 240-320 mg/day div. tid-qid

Pediatric
·Hypertension: PO ,3-4 mg/kg in 3 divided doses; MAX 8 mg/kg up to 480 mg daily in 3 divided doses

Dosing adjustments in hepatic impairment:

20%-50% normal dose

Dosing adjustments in renal impairment:

Use with caution

P:

ADR:

COMMON
constipation, dizziness, edema, headache, hypotension, nausea
SERIOUS
myocardial infarction, angina, syncope

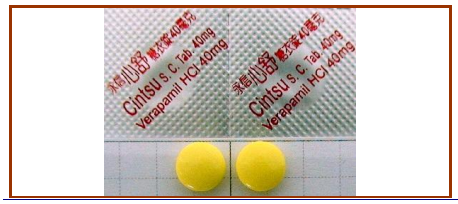
NOTE: 室溫儲存

Contraindications: cardiogenic shock, CHF, heart block (second, third degree), sick sinus syndrome, symptomatic hypotension

藥名相似: Tab: 40mg (22540), Inj: 5mg/2mL (32100)

外觀相似:

外觀描述: 黃色圓扁糖衣錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1030120

12.04D Calcium Channel Blocker(IV)

32100 ɔt be ruled out / Infant risk can

U-SODIN INJECTION 2.5MG/ML (VERAPAMIL) "優良"優賜定注射液 2 · 5 公絲/公撮（唯律脈必利）

■Verapamil inj 5mg/2mL amp

Dosage: 1常備品 32100

Adult
·Supraventricular tachyarrhythmias: IV, initial 5-10 mg (0.075-0.15 mg/kg) administered over 2 minutes, if no respond to initial dose, a second IV dose of 10 mg (0.15 mg/kg) may be given 30 minutes after the initial dose; may repeat supplemental IV dose of 5-10 mg (0.075-0.15 mg/kg) every 15-30 minutes as necessary to Max. 20 mg

Pediatric
·Atrial arrhythmia/PSVT (< 1 yr): IV, 0.1-0.2 mg/kg over 2 min, may repeat dose after 30 min
·Atrial arrhythmia/PSVT (1-15 yr): 0.1-0.3 mg/kg IV over 2 min (MAX 5 mg), may repeat dose after 30 min (MAX 10 mg)

Dosing adjustments in hepatic impairment:

20% to 50% normal dose

Dosing adjustments in renal impairment:

Use with cautiion

P: Tab: 40mg (22540), Inj: 5mg/2mL (32100)

ADR:

COMMON
constipation, dizziness, edema, headache, hypotension, nausea
SERIOUS
myocardial infarction, angina, syncope

NOTE: 室溫儲存

Contraindication: cardiogenic shock, CHF, heart block (second, third degree), sick sinus syndrome, symptomatic hypotension

藥名相似:

外觀相似:

外觀描述: 2mL透明注射液透明安瓿 ，頸部有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1027307

12.04E Miscellaneous(V)

31667 **C / Unknown(有**

ADENOZER INJECTION 3MG/ML "PURZER"(ADENOSINE) "瑞安" 緩心樂注射液3毫克/毫升(腺甘酸)

■Adenosine inj 6mg/2mL vial

Dosage: 1常備品 31667

Adult
·Paroxysmal supraventricular tachycardia: IV, initial bolus dose of 6 mg over 1-2 sec, increase to 12 mg every 1-2 min as needed for 2 doses; Max. single dose 12 mg
·Adjunct to thallium stress testing: IV infusion, 140 mcg/kg/min for 6 min (total dose of 0.84 mg/kg). The required dose of thallous (thallium) chloride TI 201 should be administered at the midpoint (after the first 3 min) of the adenosine infusion

Pediatric (<50 kg)
·Paroxysmal supraventricular tachycardia: IV, initial bolus dose of 0.05-0.1 mg/kg. If conversion does not occur within 1-2 min, increase subsequent doses by 0.05-0.1 mg/kg until sinus rhythm is established or a maximum single dose of 0.3 mg/kg (not exceeding 12 mg) has been given.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 6mg/2mL Vial(31667)

ADR:

COMMON
chest pain or pressure, dyspnea, headache, lightheadedness, flushing, neck, throat or jaw discomfort, nausea, bradycardia, bronchoconstriction (in asthmatics)
SERIOUS
arrhythmia, AV block, second degree, bradycardia (rare), bronchoconstriction (in asthmatics)

NOTE: 室溫儲存於25℃以下

Contraindication: second or third degree AV block, sinus node dysfunction

藥名相似:

外觀相似:

外觀描述: 2mL透明注射液，『紅』蓋透明玻璃小瓶，蓋上有FLIP及OFF字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1041989

12.06A Bile Acid-Binding Resins

27201 **C / Milk effects ar**

CHOLES POWDER (CHOLESTYRAMINE RESIN) "S.D." 可利舒散（可林斯提拉明酯）

Cholestyramine powder 4g pack

Dosage: 1常備品 27201

Adult
·Hypercholesterolemia: PO, initial 4 g qd or bid ac; MD 8-16 g/day in divided doses, Max. 24 g/day
·Pruritus: PO, initial 4 g qd or bid ac; MD 8-16 g/day in 2 or more divided doses, Max. 24 g/day

Pediatric
·Hypercholesterolemia: PO, 240 mg/kg/24 hr divided tid; doses normally do not exceed 8 g/24 hr
·Diarrhea: PO, 1g/day for six days or 2 g bid for 3 days.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Pow: 4g/Pack(27201)

ADR:

COMMON
abdominal discomfort, bleeding tendencies due to hypoprothrombinemia, constipation, flatulence, nausea/vomiting

NOTE: 室溫儲存

1. Give other oral medications 4–6 hr after cholestyramine or 1 hr before dose to avoid decreased absorption
2. Mix with 120-180mL of water or other fluids before use
2.Contraindications: complete biliary obstruction; hyperlipidemia types III, IV, or V
3.含阿斯巴甜，苯酮尿症者不宜使用。

藥名相似:

外觀相似:

外觀描述: 4G粉末，白色鋁箔包

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1035424

12.06B Fibric Acid Derivatives

22436 **C / Infant risk has**

LIPANTHYL* SUPRA 160MG FILM-COATED TABLET 弗尼利脂寧１６０毫克膜衣錠

Fenofibrate supra 160mg FC tab

Dosage: 1常備品 22436

ADULT
·Hypertriglyceridemia/hypercholesterolemia or mixed hyperlipidemia: PO, 1T qd with meal ; Max. 1 tab/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Use is contraindicated

Dosing adjustments in renal impairment:

CrCl 30 to 60 mL/min: Not recommended
CrCl<30mL/min: contraindicated

P: P Tab: 160mg(22436)

ADR:

COMMON
Abdominal pain, ALT/AST level raised, liver function tests abnormal, backache, headache
SERIOUS
Pancreatitis, DVT, cholestatic hepatitis, rhabdomyolysis, serum creatinine raised , pulmonary embolism

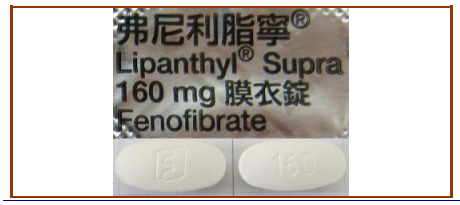
NOTE: 室溫儲存

1.Contraindications: Hypersensitivity to fenofibrate or fenofibric acid , soya lecithin, peanut or arachis oil, active liver disease, severe renal impairment or ESRD, preexisting gallbladder disease, pregnancy or breastfeeding,known photoallergy or phototoxic reaction during treatment with fibrates or ketoprofen, chronic or acute pancreatitis
2.Regular monitoring of liver function tests is suggested; discontinue therapy in patients whose enzyme levels persist above 3 times the upper limit of normal.

藥名相似:

外觀相似:

外觀描述: 白色橢圓凸錠，一面有"160"字樣，另一面有商標圖案



12.06B Fibric Acid Derivatives

22437 **C / Caution**

FENOLIP MICRONISED CAPSULES 200MG "C.H." (FENOFIBRATE) 祛脂微粒膠囊〝正和〞

Fenofibrate 200mg cap

Dosage: 1常備品 22437

Adult
·Primary hypercholesterolemia or mixed dyslipidemia: PO, 200 mg daily; Max. 200 mg/day
·Hypertriglyceridemia: PO, 67-200 mg daily; Max. 200 mg/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Use is contraindicated

Dosing adjustments in renal impairment:

Clcr<50 mL/min: 67 mg/day

P: Cap: 200mg(22437)

ADR:

COMMON
diarrhea, flatulence, muscle pain, nausea/vomiting, rash, rhinitis
SERIOUS
hepatotoxicity (rare), rhabdomyolysis (rare)

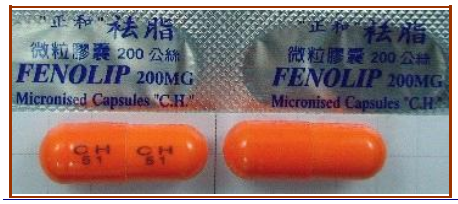
NOTE: 室溫儲存

1.Contraindications: gallbladder disease, hepatic or severe renal disease
2.Fenofibrate should be discontinued in patients who fail to achieve an adequate response after 2-3 months of therapy with the maximum dose

藥名相似:

外觀相似:

外觀描述: 橘色膠囊，有CH及51字樣)



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1042619

12.06B Fibric Acid Derivatives

22444 **demonstrated / Infant risk has**

Pravafen 40mg/160mg Hard Capsules 普脂芬膠囊40毫克/160毫克

複方 Fenofibrate 160mg & Pravastatin 40mg cap

Dosage: 1常備品 22444

ADULT
·Dyslipidemia, mixed, in patients with adequately controlled LDL-C with pravastatin 40 mg monotherapy and at high risk for coronary heart disease: PO, 1 cap once daily during the evening meal, treatment should be discontinued if an adequate response has not been achieved within 3 mons

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

·Mild: No dosage adjustment needed
·Moderate: Use not recommended
·Severe: Use contraindicated

Dosing adjustments in renal impairment:

·Mild: No dosage adjustment needed
·Moderate to severe (CrCl< 60 mL/min): Use contraindicated

P: P Cap: Pravafen* (22444); Tab: Fenofibrate 160mg (22436), Pravastatin 40mg (22447)

ADR:

COMMON
Abdominal discomfort, abdominal pain, burping, constipation, diarrhea, flatulence, indigestion, nausea, swollen abdomen, upper abdominal pain, vomiting, xerostomia, liver function tests abnormal
SERIOUS
Palpitations, exacerbated diabetes mellitus, pancreatitis, hypersensitivity reaction, immune-

mediated necrotizing disorder of muscle, rhabdomyolysis, decreased renal clearance, renal failure, interstitial lung disease, pulmonary embolism

NOTE: 室溫儲存

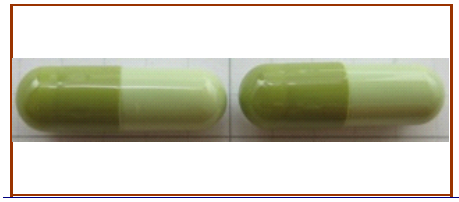
·The pharmacokinetics properties of PRAVAFEN* are not completely identical to the co-administration of the existing monotherapies when taken with fat-meal or in fasting state. Patients should not be switched from a free co-administration of fenofibrate and pravastatin preparation to PRAVAFEN*

·PRAVAFEN* is less well absorbed from an empty stomach and should always be taken with food

藥名相似:

外觀相似:

外觀描述: 淺綠/橄欖色膠囊



12.06B Fibric Acid Derivatives

22456 C /

GEMD FILM COATED TABLETS 600MG (GEMFIBROZIL) 脂福膜衣錠６００公絲（健菲布脂）

Gemfibrozil 600mg FC tab

Dosage: 1常備品 22456

Adult

·Hyperlipidemia: PO, ac, 600 mg bid

Pediatric

·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Not recommended in patients with severe renal impairment

P: Tab: 600mg(22456)

ADR:

COMMON
abdominal pain, diarrhea, flatulence, dyspepsia, muscle pain, rash, xerostomia
SERIOUS
abnormal liver function tests, rhabdomyolysis(especially when coadministered with a statin)

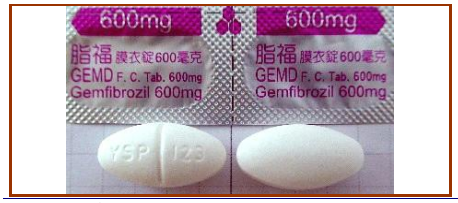
NOTE: 室溫儲存

1.Contraindications: coadministration with gemfibrozil and cerivastatin, gallbladder disease, hepatic dysfunction, including biliary cirrhosis, renal impairment (plasma creatinine >2 mg/dL)
2.The drug should be discontinued after 3 months if serum lipoprotein concentrations do not improve substantially

藥名相似:

外觀相似:

外觀描述: 白色長橢圓扁錠，一面有"YSP 123"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1037685

12.06C HMG-CoA Reductase Inhibitors(Statin)

22440 X / Unsafe

Tulip 40mg Film coated Tablets 妥寧膜衣錠 40 毫克

Atorvastatin 40mg tab

Dosage: 1常備品 22440

Adult

·Dyslipidemias: PO, initial 10 or 20mg qd; patients requiring >45% reduction in LDL-C may be started at 40mg qd; MD 10-80mg/day

Pediatric (10-17 yrs)

·Familial hypercholesterolemia: PO, initial 10mg qd; titrate at 4-wk intervals up to Max. 20mg/day

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed

Dosage adjustment for atorvastatin with concomitant medications:
Cyclosporine: atorvastatin dose should not exceed 10mg/day
Clarithromycin,Itraconzole,Ritonavir plus Saquinavir,or Lopinavir plus Ritonavir when atorvastatin dose >20mg: Ensure that the lowest dose necessary of atorvastatin is used

P:

ADR:

Common
Diarrhea , Arthralgia ,UTI, Nasopharyngitis, Pain, In extremity ,
Seriours
Dermatomyositis, Increased liver enzymes , Liver failure, Autoimmune disease, SLE, Myalgia Rhabdomyolysis (rare), Rupture of tendon, Hemorrhagic cerebral infarction

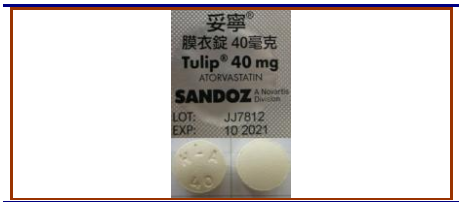
NOTE: 室溫儲存

1. The risks of rhabdomyolysis increased when renal function is impairment and atorvastatin is taken concomitantly with cyclosporine, gemfibrozil, niacin, erythromycin or azole antifungals.
2. Active liver disease or unexplained persistent elevations of serum transaminase concentrations are contraindications to use

藥名相似: Tab: 40mg(22440)

外觀相似:

外觀描述: 乳白色圓型錠，有40及HLA字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025201

12.06C HMG-CoA Reductase Inhibitors(Statin)

22441 X / Unsafe

CRESTOR 10MG FILM-COATED TABLETS 冠脂妥膜衣錠10毫克

Rosuvastatin 10mg FC tab

Dosage: 1常備品 22441

Adult
·Hyperlipidemia, mixed dyslipidemia, hypertriglyceridemia, and atherosclerosis: PO, initial 5-10mg QD, may be increased to 20mg QD after 4 wks. (The recommended initial dose in Asian patients is 5 mg orally once daily)

Pediatric
·Hyperlipidemia, Primary(heterozygous familial hypercholesterolemia; aged 10-17yrs):PO, 5- 20 mg daily; adjust dose at intervals of 4 wks or more; MAX 20 mg daily

Dosing adjustments in hepatic impairment:

1. If increases in AST or ALT of >3 times ULN or higher persist, the dosage of rosuvastatin should be reduced or the drug discontinued.
2. Contraindications: active liver disease or unexplained, persistent elevation of serum transaminases

Dosing adjustments in renal impairment:

1. Mild-to-moderate impairment: no dosage adjustment needed
2. Severe impairment (CrCl<30), without dialysis: initial 5mg QD, do not exceed 10mg QD

P: Tab: 10mg(22441)

ADR:

COMMON
Diarrhea, indigestion, nausea, asthenia, headache, pharyngitis, upper respiratory infection
SERIOUS
Drug-induced myopathy, rhabdomyolysis, proteinuria(high doses)

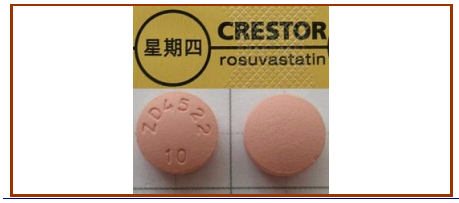
NOTE: 室溫儲存

·Increased systemic exposure has been seen in Japanese and Chinese subjects (an approximate 2-fold elevation in median AUC compared with western Caucasians).

藥名相似: Tab: 10mg(22441)

外觀相似:

外觀描述: 粉紅色圓扁錠,有ZD4522及10字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024131

12.06C HMG-CoA Reductase Inhibitors(Statin)

22442 X / Infant risk has

LINICOR* F.C.T. 500/20MG 理脂膜衣錠500/20 毫克

複方Niacin 500mg & Lovastatin 20mg

Dosage: 1常備品 22442

Adult
·Hypercholesterolemia, primary (heterozygous familial and non-familial) and mixed dyslipidemia (Fredrickson types IIa and IIb): PO, 1# qhs with a low-fat snack; may increase niacin ≦ 500 mg qhs at 4-week intervals; MAX: niacin 1000 mg /lovastatin 40 mg daily

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Contraindicated in active liver disease or unexplained persistent elevations of serum transaminases.

Dosing adjustments in renal impairment:

CrCl <30 mL/min: Use doses of lovastatin >20 mg daily with caution

P: Tab: (22442)

ADR:

Common
Flushing (up to 83%), Pruritus (7%), Diarrhea (6%), Nausea (7%), Headache (9%), Infectious disease (20%)
Serious
Dermatomyositis, Hepatic necrosis, Increased liver enzymes, Liver failure, Autoimmune disease, Systemic lupus erythematosus, Disorder of muscle, Rhabdomyolysis

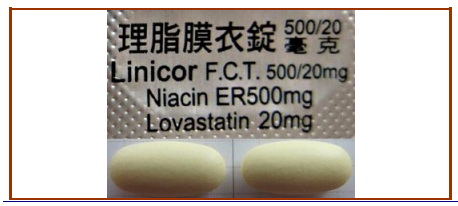
NOTE: 室溫儲存

1. Contraindications: arterial bleeding, concomitant use with strong CYP3A4 inhibitors, hypersensitivity to lovastatin, niacin, or any component of the product, active liver disease, nursing women, active peptic ulcer disease, serum transaminase elevations, unexplained persistent, women who are pregnant or may become pregnant; may cause fetal harm.
2. Premedication: aspirin up to 325 mg orally 30 minutes prior to niacin/lovastatin to reduce flushing
3. Reinitiating therapy after more than 7 days, initiate with the lowest dose

藥名相似:

外觀相似:

外觀描述: 米黃色橢圓錠



12.06C HMG-CoA Reductase Inhibitors(Statin)

22443 demonstrated / Infant risk has

LIVALO Tablets 2mg 力清之膜衣錠2毫克

Pitavastatin calcium 2mg tab

Dosage: 1常備品 22443

Adult
·Hyperlipidemia: initial, 2 mg po qd; Max 4 mg qd dosage range 1 to 4 mg daily; assess lipid levels 4 weeks after dose initiation or titration

Pediatric
·Familial hypercholesterolemia(>10yr): initial, 1 mg po qd; Max 2 mg qd

Dosing adjustments in hepatic impairment:

Adult: initial, 1 mg po qd; Max 2 mg qd ;
Pediatric(>10yr): 1mg qd

Dosing adjustments in renal impairment:

Moderate and several renal impairment (GFR 15 to 59 mL/min/1.73 m(2)) and ESRD receiving hemodialysis: initial, 1 mg po daily; Max 2 mg daily.

P: Tab: 2mg(22443)

ADR:

COMMON
Constipation, Diarrhea, Backache, Myalgia, Pain in limb
SERIOUS
Disorder of glucose regulation, Increased liver enzymes, Liver failure, Disorder of muscle, Statin-associated, Increased creatine kinase level, Rhabdomyolysis,Immune-mediated necrotizing myopathy

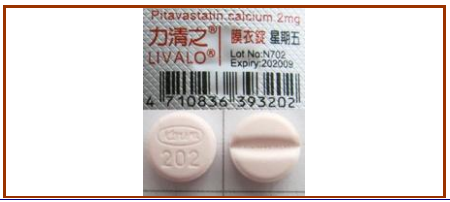
NOTE: 室溫儲存

·Contraindication: pregnancy, breastfeeding, active liver disease, serum transaminase elevations (unexplained persistent), concomitant use of cyclosporine
·仿單警語與注意事項於醣化血色素(HbA1c)上升段落，加註「但依上市後安全監測及預測性研究，pitavastatin並未有明確造成糖尿病之徵兆。」(106.02.17)
自批號9615起，仿單內容變更，摘述如下：1.「患者」或是「病患」的字眼，統一修訂為「病人」。2.警語與注意事項：更新「對骨骼肌肉的影響」之相關說明。3.不良反應：(A)嚴重不良反應增列免疫性壞死性肌肉病變。(B)增列HIV感染合併血脂異常者臨床試驗之相關資訊。(C)更新上市後經驗之相關資訊。 (公文號:12358)(106.10.17)

藥名相似:

外觀相似:

外觀描述: 淡粉紅色膜衣錠，中間具切割線，有202及KOWA商標



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025350

12.06C HMG-CoA Reductase Inhibitors(Statin)

22447 X /

MEVALOTIN PROTECT 40MG TABLETS 美百樂鎮錠 4 0 毫克

Pravastatin 40mg tab

Dosage: 1常備品 22447

Adult
·Hyperlipidemia: PO, initial, 40 mg qd; MD, 40-80 mg qd.

Pediatric
·Familial hypercholesterolemia:
8-13 yrs: PO, 20 mg qd
14-18 yrs: PO, 40 mg qd

Dosing adjustments in hepatic impairment:

Initial 10 mg daily

Dosing adjustments in renal impairment:

Initial 10 mg daily

P: Tab: 40mg(22447)

ADR:

COMMON
Rash, diarrhea, N/V, musculoskeletal pain, headache, cough, rhinitis, upper respiratory infection
SERIOUS
Pancreatitis, increased liver enzymes, disorder of muscle, rhabdomyolysis, rupture of tendon

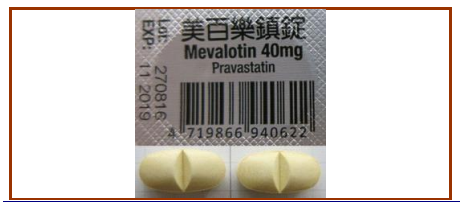
NOTE: 室溫儲存

1.Discontinue 4 to 7 days before major surgery (increased risk of rhabdomyolysis)
2. Withdrawal pravastatin therapy if AST or ALT increase to three times of the upper limit
自批號270784仿單內容變更，摘述如下：
1.警語及注意事項：加註在statin治療期間或治療之後，有極少數的案例會發生免疫引起肌肉壞死之肌肉病變。
2.副作用(使用其他statins時曾被報導過)：(A)增列免疫引起肌肉壞死之肌肉病變。(B)刪除性功能障礙。
3.藥物動力學特性：加註兒童和青少年族群之相關資訊。(106.02.09)
4.不得與fusidic acid全身性的製劑同時使用：fusidic acid治療期間及後7天內，應中止statin類藥物的治療。
5.併用秋水仙素，曾被通報發生肌病變，處方時應謹慎。(108.1.28)

藥名相似: Tab: 40mg(22447)

外觀相似:

外觀描述: 淺黃色長橢圓錠，兩面有刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023596

12.06C HMG-CoA Reductase Inhibitors(Statin)

22448 X /

LESCOL XL FILM-COATED TABLETS 80MG 益脂可長效緩釋膜衣錠80毫克

Fluvastatin XL 80mg tab

Dosage: 1常備品 22448

Adult
·Dyslipidemias: PO, 80 mg qd in the evening

PEDIATRIC
.

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed in mild to moderate renal impairment

P: XL tab: 80mg(22448)

ADR:

COMMON
abdominal pain, diarrhea, dyspepsia, headache, nausea
SERIOUS
elevated liver enzymes, rhabdomyolysis

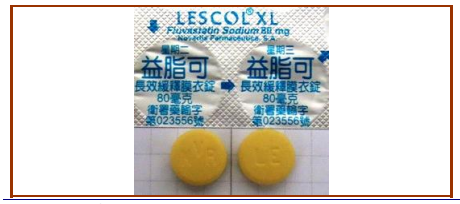
NOTE: 室溫儲存

1.Swallow whole; do not crush or chew
2.Contraindications: active liver disease, pregnancy and lactation

藥名相似: XL tab: 80mg(22448)

外觀相似:

外觀描述: 土黃色圓扁錠，一面有"NVR"及另一面有"LE"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023556

12.06D Nicotinic Acid(Niacin)

22453 /

OLBETAM 250MG CAPSULES 脂倍坦膠囊

Acipimox 250mg cap

Dosage: 1常備品 22453

Adult
·Hyperlipidemias: PO, with meal, 250 mg bid-tid; Max. 1200mg/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 30-60 mL/min: 150 mg bid
Clcr 10-30 mL/min: 150 mg qd
Clcr <10 mL/min: 150 mg qod

P: Cap: 250mg(22453)

ADR:

Headache, nausea, abdominal pain, heartburn, bloating, rash, flushing

NOTE: 室溫儲存

Contraindication: peptic ulcers

藥名相似:

外觀相似: 外盒：Sermion*(22566), Caduet*(22554)

外觀描述: 深紅色/暗橙色膠囊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2017140

12.06E Cholesterol Absorption Inhibitors

22445 X / Infant risk has

VYTORIN TABLETS 10/20MG 維妥力錠 10/20毫克

複方Ezetimibe 10mg & Simvastatin 20mg tab

Dosage: 1常備品 22445

Adult
·Familial hypercholesterolemia - homozygous: PO, Ezetimibe 10mg & Simvastatin 10-80mg once daily in the evening.
·Hyperlipidemia, Primary: PO, initial, Ezetimibe 10mg & Simvastatin 20mg once daily in the evening.
Patients who require less aggressive LDL-C reduction: Ezetimibe 10mg & Simvastatin 20mg once daily.
Patients who require >55% LDL-C reductions: Ezetimibe 10mg & Simvastatin 40mg once daily.

Pediatric(≧10yrs)
·Familial hypercholesterolemia - homozygous: PO, 1T QD.

Dosing adjustments in hepatic impairment:

Mild hepatic impairment: No dosage adjustment
Moderate to severe hepatic impairment: Not recommended

Dosing adjustments in renal impairment:

Mild to moderate renal impairment: No dosage adjustment
Severe renal impairment: Start only if patient tolerates simvastatin 5 mg; monitor closely

P: Tab:Vytorin*(22445), Ezetimibe 10mg (22446), Simvastatin 20mg (22455)

ADR:

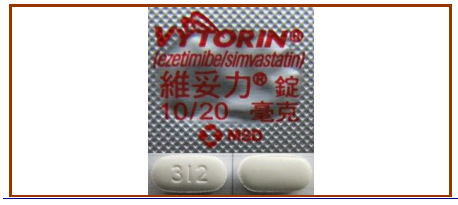
Common
Myalgia, headache, upper respiratory infection
Serious
Hepatitis, liver function tests abnormal,anaphylaxis, angioedema, drug-induced myopathy, rhabdomyolysis

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色長橢圓扁錠，一面有"312"字樣



12.06E Cholesterol Absorption Inhibitors

22446 C / Caution

EZETROL TABLETS 10MG 怡妥錠10公絲

Ezetimibe 10mg tab

Dosage: 1常備品 22446

Adult
· Hypercholesterolemia (alone or in combination with an HMG-CoA reductase inhibitor): PO, 10mg qd
· Homozygous sitosterolemia: PO, 10mg qd

Pediatric
· Adolescents ?10 years : same as adult

Dosing adjustments in hepatic impairment:

Mild impairment: No dosage adjustment needed
Moderate (Child-Pugh score 7-9) or severe (Child-Pugh score 10-15) impairment: Not recommended

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 10mg(22446)

ADR:

COMMON
Abdominal pain, diarrhea, arthralgia, back pain, myalgia, headache, sinusitis
SERIOUS
Hepatitis, increased liver function test, drug-induced myopathy (very rarely), rhabdomyolysis (very rarely)

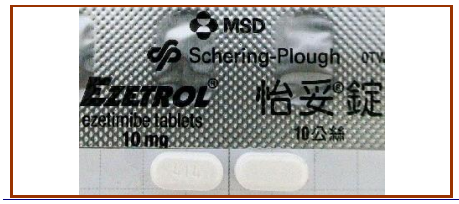
NOTE: 室溫儲存

· Ezetimibe and HMG-CoA reductase inhibitor may be administered at the same time
· Ezetimibe should be given at least 2 hours before or 4 hours after administration of a bile acid sequestrant

藥名相似:

外觀相似:

外觀描述: 白色長橢圓錠，一面印有"414"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024058

12.06F Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Inhibitors

32120 ɔt be ruled out / Infant risk can

Praluent solution for injection 75mg 保脂通注射劑75毫克

Alirocumab 75mg soln for inj in pre-filled pen

Dosage: 1常備品 32120

Adult
·Primary heterozygous familial hypercholesterolemia, Adjunct to maximally tolerated statin therapy: Initial, 75 mg SC q2w; MAX, 150 mg SC q2w.
·Primary hypercholesterolemia, Atherosclerotic cardiovascular disease; adjunct to maximally tolerated statin therapy: Initial, 75 mg SC q2w; MAX, 150 mg SC q2w

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Severe hepatic impairment(Child-PughC): Data not available,use with caution

Dosing adjustments in renal impairment:

Severe renal impairment(GFR<30mL/min/1.73m2): Data not available,use with caution

P: P Inj: 75mg pre-filled pen(37729)

ADR:

COMMON
Injection site reaction(7.2%), Nasopharyngitis(11.3%), Influenza(5.7%)
SERIOUS
Allergic reaction(8.6%), Angioedema

NOTE: 冰箱冷藏，不可冷凍。

· 《Contraindications》History of a serious hypersensitivity reaction to alirocumab ;

藥名相似:

外觀相似:

外觀描述: 白色注射筆

12.06F Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Inhibitors

32122 ɔt be ruled out / Infant risk can

REPATHA* Solution for Injection 瑞百安注射液

Evolocumab 140mg soln for inj in pre-filled pen

Dosage: 1常備品 32122

Adult
·Primary heterozygous familial hypercholesterolemia/Atherosclerotic cardiovascular disease; in combination with a statin: 140 mg SC q2W or 420 mg SC once monthly.

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Child Pugh class A and B: No dosage adjustment necessary.
Child-Pugh class C: Data not available

Dosing adjustments in renal impairment:

Mild to moderate renal impairment: No dosage adjustment necessary.
Estimated GFR <30 mL/minute/1.73 m2: Data not available

P: P Inj: 140mg pre-filled pen(32122)

ADR:

COMMON
Injection site reaction, Diabetes mellitus, Influenza, Nasopharyngitis, Upper respiratory infection

SERIOUS
Rash, Urticaria, Hypersensitivity reaction.

NOTE: 冰箱冷藏2-8°C

1.Needle cover may contain dry natural rubber and may cause allergic reaction.
2.420mg dose once monthly should be delivered using three pre-filled syringes administered consecutively within 30mins.

藥名相似:

外觀相似:

外觀描述: 1mL注射溶液，藍色預充填注射筆

12.06F Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Inhibitors

37654 **ɔt be ruled out / Infant risk can**

"Amgen" REPATHA* Solution for Injection "安進"瑞百安注射液

急罕Evolocumab 140mg soln for inj in pre-filled pen

Dosage: 2急用藥 37654

Adult
·Primary heterozygous familial hypercholesterolemia/Atherosclerotic cardiovascular disease; in combination with a statin: 140 mg SC q2W or 420 mg SC once monthly.

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Child Pugh class A and B: No dosage adjustment necessary.
Child-Pugh class C: Data not available

Dosing adjustments in renal impairment:

Mild to moderate renal impairment: No dosage adjustment necessary.
Estimated GFR <30 mL/minute/1.73 m2: Data not available

P: P Inj: 140mg pre-filled pen(32122, 罕病37654)

ADR:

COMMON
Injection site reaction, Diabetes mellitus, Influenza, Nasopharyngitis, Upper respiratory infection
SERIOUS
Rash, Urticaria

NOTE: 冰箱冷藏，不可冷凍。

1.Needle cover may contain dry natural rubber and may cause allergic reaction.
2.420mg dose once monthly should be delivered using three pre-filled syringes administered consecutively within 30mins.

藥名相似:

外觀相似:

外觀描述: 1mL注射溶液，藍色預充填注射筆

12.06G Miscellaneous

22462 **C / Milk effects ar**

OMACOR* Soft Capsules 1000 mg 脂妙清軟膠囊 1000 毫克

Omega-3-acid ethyl esters 90 1000mg cap(EPA 460mg 、DHA 380mg)

Dosage: 1常備品 22462

Adult
·Hypertriglyceridemia: PO, initial therapy :1g bid ; Max: 2g bid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: P soft cap: 1000mg(22462)

ADR:

COMMON
Burping, indigestion, taste sense altered
SERIOUS
Anaphylaxis

NOTE: 室溫儲存

1.Contraindication: hypersensitivity to omega-3-acid esters or any product component
2.Periodically monitor hepatic transaminases in patients with hepatic impairment and LDL level was suggested.
3.Symptomatic atrial fibrillation or flutter may recur more often with treatment in patients with paroxysmal or persistent atrial fibrillation, especially during the first 2 to 3 months of therapy

藥名相似:

外觀相似:

外觀描述: 透明軟膠囊，內含淡黃色魚油

12.08A1 ACE Inhibitors (ACEI)

22469 **D / Infant risk is**

Cabudan Tablets 25mg 卡布登錠25毫克

Captopril 25mg tab

Dosage: 1常備品 22469

Adult
·Hypertension: PO, 25 mg bid or tid; may be

increased after 1-2 wk to 50 mg bid or tid, MD 25-150 mg bid or tid; Max. 450 mg/day
·Congestive heart failure: PO, initial 6.25-12.5 mg tid; MD 12.5-25 mg tid; may be increased to 50-100 mg tid; Max. 450 mg/day
·Myocardial infarction: PO, initial 6.25 mg qd followed by 12.5 mg tid, then 25 mg tid; MD 50 mg tid (as tolerated)

Pediatric
·Hypertension:
Infants: PO, 0.01-0.25 mg/kg q12h; Max. 2 mg/kg/dose 2-3 times daily
Children: PO, 0.05-0.5 mg/kg 3 times a day; Max. 2 mg/kg/dose 2-3 times daily

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 10-15 mL/min: 75% of normal dose or q12-18 hr
Clcr < 10 mL/min: 50% of normal dose or q24h

P:

ADR:

COMMON
cough, edema, gynecomastia, hyperkalemia, hypotension, proteinuria, rash, taste alterations
SERIOUS
angioedema, neutropenia/agranulocytosis

NOTE: 室溫儲存

·《Contraindications》Angioedema history related to prior therapy with an ACE inhibitor; Hypersensitivity to captopril or to any other ACE inhibitor; Coadministration with aliskiren in patients with diabetes; Concomitant neprilysin inhibitors (eg, sacubitril) or within 36 hours of switching to or from sacubitril/valsartan ;
·[C] first trimester; [D] second and third trimester.

藥名相似: Tab: 25mg (22469)

外觀相似:

外觀描述: 白色圓扁錠，一面有"SYG | 25"字樣及中央有刻痕

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1038204

12.08A1 ACE Inhibitors (ACEI)

22492 UK /

TANATRIL TABLETS 10MG 田納滋錠１０毫克

Imidapril 10mg tab

Dosage: 1常備品 22492

Adult
·Hypertension: PO, initial 2.5-10mg qd

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr<30mL/min: Dose should be halved or prolong the dosing interval

P: Tab: 10mg(22492)

ADR:

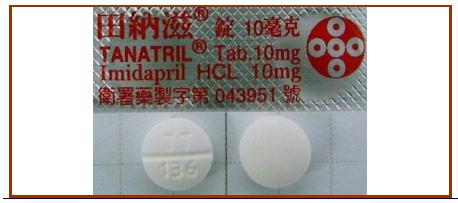
Cough, pharynx discomfort, headache, dizziness, hypotension, increase serum potassium, increase GOT/GPT, increase BUN/Scr, rash, pruritus

NOTE: 室溫儲存

藥名相似: Tab: 10mg(22492)

外觀相似:

外觀描述: 白色圓扁錠，中間有刻痕，有TT及136字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043951

12.08A1 ACE Inhibitors (ACEI)

22492 UK /

TANATRIL TABLETS 10MG 田納滋錠１０毫克

Imidapril 10mg tab

Dosage: 1常備品 22492

Adult
·Hypertension: PO, initial 2.5-10mg qd

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr<30mL/min: Dose should be halved or prolong the dosing interval

P: Tab: 10mg(22492)

ADR:

Cough, pharynx discomfort, headache, dizziness, hypotension, increase serum potassium, increase GOT/GPT, increase BUN/Scr, rash, pruritus

NOTE: 室溫儲存

藥名相似: Tab: 10mg(22492)

外觀相似:

外觀描述: 白色圓扁錠，中間有刻痕，有TT及136字樣

12.08A1 ACE Inhibitors (ACEI)

22494 D /

TRITACE 10MG TABLETS 心達舒錠 10 毫克

Ramipril 10mg tab

Dosage: 1常備品 22494

Adult
·Hypertension: PO, initial 1.25-2.5mg qd, MD 2.5-20mg once daily or in 2 divided doses
·Heart failure post MI: PO, initial 1.25-2.5mg bid, titrated to 5mg bid
·Reduction in risk of MI, stroke and death from cardiovascular causes: PO, initial 2.5mg qd for 1 week, then 5mg qd for the next 3 weeks, Max. 10mg/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr<40 mL/min: 25% of usual doses
HTN: Initial 1.25mg qd; Max. 5 mg/day
CHF: Initial 1.25mg qd, then 1.25mg bid; Max. 2.5mg bid

P: Tab: 10mg(22494), 2.5mg(22479)

ADR:

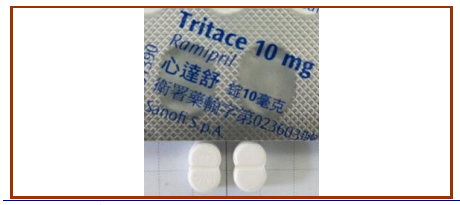
COMMON
Cough, dizziness, fatigue, hyperkalemia, hypotension, nausea/vomiting
SERIOUS
Intestinal angioedema, liver failure starting with cholestatic jaundice, angioedema(face, lips, throat)

NOTE: 室溫儲存30℃以下

藥名相似:

外觀相似:

外觀描述: 白色長橢圓形錠，中間有刻痕，有HMO字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023603

12.08A1 ACE Inhibitors (ACEI)

22511 D /

Acertil film-coated tablets 5 mg 雅施達膜衣錠5毫克

Perindopril arginine 5mg film-coated tab

Dosage: 1常備品 22511

Adult
·Hypertension: PO, initial 5 mg qd ac ; MD 2.5-10mg/day
·CHF:PO,initial 2.5mg qd ac;MD 2.5-5mg/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

30<Clcr <60 mL/min: 2.5mg/day
15<Clcr<30 mL/min: 2.5mg qod
pt with hemodialysis:
Clcr<15mL/min: 2.5mg on the day of dialysis

P:

ADR:

COMMON
Hyperkalemia, Backache, Asthenia, Dizziness, Headache, Cough
SERIOUS
Cardiac arrest, Orthostatic hypotension ,Intestinal angioedema, Pancreatitis, Agranulocytosis, Bone marrow depression, Neutropenia, Liver failure, Acute renal failure, Angioedema

NOTE: 室溫儲存

1.[C] first trimester; [D] second and third trimester
2.Contraindications: history of ACE-inhibitor induced angioedema, pregnancy

藥名相似:

外觀相似:

外觀描述: 淡綠色橢圓形扁錠，刻有商標圖案

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024725

12.08A1 ACE Inhibitors (ACEI)

22518 D / Unsafe

Acertil Plus 5 mg/1.25 mg 雅施達 加強錠 5 毫克/1.25 毫克

Perindopril arginine 5mg & Indapamide 1.25mg tab

Dosage: 1常備品 22518

Adult
·Hypertension: PO, ac, 1 tab qd ac

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Severe hepatic impairment: contraindication
Moderate hepatic impairment: no dose modification is required

Dosing adjustments in renal impairment:

Clcr<30mL/min: contraindication

P: Tab: ACERTIL* PLUS(22518), Perindopril tert-arginine 5mg(22511), Indapamide SR 1.5mg(23633)

ADR:

COMMON
Dry cough, constipation, dry mouth, nausea,anorexia epigastric pain, taste disturbance
SERIOUS
Agranulocytosis, thrombocytopenia, anemia, pancreatitis, hypersensitivity reaction, angioedema

NOTE: 室溫儲存

1.[C] first trimester; [D] second and third trimester
2.Contraindications: Hypersensitivity to any ACEI, history of angiioedema, 2nd/3rd trimesters of

pregnancy, several hepatic/renal impairment, patients with untreated decompensated heart failure

藥名相似:

外觀相似:

外觀描述: 白色長橢圓錠

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025046

12.08A2 Angiotensin II receptor (type AT1) antagonist (ARB)

22484 **D / Unknown(有**

BLOPRESS TABLETS 8MG 博脈舒錠 8 公絲

Candesartan cilexetil 8mg tab

Dosage: 1常備品 22484

Adult
·Hypertension: PO, initial 8-16 mg qd or div. bid; MD 8-32 mg/day in one or two div. doses
·Heart failure: PO, initial 4 mg qd; target dose 32 mg/day as tolerated

Pediatric
·Hypertension:(1~6yrs): PO, Initial: 0.2 mg/kg/day divided once or twice daily; titrate to response ; usual range: 0.05-0.4 mg/kg/day divided once or twice daily; maximum daily dose: 0.4 mg/kg/day ; (6-17yrs): PO, BW<50 kg: Initial: 4-8 mg/day divided once or twice daily; titrate to response ; usual range: 2-16 mg/day divided once or twice daily; maximum daily dose: 32 mg/day . If BW>50 kg: same as adult

Dosing adjustments in hepatic impairment:

Moderate hepatic impairment: Consider initiation at lower dosages (AUC increased by 145%).

Dosing adjustments in renal impairment:

moderate to severe (CrCl 15 to 60 mL/min/1.73m(2)), 8 mg daily

P: Tab:8mg (22484)

ADR:

COMMON
Hypotension, Backache, Dizziness, Pharyngitis, Rhinitis, Upper respiratory infection.

NOTE: 室溫儲存

[C] 1st trimester; [D] 2nd and 3rd trimesters

藥名相似: Tab:8mg (22484)

外觀相似:

外觀描述: 淡粉紅圓錠

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023128

12.08A2 Angiotensin II receptor (type AT1) antagonist (ARB)

22490 **D / Caution**

DIOVAN FILM-COATED TABLETS 160MG 得安穩膜衣錠 160毫克

Valsartan 160mg tab

Dosage: 1常備品 22490

Adult
·Hypertension: PO, initial 80-160mg qd; MD 80-320mg qd; Max. 320mg/day
·Congestive heart failure: PO, initial 40mg bid, MD 80-160mg bid; Max. 320mg/day

Pediatric
safety and efficacy have not been established
·Hypertension(6-16yrs): PO, initial 1.3 mg/kg qd (MAX 40 mg/day) , maintenance up to 2.7 mg/kg qd; MAX 160 mg/day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr >10mL/min: No dosage adjustment needed

P: Tab: 160mg(22490), Co-Diovan*(22485)

ADR:

COMMON
Cough, dizziness, fatigue, headache, hypotension
SERIOUS
Angioedema(face, lips, throat)

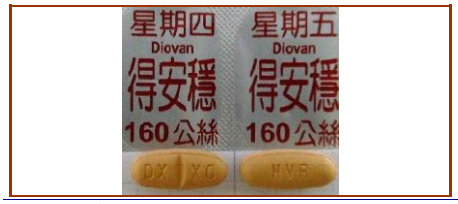
NOTE: 室溫儲存

·Pregnancy category: [C] 1st trimester; [D] 2nd and 3rd trimesters

藥名相似: Tab: 160mg(22490), Co-Diovan*(22485)

外觀相似:

外觀描述: 土黃色橢圓形錠，有DX及NVR字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023374

12.08A2 Angiotensin II receptor (type AT1) antagonist (ARB)

22498 **D / Infant risk can**

COZAAR F.C. TABLETS 100MG 可悅您 膜衣錠 1 0 0 毫克

Losartan potassium 100mg FC tab

Dosage: 1常備品 22498

Adult
·Hypertension: PO, initial 50 mg qd; MD 25-100 mg qd or div. bid
·Diabetic nephropathy: PO, initial 50 mg qd; MD 100 mg qd (based on BP response)

Pediatric (>6 yrs)
·Hypertension: PO, 0.7mg/kg once daily; Max. 50 mg/day

Dosing adjustments in hepatic impairment:

Reduce the initial dose to 25 mg

Dosing adjustments in renal impairment:

Pediatric: Use is not recommended if Clcr<30mL/min
Adult: No dosage adjustment needed

P: Tab: Losartan 100mg(22498); Hyzaar* (22487)

ADR:

COMMON
asthenia, fatigue, diarrhea, dizziness, hypotension
SERIOUS
angioedema

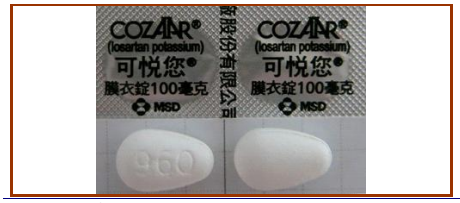
NOTE: 室溫儲存

1.[C] first trimester; [D] 2nd and 3rd trimesters
2.Contraindications: pregnancy

藥名相似: Tab: Losartan 100mg(22498); Hyzaar* (22487

外觀相似: Hyzaar* 50/12.5 Tab (22487),

外觀描述: 白色不對稱長橢圓錠，有"096"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023655

12.08A2 Angiotensin II receptor (type AT1) antagonist (ARB)

22499 D /

MICARDIS TABLETS 80MG 必康平錠 8 0 公絲

Telmisartan 80mg tab

Dosage: 1常備品 22499

Adult
·Hypertension: PO, initial 40 mg qd; MD 20-80 mg qd
·Cardiovascular event risk, Reduction: PO,80mg qd

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

hepatic impairment, biliary obstruction: provide close monitoring

Dosing adjustments in renal impairment:

volume depletion, dialysis patients: provide close monitoring for blood pressure

P: Tab: 80mg (22499)

ADR:

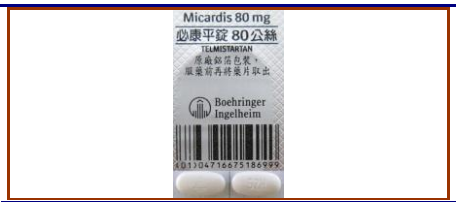
COMMON
Cough, upper respiratory infection
SERIOUS
Rhabdomyolysis (rare)

NOTE: 室溫儲存

藥名相似: Tab: 80mg (22499)

外觀相似: Rasilez* 150mg Tab(22509)

外觀描述: 白色圓扁錠，一面有商標圖案，另一面有52H字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023161

12.08A2 Angiotensin II receptor (type AT1) antagonist (ARB)

22506 D / Caution

APROVEL 300MG FILM-COATED TABLETS 安普諾維膜衣錠300毫克

Irbesartan 300mg FC tab

Dosage: 1常備品 22506

Adult
·Hypertension: PO, 150 mg qd; Max. 300 mg qd
·Diabetic nephropathy: PO, MD 300 mg qd

Pediatric
·Hypertension:
6-12 yrs: PO, 75 mg qd; may titrate to 150 mg qd

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed unless volume or salt are also depleted.

P: Tab: 300mg (22506), Coaprovel*(22496)

ADR:

COMMON
diarrhea, dyspepsia/heartburn, fatigue, headache, URI
SERIOUS
angioedema

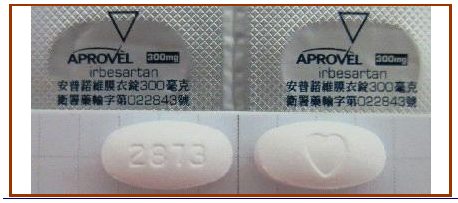
NOTE: 室溫儲存

1.[C] 1st trimester; [D] 2nd and 3rd trimesters
2.Contraindications: pregnancy

藥名相似: Tab: 300mg (22506), Coaprovel*(22496)

外觀相似: CoAprovel* 300/12.5 Tab (22516)

外觀描述: 白色橢圓膜衣錠，印有2873字樣，另一面為心形圖案



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022843

12.08A2 Angiotensin II receptor (type AT1) antagonist (ARB)

22514 D / Infant risk can

Blopress 16mg Plus 12.5mg Tablets 博脈舒加強錠16毫克/12.5毫克

Candesartan 16mg & Hydrochlorothiazide 12.5mg tab

Dosage: 1常備品 22514

Adult
·Hypertension: PO, 1 tab qd, Max. 2 tab qd

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

moderate (Child-Pugh B), not recommended for initial therapy

Dosing adjustments in renal impairment:

Clcr ≦30 mL/min: Not recommended

P: P Tab: BLOPRESS* plus(16/12.5)(22514) , BLOPRESS* 8mg(22484)

ADR:

·Candesartan
COMMON
Hypotension, Backache, Dizziness, Pharyngitis, Rhinitis, Upper respiratory infection.
·Hydrochlorothiazide
COMMON
Hypotension, Phototoxicity, Vertigo.
SERIOUS
Cardiac dysrhythmia, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Dilutional hyponatremia, Hypercalcemia, Hyperglycemia, Hypokalemia, Hypomagnesemia, Hyponatremia, Hypophosphatemia, Cholecystitis, Pancreatitis, Cholestatic jaundice syndrome, Angle-closure glaucoma, acute, Myopia, Acute transient, Renal failure, Renal impairment.

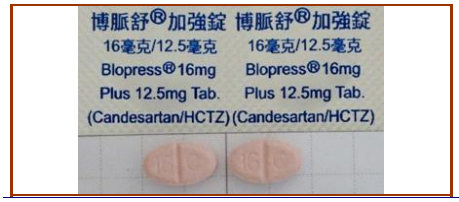
NOTE: 室溫儲存

1.Contraindications: anuria , concomitant use with aliskiren in patients with diabetes ,hypersensitivity to candesartan, hydrochlorothiazide, or other sulfonamides.
·hydrochlorothiazide可能導致低血鉀、低血鈉、低血鎂、高血鈣等電解質失衡，建議定期監測血清電解質。
·hydrochlorothiazide可能改變葡萄糖耐受、提高血清中膽固醇與三酸甘油酯、出現高尿酸血症。
·hydrochlorothiazide與非黑色素細胞惡性腫瘤(non-melanocytic skin malignancies, NMSC)之間存在具累積劑量依存性關聯，應定期監測病人皮膚是否有新增病變、現有病變惡化或任何可疑的病變。應指導病人避免暴露於陽光或其他紫外線照射，暴露於陽光或紫外線期間須使用適當的防曬措施，以減少皮膚癌的風險。

藥名相似:

外觀相似:

外觀描述: 淡粉紅色橢圓形扁錠，中間有一刻痕，有"16"及"C"字樣



12.08A2 Angiotensin II receptor (type AT1) antagonist (ARB)

22515 D / Caution

CO-DIOVAN 160/12.5 FILM COATED TABLETS 可得安穩１６０、１２．５膜衣錠

Valsartan 160mg & Hydrochlorothiazide 12.5mg tab

Dosage: 1常備品 22515

Adult
·Hypertension: PO, 1 tab qd, Max. 2 tab qd

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Severe hepatic impairment : Not recommended

Dosing adjustments in renal impairment:

Clcr ≦30 mL/min: Not recommended

P: Tab:Co-Diovan(22515), Diovan(22490)

ADR:

COMMON
cough, diarrhea, dizziness, hypotension, fatigue, headache
SERIOUS
angioedema,acute angle-closure glaucoma, ,myopia(acute transient) ,erythema multiforme,renal failure hepatitis

NOTE: 室溫儲存

1.Contraindications: pregancy , anuria,concomitant aliskiren use in diabetic patients
·hydrochlorothiazide可能導致低血鉀、低血鈉、低血鎂、高血鈣等電解質失衡，建議定期監測血清電解質。
·hydrochlorothiazide可能改變葡萄糖耐受、提高血清中膽固醇與三酸甘油酯、出現高尿酸血症。
·hydrochlorothiazide與非黑色素細胞惡性腫瘤(non-melanocytic skin malignancies, NMSC)之間存在具累積劑量依存性關聯，應定期監測病人皮膚是否有新增病變、現有病變惡化或任何可疑的病變。應指導病人避免暴露於陽光或其他紫外線照射，暴露於陽光或紫外線期間須使用適當的防曬措施，以減少皮膚癌的風險。

藥名相似:

外觀相似:

外觀描述: 暗紅色長橢圓錠，有HHH及CG字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023109

12.08A2 Angiotensin II receptor (type AT1) antagonist (ARB)

22516 D / Caution

COAPROVEL* 300mg/12.5mg FC tab 可普諾維膜衣錠 300毫克/12.5毫克

Irbesartan 300mg & Hydrochlorothiazide 12.5mg tab

Dosage: 1常備品 22516

Adult
·Hypertension: PO, 1 tab qd

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

use with caution

Dosing adjustments in renal impairment:

Clcr>30mL/min: No dosage adjustment needed
Clcr≦30mL/min: Not recommended

P: Tab: CoAprovel* 300mg/12.5mg(22516)

ADR:

COMMON
Headache, musculoskeletal pain, dizziness, fatigue
SERIOUS
Hypokalemia, angioedema(face, lips, throat)

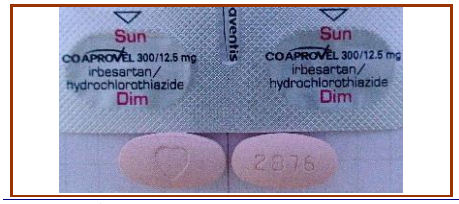
NOTE: 室溫儲存

1.Contraindications: anuria , concomitant use with aliskiren in patients with diabetes ,hypersensitivity to irbesartan, hydrochlorothiazide, or other sulfonamides
·hydrochlorothiazide可能導致低血鉀、低血鈉、低血鎂、高血鈣等電解質失衡，建議定期監測血清電解質。
·hydrochlorothiazide可能改變葡萄糖耐受、提高血清中膽固醇與三酸甘油酯、出現高尿酸血症。
·hydrochlorothiazide與非黑色素細胞惡性腫瘤(non-melanocytic skin malignancies, NMSC)之間存在具累積劑量依存性關聯，應定期監測病人皮膚是否有新增病變、現有病變惡化或任何可疑的病變。應指導病人避免暴露於陽光或其他紫外線照射，暴露於陽光或紫外線期間須使用適當的防曬措施，以減少皮膚癌的風險。

藥名相似: Tab: CoAprovel* 300mg/12.5mg(22516)

外觀相似: Aprovel* 300mg FC Tab (22506)

外觀描述: 粉橘色橢圓形膜衣錠，一面有2876字樣，另一面有心形圖案



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023267

12.08A2 Angiotensin II receptor (type AT1) antagonist (ARB)

22519 **D / Caution**

OLMETEC* FC tab 40mg 雅脈膜衣錠

Olmesartan 40mg tab

Dosage: 1常備品 22519

Adult
·Hypertension: PO, initial 20mg qd, dose may be increased to 40mg qd after 2 weeks.

Pediatric
Safety and efficacy have not been established in patients <6 yrs old
·Hypertension (6 ~16 yrs) : BW 20-35 kg, PO, initial, 10 mg qd; after 2 weeks, may titrate to MAX of 20 mg once daily ; BW>35kg , same as adult.

Dosing adjustments in hepatic impairment:

moderate to severe hepatic dysfunction:No dosage adjustment needed

Dosing adjustments in renal impairment:

CrCl <40 mL/minute: No initial dosage adjustment necessary
(AUC is increased 3-fold in patients with CrCl <20 mL/minute)

P: Tab: 20mg(22495), 40mg(22519)

ADR:

COMMON
Hypotension,dizziness, headache
SERIOUS
Disorder of intestine, Sprue-like ,rhabdomyolysis,test-allergic shock,angioedema

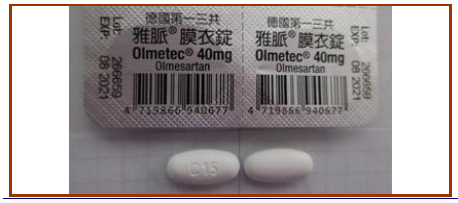
NOTE: 室溫儲存

1.Children <1yr must not receive olmesartan medoxomil for hypertension
2.Contraindication:Concomitant use with aliskiren in patients with diabetes
3.抑制RAS的藥品可能引起高血鉀症。需定期監測血清中電解質。
4.在懷孕第2和第3期時，使用腎素 - 血管昇壓素系統的藥物使胎兒腎功能降低及增加胎兒和新生兒罹病率與死亡。一旦病人確定懷孕，需立即停用此藥。

藥名相似:

外觀相似:

外觀描述: 白色橢圓形膜衣錠，一面有"C15"字樣



12.08A2 Angiotensin II receptor (type AT1) antagonist (ARB)

22520 **D / Caution**

EDARBI Tablets 40mg 易得平錠 40 毫克

Azilsartan Medoxomil 40mg tab

Dosage: 1常備品 22520

Adult
·Hypertension: PO, initial 20-40mg qd,Max:80mg qd

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

mild to moderate hepatic dysfunction: No dosage adjustment necessary

Dosing adjustments in renal impairment:

No dosage adjustment necessary

P: Tab: 40mg(22520)

ADR:

COMMON
Diarrhea
SERIOUS
Renal failure

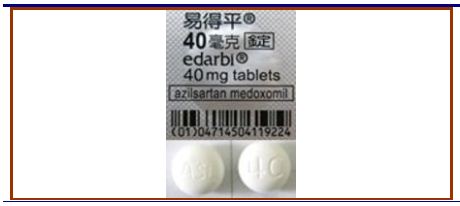
NOTE: 室溫儲存

Concomitant use with aliskiren in patients with diabetes

藥名相似:

外觀相似:

外觀描述: 白色圓錠，一面有ASL字樣，另一面有40字樣



12.08A2 Angiotensin II receptor (type AT1) antagonist (ARB)

22522 D / Unknown(有

SEVIKAR* 5/40MG FILM COATED TABLETS 舒脈康膜衣錠 5/40 毫克

複方Olmesartan 40mg & Amlodipine 5mg tab

Dosage: 1常備品 22522

Adult
·Hypertension: PO, Add-on/switch/replacement therapy:1 tab qd, dose may be titrated after 2 weeks of therapy;Max. Amlodipine 10 mg/olmesartan 40 mg /day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Use with caution in severe hepatic dysfunction

Dosing adjustments in renal impairment:

No data available

P: Tab:Sevikar*(22522 (5/40)), Olmesartan*40mg(22519),Amlodipine 5mg(22407),

ADR:

Common
Edema, dizziness, headache, fatigue, diarrhea, nausea, muscle spasms, joint swelling, UTI, nasopharyngitis, URI
Serious
Syncope, angioedema,angina/MI,arrhythmia, symptoms of sprue-like enteropathy

NOTE: 室溫儲存

1.Contraindications: concomitant use with aliskiren in patients with diabetes mellitus or GFR<60ml/min/1.73m2
2.The recommended initial dose of amlodipine (2.5 mg/day) in patients >75 years is not available in this combination product.

藥名相似:

外觀相似:

外觀描述: 淺黃色圓扁錠，一面有"C75"字樣

12.08A2 Angiotensin II receptor (type AT1) antagonist (ARB)

22523 D / Unknown(有

TWYNSTA* TABLETS 80/5 MG 倍必康平錠80/5毫克

複方Telmisartan 80mg & Amlodipine 5mg tab

Dosage: 1常備品 22523

Adult
·Hypertension: PO, Add-on/switch/replacement therapy:1 tab qd, dose may be titrated after 2 weeks of therapy;Max. telmisartan 80mg/amlodipine 10mg per day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Hepatic impairment or biliary obstructive disorders: Not recommended for initial therapy

Dosing adjustments in renal impairment:

No dosage adjustment necessary. Titrate slowly in severe impairment.

P: Tab:TWYNSTA*(22523 (80/5)), Telmisartan*80mg(22499),Amlodipine 5mg(22407),

ADR:

Common
Peripheral edema,backache,dizziness
Serious
Acute myocardial infarction, angina pectoris, hypersensitivity reaction, renal impairment,angioedema

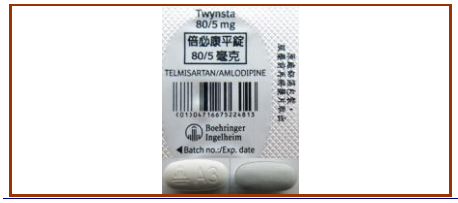
NOTE: 室溫儲存

1.Contraindications: Coadministration of aliskiren in patients with diabetes,hypersensitivity to telmisartan, amlodipine, or to any component of the product
2.The recommended initial dose of amlodipine (2.5 mg/day) in patients >75 years is not available in this combination product.

藥名相似:

外觀相似:

外觀描述: 橢圓形白/灰錠，一面有"商標"及"A3"字樣



12.08A2 Angiotensin II receptor (type AT1) antagonist (ARB)

22524 D / Infant risk can

SEVIKAR HCT* 40/5/12.5MG 舒脈優膜衣錠 40/5/12.5毫克

複方Olmesartan 40mg, Amlodipine 5mg & Hydrochlorothiazide 12.5mg tab

Dosage: 1常備品 22524

Adult
·Hypertension(not for initial therapy): PO, 1 tab qd ; Max. 1 tab/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Severe hepatic dysfunction is not recommended

Dosing adjustments in renal impairment:

CrCl <30 mL/min: not recommended

P: Tab:Sevikar HCT*(22524 (40/5/12.5)), Sevikar*(22522(40/5), Olmesartan 40mg(22519),Amlodipine 5mg(22407)

ADR:

Common
Edema, dizziness, headache, fatigue, diarrhea, nausea, muscle spasms, joint swelling, UTI, nasopharyngitis, URI
Serious
Acute myocardial infarction, angina pectoris, hypotension, electrolyte imbalance, symptoms of sprue-like enteropathy, angle-closure glaucoma, acute, myopia, acute transient, renal failure

NOTE: 室溫儲存

1.Contraindications: anuria,hypersensitivity to hydrochlorothiazide or sulfonamides, Concomitant use with aliskiren in patients with diabetes or GFR<60ml/min/1.73m2
·hydrochlorothiazide可能導致低血鉀、低血鈉、低血鎂、高血鈣等電解質失衡，建議定期監測血清電解質。
·hydrochlorothiazide可能改變葡萄糖耐受、提高血清中膽固醇與三酸甘油酯、出現高尿酸血症。
·hydrochlorothiazide與非黑色素細胞惡性腫瘤(non-melanocytic skin malignancies, NMSC)之間存在具累積劑量依存性關聯，應定期監測病人皮膚是否有新增病變、現有病變惡化或任何可疑的病變。應指導病人避免暴露於陽光或其他紫外線照射，暴露於陽光或紫外線期間須使用適當的防曬措施，以減少皮膚癌的風險。

藥名相似:

外觀相似:

外觀描述: 淺黃色圓扁錠，一面有"C53"字樣

12.08A3 Renin inhibitors

22509 **D / Unsafe**

Rasilez Film-Coated Tablet 150mg 絡舒樂適膜衣錠 150 毫克

Aliskiren 150mg tab

Dosage: 1常備品 22509

Adult
·Hypertension: PO, initial 75-150mg qd; may increase to 300mg/day based on clinical response

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Mild to moderate impairment: No dosage adjustment needed
Severe renal impairment: Use with caution

P:

ADR:

COMMON
Rash, diarrhea, increased creatine kinase level, cough
SERIOUS
Excessive hypotension, Torsades de pointes, acute renal failure, angioedema

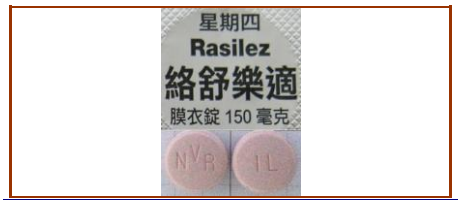
NOTE: 室溫儲存30°C 以下

·Concomitant use of aliskiren with either diuretics or angiotensin II receptor blockers (eg, valsartan) will have additive antihypertensive effects. However, it is not known whether additive effects are present when aliskiren is used with ACE inhibitors or beta-blockers.

藥名相似:

外觀相似:

外觀描述: 粉紅色圓扁錠，一面有IL字樣，另一面有NVR字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024884

12.08A4 Neprilysin Inhibitors

22521 **demonstrated / Infant risk has**

ENTRESTO 100mg film-coated tablets 健安心100毫克膜衣錠

Sacubitril 49mg & Valsartan 51mg tab

Dosage: 1常備品 22521

· Chronic heart failure (NYHA Class II-IV) and reduced ejection fraction: PO, initial
(a) Not taking ACEI or ARB, or taking low doses of these agents : 50mg bid
(b) Switching from an ACEI or ARBs at a standard dosage: 100mg bid
Maintenance dose: PO, double the dose every 2-4 wks to a target dosage of 200mg bid as tolerated

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Mild (Child-Pugh class A): No adjustment necessary
Moderate (Child-Pugh class B): Initial, 50mg bid; double dose q2-4 wks to target dosage of 200mg bid
Severe (Child-Pugh class C): Use not recommended

Dosing adjustments in renal impairment:

Mild to moderate (eGFR≧ 30 mL/min): No adjustment necessary
Severe (eGFR< 30 mL/min): Initial, 50mg bid; double dose q2-4 wks to target dosage of 200mg bid

P: Tab: ENTRESTO*(100mg:22521; 200mg 22525), Co-Diovan*(22515), Valsartan(22490)

ADR:

COMMON
Hypotension, hyperkalemia, dizziness.

SERIOUS
Renal failure, angioedema

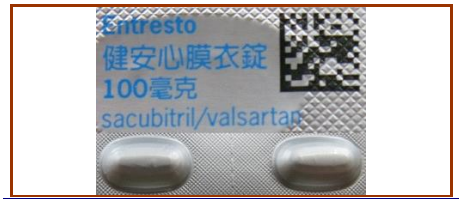
NOTE: 室溫儲存

1.If switching from an ACE inhibitor, allow a 36-hour washout period before initiating sacubitril/valsartan
2.Valsartan 51 mg in Entresto is equivalent to valsartan 80 mg in other marketed tab formulations

藥名相似:

外觀相似:

外觀描述: 淺黃色膜衣錠，一面刻印 NVR，另一面有 L1 字樣



12.08A4 Neprilysin Inhibitors

22525 **demonstrated / Infant risk has**

ENTRESTO* 200mg film-coated tablets 健安心200毫克膜衣錠

Sacubitril 97mg & Valsartan 103mg tab

Dosage: 1常備品 22525

Adult
· Chronic heart failure (NYHA Class II-IV) and reduced ejection fraction: PO, initial
(a) Not taking ACEI or ARB, or taking low doses of these agents : 50mg bid
(b) Switching from an ACEI or ARBs at a standard dosage: 100mg bid
Maintenance dose: PO, double the dose every 2-4 wks to a target dosage of 200mg bid as tolerated

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Mild (Child-Pugh class A): No adjustment necessary
Moderate (Child-Pugh class B): Initial, 50mg bid; double dose q2-4 wks to target dosage of 200mg bid
Severe (Child-Pugh class C): Use not recommended

Dosing adjustments in renal impairment:

Mild to moderate (eGFR≧ 30 mL/min): No adjustment necessary
Severe (eGFR< 30 mL/min): Initial, 50mg bid; double dose q2-4 wks to target dosage of 200mg bid

P: Tab: ENTRESTO*(100mg:22521 ; 200mg 22525), Co-Diovan*(22515), Valsartan(22490)

ADR:

COMMON
Hypotension, hyperkalemia, dizziness.
SERIOUS
Renal failure, angioedema

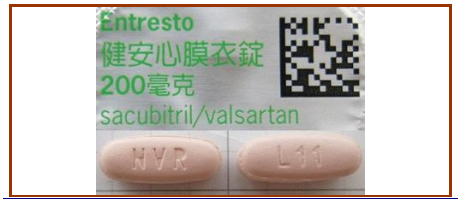
NOTE: 室溫儲存

1.If switching from an ACE inhibitor, allow a 36-hour washout period before initiating sacubitril/valsartan
2.Valsartan 51 mg in Entresto is equivalent to valsartan 80 mg in other marketed tab formulations

藥名相似:

外觀相似:

外觀描述: 淺粉紅色膜衣錠，一面刻印 NVR，另一面有 L11 字樣



12.08B Antiadrenergic Agents - Centrally Acting

22465 **B / Infant risk is**

METHYLDOPA F.C. TABLETS "JOHNSON" "強生"脈得保膜衣錠（美基豆帕）

Methyldopa 250mg tab

Dosage: 1常備品 22465

Adult
·Hypertension: PO, initial 250 mg bid-tid; increase dose PRN Q2 days; MD 500-2000 mg/day div. 2-4 doses; Max. 3 g/day

Pediatric
·Hypertension: PO, initial 10 mg/kg/day in 2-4 div. doses; increase dose PRN Q2 days; Max. 65 mg/kg/day or 3g/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Dosage adjustment required

P:

ADR:

COMMON
amenorrhea, fever, gynecomastia, impotence, angina, bradycardia, hypotension, anxiety, asthenia, depression, dizziness, arthralgia, myalgia, constipation, diarrhea, dry mouth, headache, nightmares, sedation, nasal congestion, nausea, sore or black tongue, vomiting, rash
SERIOUS
bone marrow depression, colitis, congestive heart failure, granulocytopenia, hemolytic anemia, hypersensitivity reactions, leukopenia, liver dysfunction, lymphoma, neutropenia, parkinsonism, pancreatitis,
systemic lupus erythematosus, thrombocytopenia, toxic epidermal necrolysis

NOTE: 室溫儲存

Contraindications: current MAOI therapy, liver disease (with or without previous association with methyldopa therapy)

藥名相似:

外觀相似:

外觀描述: 淺黃色膜衣錠，一面中央有一刻痕

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1019461

12.08C Antiadrenergic Agents - Alpha 1 Adrenergic Blocker

22459 ɔt be ruled out / Infant risk can

Xadosin SR F.C. Tablets 4 mg 薩多心持續性藥效錠 4 毫克

Doxazosin 4mg SR tab

Dosage: 1常備品 22459

Adult
·Hypertension, BPH: PO, initial 4 mg qd, increased to 8 mg qd if necessary; Max. 8 mg/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Hepatic impairment (severe, Child-Pugh C): Use not recommended

Dosing adjustments in renal impairment:

No dosage adjustment needed

P:

ADR:

COMMON
edema, hypotension, palpitations, anxiety, dizziness, fatigue, headache, somnolence, vertigo, abdominal pain, nausea.
SERIOUS
blood dyscrasias, hepatitis, priapism.

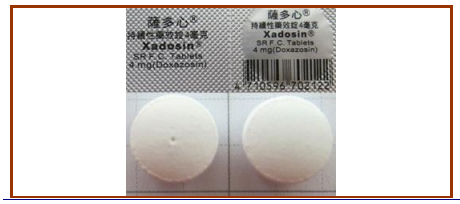
NOTE: 室溫儲存

1. Doxaben XL , which is a GITS (gastrointestinal therapeutic system) formulation, provided 24 hour consistent therapeutic blood levels, with a much lower peak level.
2. Doxaben XL(4 or 8 mg once daily) is as effective as the standard tablet formulation of doxazosin (1 to 8 mg once daily). GITS formulation appears to eliminate the need for dose titration in most patients.
3. Swallow whole, do not chew, divide, or crush.

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049920

12.08C Antiadrenergic Agents - Alpha 1 Adrenergic Blocker

22467 C / Caution

HYTRIN TABLETS 2MG 定脈平錠 2 毫克（英國廠）

Terazosin 2mg tab

Dosage: 1常備品 22467

Adult
·Hypertension: PO, initial 1mg hs, may be increased gradually to 5mg/day; Max. 20-40 mg/day
·Benign prostatic hyperplasia: PO, initial 1mg hs, may be increased in a stepwise manner to 2, 5 and 10 mg/day as necessary; Max. 20 mg/day

Pediatric
Safety and efficacy have not been established
·Hypertension: PO, initial 1 mg/day once daily; MAX, 20 mg/day

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 2mg (22467)

ADR:

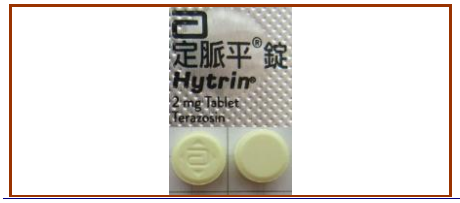
COMMON
edema, hypotension, palpitation, syncope, tachycardia, asthenia, dizziness, fatigue, headache, lightheadedness, somnolence,
nausea, impotence,amblyopia, blurred vision, dyspnea, nasal congestion, rhinitis, sinusitis
SERIOUS
blood dyscrasias (rare), priapism (rare)

NOTE: 室溫儲存

藥名相似: Tab: 2mg (22467)

外觀相似: Trazodone HCl 50mg tab(22931)

外觀描述: 淺黃色圓扁錠，一面商標刻圖樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022959

12.08D Antiadrenergic Agents - Alpha 2 Adrenergic Agonists

22460 C / Unsafe

CATAPRES TABLETS 75 μg 降保適錠 75 微公克 (法國廠)

Clonidine HCl 75mcg tab

Dosage: 1常備品 22460

Adult
·Hypertension: PO, initial 0.1 mg twice daily (morning and bedtime), increase by 0.1 mg/day at weekly intervals; MD 0.2-0.6 mg/day in div. doses; Max. 2.4 mg/day

Pediatric
Safety and efficacy have not been established
·Hypertension(1-17yrs): PO, Initial: 5-10 mcg/kg/day in divided doses q8-12hrs; increase gradually as needed; usual range: 5-25 mcg/kg/day in divided doses q6h; maximum dose: 0.9 mg/day
·Hypertension,urgency and emergency(1-17yrs): PO,0.05-0.1 mg/dose; may repeat dose up to a max dose 0.8 mg

·ADHD(>6 yrs): PO,>45 kg: Initial: 0.05 mg hs; sequentially increase q 3-7 days in 0.05 mg/day increments given as 0.05 mg bid-qid; Max dose weight-dependent: 27-40.5kg: 0.2mg/day; 40.5-45 kg; 0.3 mg/day ; >45 kg: Initial: 0.1 mg hs; sequentially increase q3-7 days in 0.1 mg/day increments given as 0.1 mg bid-qid,; Max dose: 0.4 mg/day
·Clonidine tolerance test (test of growth hormone release from the pituitary): PO, 0.15 mg/m2 or 5 mcg/kg as a single dose; maximum dose: 0.25 mg
·Tic disorders and Tourette's syndrome: PO, Initial: 0.025-0.05 mg/day; gradual titration to 3-4 times daily schedule using small increments (0.025 mg); target daily dose: 0.2-0.3 mg/day; doses up to 0.4 mg/day
·Neonatal abstinence syndrome (opioid withdrawal): PO: 0.5-1 mcg/kg/dose q 4-6 hrs upon stabilization, clonidine doses were stopped or tapered by 0.25 mcg/kg q6h if needed
·Neuropathic pain: PO, 2-4 mcg/kg/dose every 4-6 hours; increase incrementally over several days

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Lower initial dose is recommended

P: Tab: 75mcg (22460)

ADR:

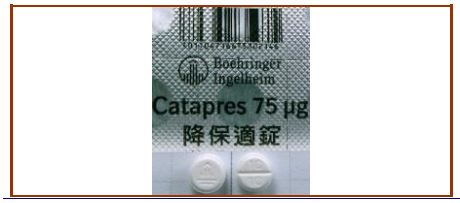
COMMON
contact dermatitis, erythema, pruritus, xerostomia, dizziness, headache, sedated , somnolence, fatigue
SERIOUS
Atrioventricular block

NOTE: 室溫儲存

藥名相似: Tab: 75mcg (22460)

外觀相似:

外觀描述: 白色圓扁錠，有1C字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025391

12.08E Antiadrenergic Agents - Alpha/Beta-Adrenergic Blocker

22408 **C /**

SYNTREND* 25mg tab 心全錠25公絲

Carvedilol 25mg tab

Dosage: 1常備品 22408

Adult
·Hypertension: PO, initial 6.25 mg bid for 1-2 wks, then increased to 12.5 mg bid; Max. 50 mg/day
·CHF: PO, 3.125 mg bid for 2 wks, then doubled every 2 wks if necessary; Max. 50 mg/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Initial, 20% of the normal dose

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 25mg (22408), 6.25mg (22409)

ADR:

COMMON
angina, atrioventricular block, bradycardia, edema, hypertension, hypotension, palpitations, syncope, fatigue, dizziness, headache, insomnia, somnolence, hyperglycemia, abdominal pain, diarrhea, nausea, vomiting, erectile dysfunction, reduced libido, visual abnormalities, bronchospasm, dyspnea, pharyngitis, rhinitis, skin rash, pruritus, myalgia, back pain, joint pain
SERIOUS
hepatotoxicity, status asthmaticus, thrombocytopenia

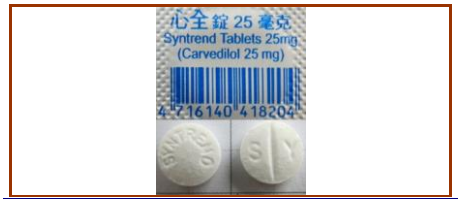
NOTE: 室溫儲存

Contraindications: bronchial asthma or chronic obstructive pulmonary disease, cardiogenic shock, overt cardiac failure, second and third degree AV block, severe liver failure, severe sinus bradycardia, sick sinus syndrome

藥名相似: Tab: 25mg (22408), 6.25mg (22409)

外觀相似:

外觀描述: 白色圓扁錠，一面"SYNTREND"，另一面中間有刻痕及"S" "Y"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046404

12.08E Antiadrenergic Agents - Alpha/Beta-Adrenergic Blocker

22409 **C /**

SYNTREND TABLETS 6.25MG 心全錠 6.25毫克

Carvedilol 6.25mg tab

Dosage: 1常備品 22409

Adult
·Hypertension: PO, initial 6.25 mg bid for 1-2 wks, then increased to 12.5 mg bid; Max. 50 mg/day
·CHF: PO, 3.125 mg bid for 2 wks, then doubled every 2 wks if necessary; Max. 50 mg/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Initial, 20% of the normal dose

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 6.25mg (22409), 25mg (22408)

ADR:

COMMON
angina, atrioventricular block, bradycardia, edema, hypertension, hypotension, palpitations, syncope,

fatigue, dizziness, headache, insomnia, somnolence, hyperglycemia, abdominal pain, diarrhea, nausea, vomiting, erectile dysfunction, reduced libido, visual abnormalities, bronchospasm, dyspnea, pharyngitis, rhinitis, skin rash, pruritus, myalgia, back pain, joint pain
SERIOUS
hepatotoxicity, status asthmaticus, thrombocytopenia

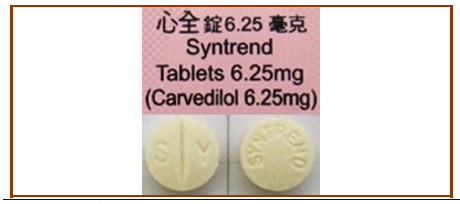
NOTE: 室溫儲存

Contraindications: bronchial asthma or chronic obstructive pulmonary disease, cardiogenic shock, overt cardiac failure, second and third degree AV block, severe liver failure, severe sinus bradycardia, sick sinus syndrome

藥名相似:

外觀相似: Novonorm* 1mg Tab(25701)

外觀描述: 米白色圓扁錠，一面有"SYNTREND"，另一面中間有一刻痕有"S"及"Y"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046699

12.08E Antiadrenergic Agents - Alpha/Beta-Adrenergic Blocker

22468 C / Infant risk is

LABTAL F.C. TABLETS 200MG (LABETALOL) "SINPHAR" "杏輝" 壓血泰膜衣錠２００毫克（拉貝他樂）

Labetalol HCl 200mg FC tab

Dosage: 1常備品 22468

Adult
·Hypertension: PO, initial 100 mg bid; may increase dose in increments of 100 mg bid every 2-3 days; MD, 200-400 mg bid; Max. 2.4 g/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Dosage reduction may be necessary

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab:200mg (22468), Inj:25mg/5mL (31706)

ADR:

COMMON
bradycardia, edema, orthostatic hypotension, dizziness, fatigue, lightheadedness, paresthesias, abdominal pain, constipation, diarrhea, dyspepsia, ejaculation failure, impotence, elevated liver enzymes, elevated BUN, elevated serum creatinine, dyspnea, nasal stuffiness, wheezing,diaphoresis, pruritus, skin rash, scalp tingling
SERIOUS
bronchospasm, hyperkalemia, severe hepatotoxicity, ventricular arrhythmias

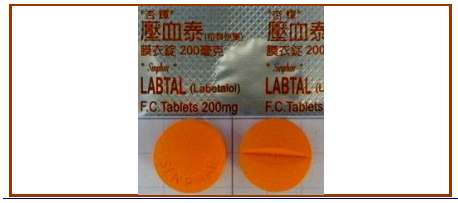
NOTE: 室溫儲存

Contraindications: bronchial asthma or chronic obstructive pulmonary disease, cardiogenic shock, conditions associated with severe and prolonged hypotension, overt cardiac failure, second and third degree AV block, severe sinus bradycardia

藥名相似:

外觀相似: Pk-Merz* 100mg Tab(27227)

外觀描述: 橘色圓扁錠，中間有刻痕，另一面有SINPHAR字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1039703

12.08E Antiadrenergic Agents - Alpha/Beta-Adrenergic Blocker

31706 C / Infant risk is

CHENDAY INJECTION 5MG/ML 壓泰定注射液5毫克/毫升

■Labetalol inj 25mg/5mL amp

Dosage: 1常備品 31706

Adult
·Hypertension: IV, 20 mg over 2 min, additional 40 mg or 80 mg may be given at 10 min intervals until the desired BP is achieved or to a total dose of 300 mg; IV infusion, 200 mg is added to 160-250 mL of IV fluid administered at 2 mg/min

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Dosage reduction may be necessary

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 200mg (22468); Inj: 25mg/5mL (31706)

ADR:

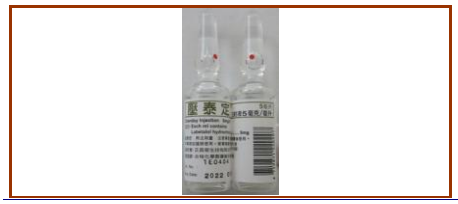
NOTE: 室溫儲存

1.Max. effect usually occurs within 5 min of each injection
2.Contraindications: bronchial asthma or chronic obstructive pulmonary disease, cardiogenic shock, conditions associated with severe and prolonged hypotension, overt cardiac failure, second and third degree AV block, severe sinus bradycardia

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液,透明安瓿頸部有紅點,白紙黑字標籤,有墨綠色"壓泰定"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049550

12.08F Antiadrenergic Agents - Beta Adrenergic Blocker

22110 C / Infant risk can

BISO F.C. TABLETS 5MG 百適歐膜衣錠 5 公絲

Bisoprolol fumarate 5mg tab

Dosage: 1常備品 22110

Adult
·Hypertension: PO, initial 2.5-5 mg qd; MD 2.5-20 mg qd; Max. 40 mg/day
·Congestive heart failure: PO, initial 1.25 mg qd, titrate to Max. 10 mg/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Initial 2.5 mg/day; Max. 10 mg/day

Dosing adjustments in renal impairment:

Initial 2.5 mg/day; Max. 10 mg/day
Hemodialysis: dose replacement is not necessary

P: Tab: 5mg(22110), 1.25mg(22111)

ADR:

· Cardiovascular Effects: rebound Angina pectoris, Bradyarrhythmia, Cold extremity, Congestive heart failure, Intermittent claudication, Orthostatic hypotension, Rebound hypertension.
· Dermatologic Effects: Drug-exacerbated psoriasis.
· Endocrine/Metabolic Effects: Disorder of glucose regulation, Hyperkalemia, Hyperlipidemia, Increased lipoprotein.
· Gastrointestinal Effects: Diarrhea, Nausea, Vomiting.
· Hepatic Effects: Increased liver aminotransferase level.
· Immunologic Effects: Anaphylaxis.
· Musculoskeletal Effects: Arthralgia.
· Neurologic Effects: Asthenia, Headache, Insomnia, Sleep disorder.
· Ophthalmic Effects: Blurred vision, Conjunctivitis.
· Renal Effects: Erectile dysfunction, Kidney disease, Peyronie’ s disease, Polyuria, Reduced libido.
· Respiratory Effects: Pulmonary function studies abnormal, Rhinitis, Sinusitis, Upper respiratory infection.
· Other: Fatigue, Withdrawal symptom.

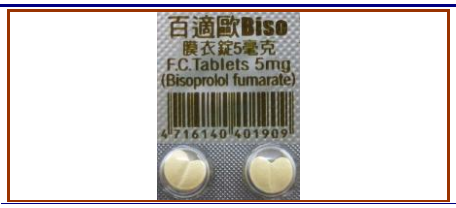
NOTE: 室溫儲存

· Contraindications: cardiogenic shock, overt cardiac failure, second and third degree AV block, severe sinus bradycardia
· 有支氣管氣喘或慢性阻塞性肺疾病者可能引起症狀，應給與支氣管擴張劑伴隨治療，偶而因呼吸道阻力增加引起氣喘，可增加 β2 - 興奮劑治療。與其他β blocker類似，可能增加下列二者：過敏原敏感度，及過敏性的嚴重性。

藥名相似: Tab: 5mg(22110), 1.25mg(22111)

外觀相似:

外觀描述: 黃色心形扁錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045348

12.08F Antiadrenergic Agents - Beta Adrenergic Blocker

22111 C / Infant risk can

CONCOR 1.25 康肯1.25公絲

Bisoprolol fumarate 1.25mg tab

Dosage: 1常備品 22111

Adult
·Hypertension: PO, initial 2.5-5mg qd; MD 2.5-20mg qd; Max. 40mg/day
·Congestive heart failure: PO, initial 1.25mg qd, titrate to Max. 10mg/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Use with caution; Max:10mg/day

Dosing adjustments in renal impairment:

Use with caution; Max:10mg/day

P: Tab: 5mg(22110), 1.25mg(22111)

ADR:

· Cardiovascular Effects: rebound Angina pectoris, Bradyarrhythmia, Cold extremity, Congestive heart failure, Intermittent claudication, Orthostatic hypotension, Rebound hypertension.
· Dermatologic Effects: Drug-exacerbated psoriasis.
· Endocrine/Metabolic Effects: Disorder of glucose regulation, Hyperkalemia, Hyperlipidemia, Increased lipoprotein.
· Gastrointestinal Effects: Diarrhea, Nausea, Vomiting.
· Hepatic Effects: Increased liver aminotransferase level.
· Immunologic Effects: Anaphylaxis.
· Musculoskeletal Effects: Arthralgia.
· Neurologic Effects: Asthenia, Headache, Insomnia, Sleep disorder.
· Ophthalmic Effects: Blurred vision, Conjunctivitis.
· Renal Effects: Erectile dysfunction, Kidney disease, Peyronie’ s disease, Polyuria, Reduced libido.
· Respiratory Effects: Pulmonary function studies abnormal, Rhinitis, Sinusitis, Upper respiratory infection.
· Other: Fatigue, Withdrawal symptom.

NOTE: 室溫儲存

· Contraindications: cardiogenic shock, overt cardiac failure, second and third degree AV block, severe sinus bradycardia
· 有支氣管氣喘或慢性阻塞性肺疾病者可能引起症狀，應給與支氣管擴張劑伴隨治療，偶而因呼吸道阻力增加引起氣喘，可增加 β2 - 興奮劑治療。與其他β blocker類似，可能增加下列二者：過敏原敏感度，及過敏性的嚴重性。

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024039

12.08F Antiadrenergic Agents - Beta Adrenergic Blocker

22114 **D / Unsafe**

UROSIN FILM COATED TABLETS 50MG (ATENOLOL) 優心膜衣錠50毫克(阿廷諾)

Atenolol 50mg tab

Dosage: 1常備品 22114

Adult
·Hypertension: PO, 50-100 mg qd
·Angina: PO, initial 50 mg qd; titrate to MD 50-100 mg qd after 1 wk; Max. 200 mg/day

Pediatric
safety and effectiveness have not been established
·Cardiac dysrhythmia:PO,0.3 to 1.4 mg/kg qd; titration, may increase by 0.5 mg/kg/day increments every 3 to 4 days; MAX dose, 2 mg/kg
·Hypertension: PO, 0.5 to 1 mg/kg/day in 1 to 2 divided doses; MAX 2 mg/kg/day ORALLY up to 100 mg/day in 1 to 2 divided doses

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 15-35 mL/min: Max. 50 mg/day;
Clcr < 15 mL/min: Max. 25 mg/day
hemodialysis: 25 to 50 mg after each dialysis session

P: Tab: 50mg (22114)

ADR:

COMMON
cold extremities, hypotension,dizziness, depression, insomnia, tiredness, diarrhea, nausea, bradycardia
SERIOUS
lupus syndrome

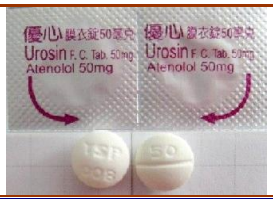
NOTE: 室溫儲存

Contraindications: cardiogenic shock, overt cardiac failure, second and third degree AV block, severe sinus bradycardia

藥名相似: Tab: 50mg (22114)

外觀相似:

外觀描述: 白色圓扁錠，一面中間有一刻痕及50 字樣，一面有YSP、008字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044843

12.08F Antiadrenergic Agents - Beta Adrenergic Blocker

22118 **ɔt be ruled out / Infant risk can**

Nebilet 5 mg 耐比洛錠5毫克

Nebivolol hydrochloride 5mg tab

Dosage: 1常備品 22118

·Hypertension: PO, initial, 5mg QD, with or without food; dose may be titrated at 2-week intervals up to 40mg QD

·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

·Mild (Child-Pugh A): Use caution
·Moderate (Child-Pugh B): Initial dose 2.5mg QD, titrate cautiously
·Severe (Child-Pugh C): Use is contraindicated

Dosing adjustments in renal impairment:

·CrCl < 30 mL/min: Initial 2.5mg QD, titrate cautiously

P: P Tab: 5mg(22118)

ADR:

COMMON
Nausea, dizziness, headache, somnolence
SERIOUS
Angina pectoris, myocardial infarction, ventricular arrhythmia

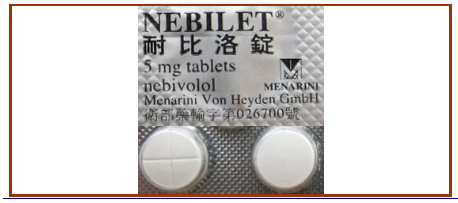
NOTE: 室溫儲存

·Contraindications: severe bradycardia, decompensated cardiac failure, cardiogenic shock, second and third degree heart block, severe hepatic impairment(Child-Pugh > B), hypersensitivity to any component of the product, sick sinus syndrome (unless a permanent pacemaker is in place)

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有十字刻痕



12.08G Calcium Channel Blocking Agents(CCB)

22407 **C / Caution**

NOBAR TABLETS 5MG (AMLODIPINE BESYLATE) 諾怡錠5毫克（安脈狄平）

Amlodipine besylate 5mg tab

Dosage: 1常備品 22407

Adult
·Hypertension: PO, initial 2.5-5mg qd; MD 5-10mg qd; Max. 10mg/day
·Angina: PO, 5-10 mg qd

Pediatric
·Hypertension (6 to 17 yr): PO ,2.5-5 mg once daily

Dosing adjustments in hepatic impairment:

Begin therapy at 2.5mg/day for hypertension and 5mg for angina

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 5mg (22407)

ADR:

COMMON
dizziness, fatigue, flushing, headache, palpitation, peripheral edema
SERIOUS
myocardial infarction, angina, arrhythmia

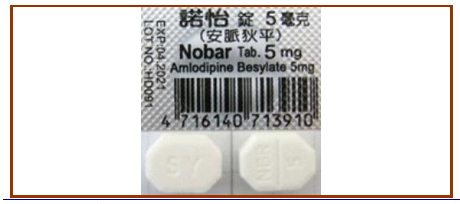
NOTE: 室溫儲存

1.仿單藥物交互作用段落加註：許多腎臟移植患者的試驗顯示，本藥併用cyclosporin會影響cyclosporin的波谷濃度，應考慮對腎臟移植且使用amlodipine者監測cyclosporin濃度。(版本Australia LPD 20130729-2)
2.The recommended initial dose of amlodipine in patients ?75 years: PO 2.5 mg/day

藥名相似: Tab: 5mg (22407)

外觀相似:

外觀描述: 白色八角形錠劑，一面中間有一刻痕及NBR及5字樣，另一面有SY字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1042704

12.08G Calcium Channel Blocking Agents(CCB)

22491 UK /

Lesyn F.C. Tablets 4mg 樂壓定膜衣錠 4 毫克

Lacidipine 4mg tab

Dosage: 1常備品 22491

Adult
·Hypertension: PO, initial 2mg once daily, preferably in the morning; may increase after 3-4 weeks to 4mg/day; Max. 6mg/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 4mg(22491)

ADR:

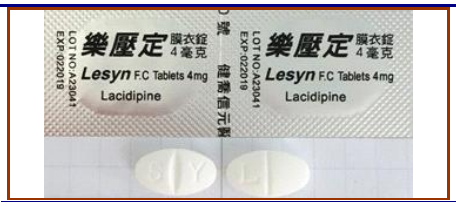
Headache, flushing, edema, dizziness, palpitation, asthenia, skin rash, gastric upset, nausea, polyuria, gingival hyperplasia

NOTE: 室溫儲存

藥名相似: Tab: 4mg(22491)

外觀相似:

外觀描述: 白色長橢圓扁錠，中間有刻痕，有"S Y"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048064

12.08G Calcium Channel Blocking Agents(CCB)

22507 /

AMTREL TABLETS 諾壓錠

複方Amlodipine besylate 5mg & Benazepril hydrochloride10mg

Dosage: 1常備品 22507

Adult
·Hypertension, Second-line therapy: PO, initial, 2.5-10mg(amlodipine) & 10-40mg(benazepril) once daily, based on clinical response.

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Initial dose, amlodipine 2.5 mg

Dosing adjustments in renal impairment:

Severe renal impairment(Clcr<=30mL/min) : Not recommended

P: Tab: Amtrel* (22507), Amlodipine(22407)

ADR:

COMMON
Edema, Dizziness, Headache, Cough
SERIOUS
Intestinal angioedema, Angioedema(face, lips, throat; more frequent in Black patients)

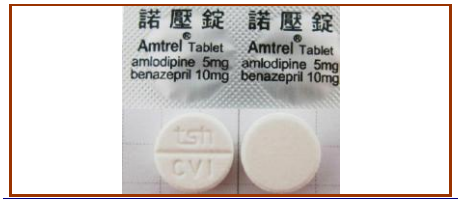
NOTE: 室溫儲存

1.Pregnancy Category : Amlodipine [C] ,Benazepril [D]
2.The recommended initial dose of amlodipine (2.5 mg/day) in patients >75 years is not available in this combination product.

藥名相似: Tab: Amtrel* (22507), Amlodipine(22407)

外觀相似: Aleviatin* 100mg(22863),

外觀描述: 白色圓扁錠，一面中央有刻痕 ，有"tsh"及"CVI"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046742

12.08G Calcium Channel Blocking Agents(CCB)

22512 C / Unknown(有

Exforge film-coated tablet 5/160mg 易安穩膜衣錠 5/160 毫克

複方Amlodipine 5mg & Valsartan 160mg tab

Dosage: 1常備品 22512

Adult
·Hypertension: PO, 5-10mg(amlodipine) & 80-320

mg(valsartan) once daily,with dose titration occurring every 1 to 2 weeks if necessary.

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

initial dose, amlodipine 2.5 mg

Dosing adjustments in renal impairment:

Clcr>10mL/min : No dosage adjustment necessary.
Clcr<=10mL/min : Use caution

P: Tab:Exforge*(22508 (5/80), 22512 (5/160)),Valsartan 80mg (22478), Amlodipine 5mg(22407)

ADR:

Common
Hypotension, peripheral edema, flushing, dizziness, headache, cough, nasopharyngitis, upper respiratory infection, fatigue
Serious
Acute myocardial infarction, cardiac dysrhythmia, kidney disease

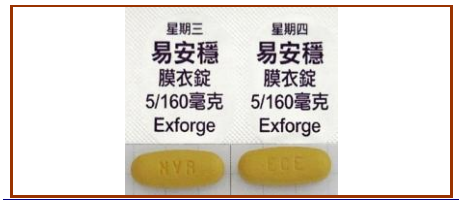
NOTE: 室溫儲存

1. Pregnancy Category : Amlodipine [C] ,Valsartan [D]
2. Contraindications: Hypersensitivity to amlodipine, valsartan, or any component of the formulation; concomitant use with aliskiren in patients with diabetes mellitus.
3.The recommended initial dose of amlodipine (2.5 mg/day) in patients >75 years is not available in this combination product.

藥名相似:

外觀相似:

外觀描述: 土黃色長橢圓形扁錠，一面有"ECE"，另一面有"NVR"字樣



12.08G Calcium Channel Blocking Agents(CCB)

22527 **C / Unsafe**

PROGOR CAPSULE 180MG 保樂康緩釋膠囊１８０公絲

Diltiazem HCl SR 180mg cap

Dosage: 1常備品 22527

Adult
·Hypertension: PO, initial 180mg once daily, titrate after 14 days; MD 180-360 mg/day; Max. 360 mg/day
·Angina: PO, initial 180 mg once daily; titrated over 7-14 days, Max. 360 mg/day

Pediatirc
Safety and efficacy have not been established
·Hypertension: PO, 1.5 to 2 mg/kg(extended release formulations may be dosed once or twice daily; MAX 3.5 mg/kg daily has been used

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P:

ADR:

COMMON
AV block, bradycardia, dizziness, fainting, gingival hyperplasia, headache, peripheral edema, CHF exacerbation
SERIOUS
Cardiac conduction disturbances

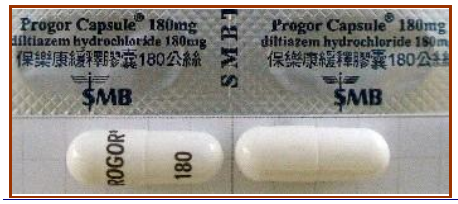
NOTE: 室溫儲存

1.Contraindication: acute MI with pulmonary congestion on x-ray; heart block, sick sinus syndrome, Wolff-Parkinson-White; symptomatic hypotension (90 mmHg systolic or less)
2.Reduced doses may be required in the elderly or those with renal or hepatic impairment
3.Swallow whole, do not chew or crush

藥名相似: Tab: 30mg (22529), Cap: 180mg (22527)

外觀相似:

外觀描述: 白色膠囊，有PROGOR及180字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022997

12.08G Calcium Channel Blocking Agents(CCB)

22529 **C / Unsafe**

CARTIL* TABLETS 30MG 卡迪爾錠３０毫克

Diltiazem HCl 30mg tab

Dosage: 1常備品 22529

Adult
·Angina: PO, initial 30 mg qid; usual dose 180-360 mg/day div. 3-4 doses
·Hypertension: PO, initial 30 mg tid; Max. 360 mg/day div. 3-4 doses

Pediatric
Safety and efficacy have not been established
·Hypertension: PO, 1.5 to 2 mg/kg daily in 3 to 4 divided doses; MAX 3.5 mg/kg daily has been used

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 30mg (22529) Cap: 180mg (22527)

ADR:

COMMON
AV block, bradycardia, dizziness, fainting, gingival hyperplasia, headache, peripheral edema, CHF exacerbation
SERIOUS
cardiac conduction disturbances

NOTE: 室溫儲存

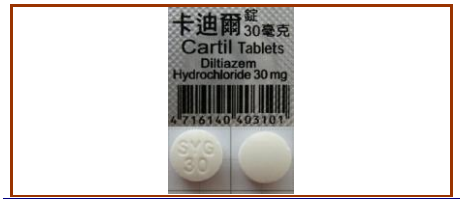
Contraindication: acute MI with pulmonary congestion on x-ray; heart block, sick sinus

syndrome, Wolff-Parkinson-White; symptomatic hypotension (90 mmHg systolic or less)

藥名相似: Tab: 30mg (22529) Cap: 180mg (22527)

外觀相似:

外觀描述: 白色圓扁錠，一面有"SYG 30"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1036966

12.08G Calcium Channel Blocking Agents(CCB)

22534 C /

FELPIN EXTENDED RELEASE TABLETS 5MG 'S.T..' (FELODIPINE) "信東" 菲可平持續釋放膜衣錠 5 公絲

Felodipine 5mg SR tab

Dosage: 1常備品 22534

Adult
·Hypertension: PO, initial 5 mg/day; MD 2.5-10 mg qd; Max. 20mg/day
·Angina: PO, 2.5-5mg bid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Initial 2.5mg/day; Max. 10mg/day

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 5mg (22534)

ADR:

COMMON
dizziness, flushing, gingival hyperplasia, headache, peripheral edema
SERIOUS
myocardial infarction, angina, tachycardia, hypotension (rare)

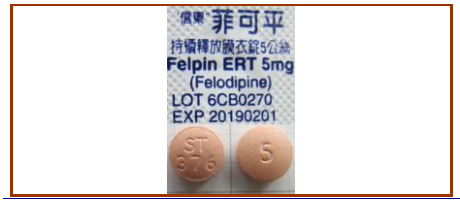
NOTE: 儲存25℃以下

Swallow whole; do not crush or chew

藥名相似:

外觀相似: Lexotan* 3mg Tab(23100)

外觀描述: 粉橘色圓扁錠，一面有5，另一面有ST及376字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045392

12.08G Calcium Channel Blocking Agents(CCB)

22543 C / Infant risk is

ATANAAL CAPSULE 5 壓達能軟膠囊 5 公絲

Nifedipine 5mg Soft cap

Dosage: 1常備品 22543

Adult
·Angina: PO, initial 10 mg tid; MD 10-30 mg tid-qid; Max. 180 mg/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 30mg (22545); Soft Cap: 5mg (22543)

ADR:

COMMON
dizziness, flushing, headache, constipation, nausea, heartburn, peripheral edema, palpitation
SERIOUS
angina, MI

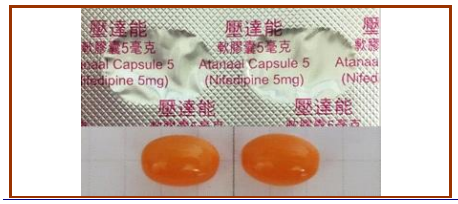
NOTE: 室溫儲存

Bite-and-swallow approach usually has a more rapid onset than sublingual administration

藥名相似:

外觀相似:

外觀描述: 橙色卵型軟膠囊



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022593

12.08G Calcium Channel Blocking Agents(CCB)

22545 C / Infant risk is

NIFEDIPINE* S.R.F.C. TABLETS 30MG "CYH" 恆脈循持續性膜衣錠30毫克

Nifedipine 30mg tab

Dosage: 1常備品 22545

Adult
·Angina: PO, initial 30-60 mg qd; Max.120 mg/day
·Hypertension: PO, initial 30-60 mg qd; MD 30-90 mg qd; Max.120 mg/day

Pediatric
·Hypertension: PO, Initial: 0.25-0.5 mg/kg/day once daily or divided in 2 doses per day; do not exceed initial adult dose (30-60 mg/day); titrate dose to effect; maximum dose: 3 mg/kg/day up to 120 mg/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No data available

P: Tab: 30mg (22545), Soft Cap: 5mg (22543)

ADR:

COMMON
Hypotension, Palpitations, Peripheral edema, Flushing, Nausea, Dizziness, Headache, Feeling nervous, Cough, Dyspnea

SERIOUS
Myocardial infarction, Ventricular arrhythmia, Gastrointestinal obstruction, Gastrointestinal ulcer, Aplastic anemia

NOTE: 室溫保存

1.Swallow whole; do not crush or chew
2.服用鋇顯影劑進行X光照射檢查時，本藥會造成偽陽性反應(陰影會被誤判為息肉)
3.當給予Nifedipine同時靜脈注射Magnesium sulfate時，須小心監控血壓，由於可能會導致血壓過度下降，危害母親及胎兒。
4.服用時須注意病患是否有嚴重的腸胃道狹窄，否則可能因此引起阻塞症狀。極少數案例會發生胃腸結石且可能需要手術治療。但也有一些造成腸阻塞的個案是之前並沒有任何的腸胃道異常的病史。
5.病人併有肝功能不全時，應小心監控，嚴重病患必要時應減少劑量。
6.每錠藥品鈉含量24mg。

藥名相似:

外觀相似:

外觀描述: 淺磚紅色圓扁錠

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1057219

12.08G Calcium Channel Blocking Agents(CCB)

22548 **c / Infant risk can**

ZANIDIP F.C. TABLET 10MG 利壓膜衣錠１０公絲

Lercanidipine HCl 10mg tab

Dosage: 1常備品 22548

Adult
·Hypertension: PO, initial 10 mg qd, MD 10-20 mg qd; Max. 30 mg qd

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

contraindicated in severe hepatic dysfunction patients

Dosing adjustments in renal impairment:

contraindicated in (GFR < 30 ml/min) or patient on hemodialysis / peritoneal dialysis

P: Tab: 10mg (22548)

ADR:

·Cardiovascular Effects: Orthostatic Hypotension, Palpitations, Edema.
·Dermatologic Effects: Flushing, Rash.
·Neurologic Effects: Headache, Vertigo.
·Renal Effects: Increased Diuresis.

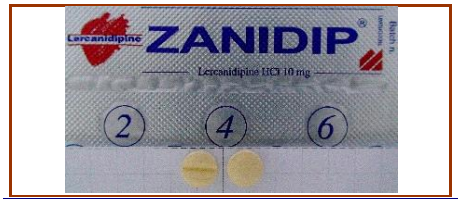
NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to lercanidipine；
·《仿單禁忌》
。對主成份或任一賦形劑過敏者。
。併有左心室流出道阻塞的病人。
。未治療的充血性心臟衰竭之病人。
。不穩定心絞痛，或近期(1 個月內)發生過心肌梗塞之病人。
。重度肝功能不全之病人。
。重度腎功能不全之病人(GFR < 30 ml/min)，包括正在接受透析的病人。
。避免同時使用：
-與強效的CYP3A4 之抑制劑併用。
-與Cyclosporin 併用。
-與葡萄柚或葡萄柚汁併用。
· 最大降壓作用出現在服藥後2星期，劑量需漸進調整，不可立即增加。
· 本品含有乳糖，有半乳糖不耐症、 總乳糖胸缺乏症或葡萄糖 半乳糖吸收不良等，應避免使用。

藥名相似: Tab: 10mg (22548)

外觀相似: 外盒：Tritace* 2.5mg Tab (22479),

外觀描述: 黃色圓形雙凸錠，一面中央有刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023293

12.08G Calcium Channel Blocking Agents(CCB)

22549 **C /**

NIMOTOP F.C. TABLETS 30MG 腦妥膜衣錠30毫克

Nimodipine 30mg tab

Dosage: 1常備品 22549

Adult
·Subarachnoid hemorrhage: PO, 60mg q4h for 21 days

Dosing adjustments in hepatic impairment:

Dosage should be reduced to 30 mg q4h in patients with hepatic failure

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 30mg (22549), Inj: 10mg/50mL (32407)

ADR:

COMMON
decreased blood pressure, diarrhea, nausea, stomach cramps
SERIOUS
heart failure, arrhythmia

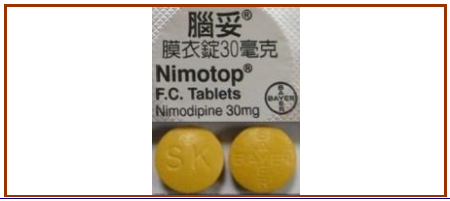
NOTE: 室溫儲存

Avoid grapefruit juice during nimodipine therapy

藥名相似:

外觀相似:

外觀描述: 土黃色圓扁錠，有BAYER及SK字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2018842

12.08G Calcium Channel Blocking Agents(CCB)

22555 **demonstrated / Infant risk has**

CADUET* 5MG/20MG TABLET 脂脈優5毫克/20毫克

複方Amlodipine 5mg & Atorvastatin 20mg tab

Dosage: 1常備品 22555

Adult

·Hyperlipidemia - Hypertension: PO,amlodipine: 5-10 mg/atorvastatin 10-20mg once daily, MAX amlodipine 10 mg/atorvastin 80 mg per day

Pediatric

· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Amlodipine: initial antihypertensive dose is 2.5mg/day. for chronic stable or vasospastic angina the lower dose of the recommended range (5 to 10 mg) is suggested

Atorvastatin:contraindicated in patients with active liver disease or unexplained persistent elevations of serum transaminases

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab:Caduet 5mg/20mg(22555)

ADR:

Common

Edema, Abdominal pain, Constipation, Diarrhea, Indigestion, Dizziness, Headache

Serious

Acute myocardial infarction, Angina, Erythema multiforme, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Hepatitis , Liver function tests abnormal, Disorder of muscle, Rhabdomyolysis, Hemorrhagic cerebral infarction, Angioedema

NOTE: 室溫儲存

The recommended initial dose of amlodipine (2.5 mg/day) in patients >75 years is not available in this combination product.

·仿單內容變更，摘述如下：(版本：CDS 20130708-2)

1.用法用量：增列已有報導使用HIV蛋白胨抑制劑(lopinavir/ritonavir、saquinavir/ritonavir、darunavir/ritonavir、fosamprenavir、fosamprenavir/ritonavir與nelfinavir)、C型肝炎蛋白?抑制劑(boceprevir)、clarithromycin與itraconazole，會造成atorvastatin濃度上升，併用時應特別謹慎。

2.特殊警語及注意事項：增列HMG-CoA還原胨抑制劑若併用boceprevir，會增加發生肌病之危險性。

3.藥物交互作用：新增許多針對腎臟移植者的試驗顯示amlodipine併用cyclosporine時，對cyclosporine最低濃度的影響，為無變化至最多平均增加40%。腎臟移植者使用amlodipine時，應考慮監測cyclosporine的濃度。

4.上市後的經驗：增列免疫媒介性壞死性肌肉病變。

·仿單內容變更，摘述如下：(版本：CDS 20130708-2 + TFDA 1021402914B-3)

1.特殊警語及注意事項：加註(A)對肝臟的影響：使用本品可能引起病人肝轉氨?的持續升高，建議病人治療前接受肝功能檢測並注意是否出現肝損傷之症狀(包括疲勞、食慾減退、右上腹不適、尿色深或黃疸等)。(B)內分泌功能：加註治療後曾有HbA1c及/或空腹血糖上升的情況。

2.藥物交互作用：加註與HIV蛋白?抑制劑、boceprevir、telaprevir及nefazodone等併用時，會減少本藥的排除，增加發生肌病的風險。

3.上市後不良反應報告：增列可逆性認知障礙。

仿單內容變更，摘述如下：(版本：CDS 20151009-2)

1.特殊警語及注意事項：對骨骼肌的影響段落加註不建議同時使用atorvastatin和fusidic acid。

2.藥物交互作用：Atorvastatin交互作用增列fusidic acid，併用者有較高的橫紋肌溶解風險。須使用全身性fusidic acid的病患，應於fusidic acid治療期間全程停用statin療法。Statin療法可在最後一劑fusidic acid的7天後重新開始施用。

3.儲存溫度由室溫變更為15-30℃。

仿單內容變更，摘述如下：(版本：CDS 20151009-2)

仿單更新生育、懷孕與授乳之相關資訊。 含有Atorvastatin，故禁用於孕婦。有生育能力的婦女必須採用適當的避孕方法。

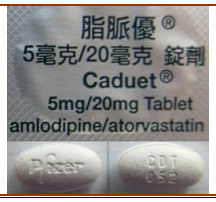
仿單內容變更，摘述如下：(版本：CDS 20161123-1)

授乳之相關資訊：嬰兒透過母乳接受amlodipine的每天劑量估計為4.17 微克/公斤。

藥名相似:

外觀相似: 外盒：Sermion*(22566), Olbetam* (22453)

外觀描述: 白色長橢圓扁錠，有pfizer及CDT 052字樣



12.08G Calcium Channel Blocking Agents(CCB)

32105 **C / Infant risk can**

Zedipine Injection 1mg/ml 樂吉平注射液 1毫克/毫升

■Nicardipine inj HCl 10mg/10mL amp

Dosage: 1常備品 32105

Adult

·Hypertension: IV infusion, initial 5 mg/hr; titrate 2.5 mg/hr at 5-15 min intervals, Max. 15 mg/hr; MD 3 mg/hr (after reaching BP goal)

Pediatric

Safety and efficacy have not been established

·Hypertension: (neonates) IV infusion, initial 0.5 mcg/kg/min,adjust to therapeutic response ; (1 to 17 yr of age) 1 to 3 mcg/kg/min IV infusion

Dosing adjustments in hepatic impairment:

consider lower initial dosages and titrate infusion gradually

Dosing adjustments in renal impairment:

Dosage adjustment required

P: Inj: 10mg/10mL (32105)

ADR:

COMMON

Hypotension, Peripheral edema, Tachyarrhythmia, Phlebitis, Nausea, Vomiting, Headache.

SERIOUS

Myocardial ischemia, Acute Hepatitis.

NOTE: 室溫儲存

·《Contraindications》Advanced aortic stenosis; Hypersensitivity to niCARdipine ;

藥名相似:

外觀相似:

外觀描述: 10mL透明淡黃色注射液『棕』色安瓿頸部有白點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048803

12.08G Calcium Channel Blocking Agents(CCB)

32407 C / Unknown(有

NIMOTOP INFUSION SOLUTION 0.02%W/V 腦妥靜脈輸注液0．02%W/V

■Nimodipine inj 0.02% 50mL vial

Dosage: 1常備品 32407

Adult
·Subarachnoid hemorrhage: IV infusion, initial 1 mg/hr for 2 hrs to minimize the development of hypotension; then, 1-3 mg/hr (24-72 mg daily) for 1-2 wks, followed by 1-3 wks of oral nimodipine therapy

NDA

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 30mg (22549); Inj: 10mg/50mL (32407)

ADR:

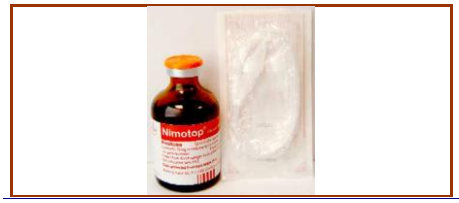
COMMON
abdominal cramps, decreased blood pressure, diarrhea, nausea
SERIOUS
heart failure, arrhythmia

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 50mL透明注射液『橙』蓋棕色玻璃瓶，蓋上有FLIP及OFF字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2018843

12.10A Nitrates & Nitrites

22530 B / Infant risk can

COXINE TABLETS 20MG 冠欣錠20公毫克

Isosorbide mononitrate 20mg tab

Dosage: 1常備品 22530

Adult
·Angina: PO, 20mg bid, with the 2 doses administered 7 hrs apart

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustmetn needed

P: Tab: 20mg (22530), 60mg (22531)

ADR:

COMMON
dizziness, headache, lightheadedness, restlessness, constipation, diarrhea, nausea, vomiting, orthostatic hypotension, tachycardia
SERIOUS
arrhythmias, cardiac failure, severe hypotension

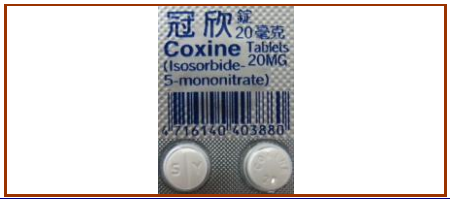
NOTE: 室溫儲存

1. Asymmetrical dosing regimen of 7 AM and 3 PM or 9 AM and 5 PM to allow for a nitrate-free dosing interval to minimize nitrate tolerance
2. Do not crush or chew but can cut half

藥名相似: Tab: 20mg (22530), 60mg (22531)

外觀相似: Isobide* 10mg Tab (22535)

外觀描述: 白色圓扁錠，一面中間有刻痕及S Y字樣，一面有COXINE 20字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043364

12.10A Nitrates & Nitrites

22531 C / Caution

IBIMO C.R.F.C. TABLETS 60 MG "S.C." "十全"愛彼脈持續性藥效膜衣錠60毫克

Isosorbide mononitrate 60mg CR tab

Dosage: 1常備品 22531

Adult
·Angina: PO, initial 30-60mg qd, may be increased to 120 mg qd

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 20mg (22530), 60mg (22531)

ADR:

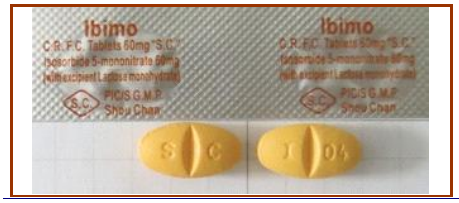
NOTE: 室溫儲存

1. The daily dose should be taken in the morning.
2. Imdur* CR should be swallowed whole not chewed, but it can be administered half of a tablet at a time.

藥名相似:

外觀相似:

外觀描述: 橘色長扁錠，一面中央有刻痕及S C 字樣，一面中央有刻痕及I 04 字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049514

12.10A Nitrates & Nitrites

22532 b3 /

Nirandil tablets 5 mg (Nicorandil) "Standard" "生達" 利可心錠 5 毫克

Nicorandil 5mg tab

Dosage: 1常備品 22532

Adult
·Stable angina: PO, 10-20 mg bid; Max. 40 mg bid
·Variant angina: PO, 5-10 mg qid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 5mg (22532)

ADR:

Headache, postural hypotension, GI disturbances, flushing, rash, dizziness, diarrhea

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面中央有刻痕與"S"及"T"字樣,另一面有"1001"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048991

12.10A Nitrates & Nitrites

22535 C / Caution

ISOBIDE TABLETS 10MG "WEIDAR" "衛達" 易適倍錠 1 0公絲（伊索倍雷）

Isosorbide dinitrate 10mg tab

Dosage: 1常備品 22535

Adult
·Angina: PO, ac, initial 5-20 mg bid-tid; MD 10-40 mg bid-tid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment provided in manufacturer' s labeling

P: Tab: 10mg (22535); Inj: 10mg/10mL (32104)

ADR:

COMMON
headache, hypotension, dizziness, lightheadedness, tachycardia
SERIOUS
methemoglobinemia, syncope, crescendo angina, rebound hypertension

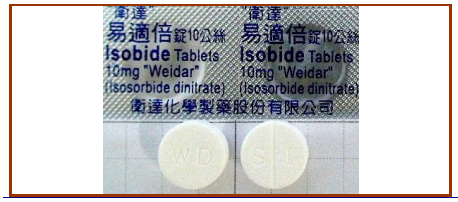
NOTE: 室溫儲存

Dosing interval may be bid or tid and last dose no later than 7 PM to minimize nitrate tolerance

藥名相似: Tab: 10mg (22535); Inj: 10mg/10mL (32104)

外觀相似: Coxine* 20mg Tab (22530)

外觀描述: 白色圓扁錠，一面有WD字樣，另一面刻痕及I S 字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1027438

12.10A Nitrates & Nitrites

22537 ɔt be ruled out / Infant risk can

NITROSTAT 0.6MG 耐絞寧錠 0 · 6 毫克

Nitroglycerin 0.6mg sublingual tab

Dosage: 1常備品 22537

Adult
·Angina, prophylaxis and treatment: sublingual, 0.3-0.6 mg every 5 min x 3; may be taken prophylactically before activity which might induce an attack

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 0.6mg (22537) Inj: 50mg/10mL (32101) Spray: 0.4mg/sp (29051)

ADR:

COMMON
dizziness, lightheadedness, weakness, headache, hypotension, tachycardia, vision disorders, xerostomia, rash
SERIOUS
methemoglobinemia, prolonged bleeding time, thrombocytopenia, exfoliative dermatitis, syncope, crescendo angina, rebound hypertension

NOTE: 避光室溫儲存20-25℃

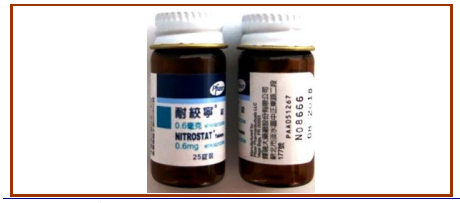
1.It should be preserved in tight glass containers
2.Contraindications: severe anemia; concurrent use

with phosphodiesterase type 5 (PDE-5) inhibitors(eg:sildenafil) or soluble guanylate cyclase inhibitors (riociguat), early myocardial infarction, increased intracranial pressure, symptomatic hypotension
・本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，有N及6字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2020802

12.10A Nitrates & Nitrites

32104 **C / Unknown(有**

ANGIDIL INJECTION 0.1% 怡心通注射液 0.1%

Isosorbide dinitrate 10mg/10mL amp

Dosage: 1常備品 32104

Adult
·Angina: IV infusion, 2-12 mg/hr, up to 20 mg/hr
·CHF: IV infusion, 2-8 mg/hr

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 10mg (22535); Inj: 10mg/10mL (32104)

ADR:

COMMON
headache, hypotension, dizziness, lightheadedness, tachycardia
SERIOUS
methemoglobinemia, syncope, crescendo angina, rebound hypertension

NOTE: 室溫儲存

1.主成分為過飽和狀態，未稀釋下可能會發生結晶現象。若發現結晶，不可使用。稀釋後的溶液應立即使用。若瓶內有剩餘應丟棄。
2.本品應考量藥品吸附問題，適用於玻璃輸注瓶、PE、PP和PTFE材質的輸注裝置，如PE set (例如:Tridil set，NTG set)。
3.配製方法如下：5支10mL Amps(50mg) 稀釋在500mL D5W 形成濃度為100mcg/mL之溶液，輸注速度10mL/hr(=1mg/hr)。限水時，亦可將10支10mL Amps(100mg) 稀釋在200~500mL 中，形成濃度為333~200mcg/mL之溶液， 輸注速度依其配製溶液計算。

藥名相似: Tab: 10mg (22535); Inj: 10mg/10mL (32104)

外觀相似:

外觀描述: 10mL注射液,透明玻璃安瓿

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044974

12.10A Nitrates & Nitrites

32106 **C / Unknown(有**

MILLISROL INJECTION 敏立舒注射液

Nitroglycerin inj 5mg /10mL amp

Dosage: 1常備品 32106

Adult
·Angina: IV infusion, initial 5 mcg/min with increases of 5 mcg/min every 3-5 min until response is noted or infusion rate is 20 mcg/min
·Hypertensive emergencies: IV infusion, 5-100 mcg/min
·Acute myocardial infarction: IV infusion, initial 12.5-25 mcg, followed by continuous infusion at 10-20 mcg/min, increasing the dosage in 5-10 mcg/min increments at 5-10 min intervals as necessary

Pediatric
·

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 0.6mg (22537), Inj:Nitroglycerin 5mg & Mannitol 500mg 10mL Amp (32106)

ADR:

COMMON
dizziness, lightheadedness, asthenia, headache, hypotension, tachycardia, vision disorders, xerostomia, rash
SERIOUS
methemoglobinemia, prolonged bleeding time, thrombocytopenia, scaling eczema, syncope, unstable angina, rebound hypertension

NOTE: 室溫儲存

1. It should be diluted (D5W or NS) before use; glass containers and special nitroglycerin IV sets (non-PVC) should be used
2. Contraindications: concurrent use with sildenafil, constrictive pericarditis, pericardial tamponade, restrictive cardiomyopathy, symptomatic hypotension

藥名相似:

外觀相似:

外觀描述: 10mL注射液棕色安瓿

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2018979

12.10A Nitrates & Nitrites

32109 C / Unknown(有

N.T.G. Premixed Injection 0.2mg/ml 恩舒注射劑 0.2毫克/毫升

Nitroglycerin 50mg /250mL premixed inj

Dosage: 1常備品 32109

Adult
·Angina/coronary artery disease: IV infusion, initial 5 mcg/min with increases of 5 mcg/min every 3-5 min until response is noted or infusion rate is 20 mcg/min.If no response at 20 mcg/minute, may increase by 10 to 20 mcg/minute every 3 to 5 minutes

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Tab: 0.6mg (22537), Inj:Nitroglycerin 50mg/250mL (32109),MILLISROL*5mg (32106)

ADR:

COMMON
Hypotension , flushing , dizziness , headache , Lightheadedness
SERIOUS
Anaphylactoid reaction , methemoglobinemia , raised intracranial pressure

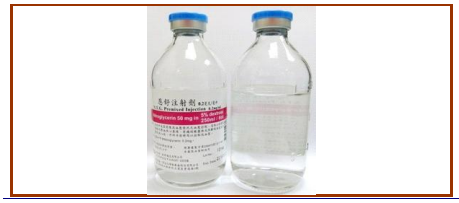
NOTE: 室溫儲存

Contraindications: concurrent use with phosphodiesterase type 5 (PDE-5) inhibitors , constrictive pericarditis, pericardial tamponade, restrictive cardiomyopathy, symptomatic hypotension

藥名相似:

外觀相似:

外觀描述: 250mL透明注射液透明玻璃瓶



12.10B Phosphodiesterase Inhibitor

25236 C /

Pleya Tablets 100 mg 欣行健錠 100 毫克

Cilostazol 100mg tab

Dosage: 1常備品 25236

Adult
·Intermittent claudication: PO, ac, 100mg bid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Use with caution in moderate to severe hepatic impairment

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 100mg (25236)

ADR:

Common
Palpitations, peripheral edema, tachyarrhythmia, abdominal pain, diarrhea, feces contents abnormal, Indigestion, decreased platelet aggregation, backache, myalgia, dizziness, headache, cough, pharyngitis, rhinitis, infectious disease
Serious
Atrial fibrillation, congestive heart failure, myocardial infarction, ventricular tachycardia, Stevens-Johnson syndrome, gastrointestinal ulcer, hematemesis, agranulocytosis, aplastic anemia, ecchymosis, leukopenia, thrombocytopenia, blood in eye, epistaxis, hemoptysis

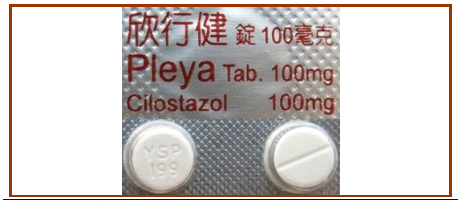
NOTE: 室溫儲存

1. Dosage should be reduced to 50 mg bid during concurrent therapy with inhibitors of CYP3A4 (eg. Diltiazem, itraconazole, ketoconazole, erythromycin, grapefruit juice) or CYP2C19 (eg. Omeprazole).
2. Contraindicated in CHF

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有"YSP 199"字樣，另一面中央有刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1050027

12.10B Phosphodiesterase Inhibitor

25238 B / Caution

CIALIS FILM-COATED TABLETS 5MG 犀利士膜衣錠5毫克

Tadalafil 5mg Tab

Dosage: 1常備品 25238

Adult
·Erectile dysfunction: PO, 2.5 mg once daily at the same time each day; may increase to 5 mg once daily
·Benign prostatic hyperplasia: PO, 5 mg once daily at the same time each day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Child-Pugh class A or B: Use with caution.
Child-Pugh class C: Use is not recommended.

Dosing adjustments in renal impairment:

Clcr 31-50 mL/minute: PO, 2.5 mg once daily; may increase to 5 mg once daily
Clcr <30 mL/minute and on hemodialysis: Use not recommended

P:

ADR:

COMMON
headache, nasal congestion, flushing, back pain,

myalgia, pain in limb, dyspepsia, hypertension (rare), hypotension (rare), tachycardia (rare)
SERIOUS
angina (rare), chest pain (rare), myocardial infarction (rare)

NOTE: 室溫儲存

1. concomitant use of nitrates (any form) either regularly or intermittently
2. hypersensitivity to tadalafil, known serious; Stevens-Johnson syndrome and exfoliative dermatitis have been reported

藥名相似:

外觀相似:

外觀描述: 淡黃色水滴型扁錠，有C5字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025147

12.10B Phosphodiesterase Inhibitor

27221 **B / Caution**

VIAGRA FILM-COATED TABLETS 100MG 威而鋼膜衣錠１００公絲

Sildenafil citrate 100mg FC tab

Dosage: 1常備品 27221

Adult
·Erectile dysfunction: PO, 25-100 mg (50 mg usual dose) 1 hr (range 0.5-4 hr) prior to sexual activity; Max. frequency of administration once daily

Pediatric
Safety and efficacy have not been established
·Pulmonary hypertension: PO (Full-term neonates) 0.5-3 mg/kg/dose q6-12 hrs ;(Infants): Initial: 0.25 mg/kg/dose q6h or 0.5 mg/kg/dose q8h; titrate as needed; Max dose: 1-2 mg/kg/dose q6-8h ;(Children and Adolescents <18 yrs):8-20 kg: 10 mg tid ; >20~45 kg: 20 mg tid ; >45 kg: 40 mg tid

Dosing adjustments in hepatic impairment:

Initial 25mg

Dosing adjustments in renal impairment:

Clcr< 30 mL/min: initial 25 mg

P:

ADR:

COMMON
flushing, dizziness, headache, diarrhea, dyspepsia, abnormal vision, nasal congestion, skin rash.
SERIOUS
myocardial infarction, priapism.

NOTE: 室溫儲存

1.Contraindications: concurrent use of nitrates (eg, nitroglycerin)
2.In pediatric patients (1-17 years of age) with PAH, an increased mortality risk was associated with long-term use (>2 years) at dosage levels of 0.88-2.5 mg/kg/dose administered three times daily

藥名相似:

外觀相似:

外觀描述: 藍色四角形扁錠，有VGR 100及Pfizer字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022383

12.10B Phosphodiesterase Inhibitor

27224 **B / Infant risk can**

Viagra orodispersible tablets 50 mg 威而鋼口溶錠50毫克

Sildenafil citrate 50mg OD tab

Dosage: 1常備品 27224

Adult
·Erectile dysfunction: PO, 50mg 1hr (30 min - 4 hrs) before sexual activity for most patients, dose range : 25-100 mg/day, Max. 100mg qd

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Liver disease: initial, 25 mg

Dosing adjustments in renal impairment:

Clcr less than 30 mL/min: initial, 25 mg

P:

ADR:

COMMON
flushing, dizziness, headach, diarrhea, dyspepsia, abnormal vision, nasal congestion, skin rash.
SERIOUS
myocardial infarction, priapism.

NOTE: 室溫儲存

·Contraindications: concurrent use of nitrates (eg, nitroglycerin) or guanylate cyclase stimulator (eg, riociguat) or HIV protease inhibitors or elvitegravir/cobicistat/tenofovir/emtricitabine
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 藍色菱形扁錠，有pfizer及VGR 50字樣

12.10B Phosphodiesterase Inhibitor

27233 **B / Infant risk can**

CIALIS FILM-COATED TABLETS 20MG 犀利士 膜衣錠２０公絲

Tadalafil 20mg tab

Dosage: 1常備品 27233

Adult

·Erectile dysfunction: PO, initial 10 mg qd; MD 5-20 mg qd

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Child-Pugh Class A or B: Max. 10 mg once daily
Child-Pugh Class C: not recommended

Dosing adjustments in renal impairment:

Clcr < 30 mL/min (on HD): Max. 5 mg once daily; do not repeat more frequently than once every 72 hours
Clcr 31- 50 mL/min: 5 mg once daily; Max. 10 mg q48h

P: Tab:20mg (27233) , 5mg (25238)

ADR:

COMMON
headache, nasal congestion, flushing, back pain, myalgia, pain in limb, dyspepsia, hypertension (rare), hypotension (rare), tachycardia (rare)
SERIOUS
angina (rare), chest pain (rare), myocardial infarction (rare)

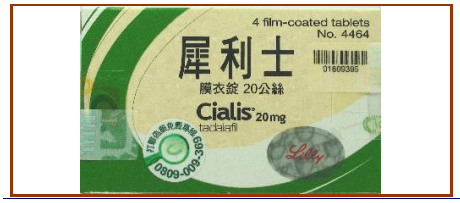
NOTE: 室溫儲存

1. Cialis* improves erectile function for up to 36 hrs following dosing; a possible advantage over sildenafil and vardenafil
2. Contraindication: use of nitrates either regularly or intermittently, use of alpha-blockers other than 0.4 mg tamsulosin

藥名相似:

外觀相似:

外觀描述: 土黃色水滴型扁錠，有C20字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023774

12.10B Phosphodiesterase Inhibitor

27251 ɔt be ruled out / Infant risk can

Revatio 20mg Film-Coated Tablets 瑞肺得膜衣錠20毫克

Sildenafil citrate 20mg FC tab

Dosage: 1常備品 27251

Adult
·Pulmonary hypertension: PO, 20 mg tid; give doses approximately 4 to 6 hr apart.

Pediatric
Safety and efficacy have not been established
·Pulmonary hypertension: PO (Full-term neonates) 0.5-3 mg/kg/dose q6-12 hrs ;(Infants): Initial: 0.25 mg/kg/dose q6h or 0.5 mg/kg/dose q8h; titrate as needed; Max dose: 1-2 mg/kg/dose q6-8h ;(Children and Adolescents <18 yrs):8-20 kg: 10 mg tid ; >20~45 kg: 20 mg tid ; >45 kg: 40 mg tid

Dosing adjustments in hepatic impairment:

no adjustments needed (Child-Pugh class A and B)

Dosing adjustments in renal impairment:

no adjustments needed

P: Tab: 20mg(27251), 100mg(27221)

ADR:

COMMON
Erythema, flushing, indigestion, headache, insomnia, visual disturbance, epistaxis, nasal congestion, rhinitis
SERIOUS
Cardiovascular morbidity, myocardial infarction, sickle cell anemia with vasoocclusive crisis, non-arteritic ischemic optic neuropathy, retinal hemorrhage, sudden decrease of hearing(less than 2%), sudden hearing loss, priapism, prolonged erection of penis

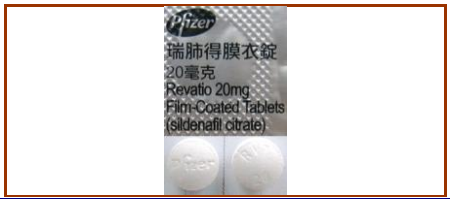
NOTE: 室溫儲存

1.Contraindications: concurrent use of nitrates (eg, nitroglycerin) and riociguat
2.In pediatric patients (1-17 years of age) with PAH, an increased mortality risk was associated with long-term use (>2 years) at dosage levels of 0.88-2.5 mg/kg/dose administered three times daily
3.仿單內容變更，摘述如下：(版本USPI 201208-4)
·加註目前尚未對正在使用bosentan者充分評估過使用本藥治療肺動脈高血壓的療效。
·.禁忌：加註曾在使用sildenafil期間發生過敏反應者。
·警語及注意事項：加註(A)用於兒童時的死亡率-兒童長期試驗曾觀察到死亡率隨本藥劑量增加而升高的現象，死亡的病例最早見於大約1年之後。不建議對兒童使用本藥，尤其是長期使用。(B)視力喪失-增列發生非動脈炎性前部缺血性視神經病變(NAION)的危險因子。?聽力喪失-建議患者在使用PDE-5抑制劑(包括本藥)期間，萬一聽力突然減弱或喪失，應立即就醫。
·不良反應：加註低血壓。
·兒童使用：加註未核准用於18歲以下兒童的適應症。
·藥物交互作用研究：(A)增列其他藥物對本藥之藥動學的影響及本藥對其他藥物之暴露量的影響之體內研究結果。(B)加註與β阻斷劑併用時，本藥的清除率會降低約34%。?加註與與輕度CYP3A誘導劑併用時，本藥的清除率會升高約3倍。與強效的誘導劑合併投予預期會導致本藥的血中濃度明顯降低。
3.仿單內容變更，摘述如下：(版本USPI 201504-2)
1.禁忌：增列併用riociguat。(可能增強riociguat的降壓作用)
2.警語與注意 事項：更新視力喪失之相關資訊。

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有RVT及20字樣，另一面有Pfzer字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024622

12.10C Miscellaneous

22463 C / Infant risk is

STABLE* 10mg tab 血得平錠

Hydralazine HCl 10mg tab

Dosage: 1常備品 22463

Adult
·Hypertension: PO, initial 10 mg qid for 2-4 days then increased to 25 mg qid for remainder of first wk; second and subsequent wks, increase to 50 mg qid; Max. 300 mg/day
·CHF: PO, 200-300 mg/day div. bid-qid

Pediatric
·Essential hypertension: PO, 0.75 mg/kg/day in 4 divided doses; increase dose gradually over 3 to 4 weeks, MAX dose 7.5 mg/kg or 200 mg daily

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Increase dosing interval to every 8-16 hr

P: Tab: 10mg (22463), 50mg (22464), Inj: 20mg/1mL (32031)

ADR:

COMMON
anorexia, diarrhea, nausea, vomiting, chest pain, hypotension, palpitations, tachycardia, dyspnea, nasal congestion, headache, peripheral neuropathy
SERIOUS
agranulocytosis, hepatotoxicity, leukopenia, systemic lupus erythematosus

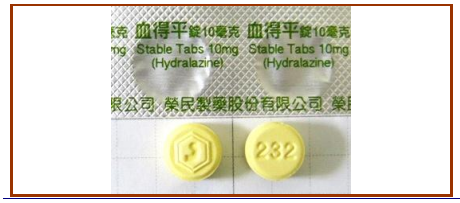
NOTE: 室溫儲存

Contraindications: dissecting aortic aneurysm

藥名相似:

外觀相似:

外觀描述: 黃色圓扁錠，一面印有232字樣，另一面有商標圖案



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1031540

12.10C Miscellaneous

22464 **C / Infant risk is**

Hydralazine HCl 50mg tab

Dosage: 1常備品 22464

Adult
·Hypertension: PO, initial 10 mg qid for 2-4 days then increased to 25 mg qid for remainder of first wk; second and subsequent wk, increase to 50 mg qid; Max. 300 mg/day
·CHF: PO, 200-300 mg/day div. bid-qid

Pediatric
·Essential hypertension: PO, 0.75 mg/kg/day in 4 divided doses; increase dose gradually over 3 to 4 weeks, MAX dose 7.5 mg/kg or 200 mg daily

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Increase dosing interval to q8-16h

P: Tab: 10mg (22463), 50mg (22464), Inj: 20mg/1mL (32031)

ADR:

COMMON
anorexia, diarrhea, nausea, vomiting, chest pain, hypotension, palpitations, tachycardia, dyspnea, nasal congestion, headache, peripheral neuropathy
SERIOUS
agranulocytosis, hepatotoxicity, leukopenia, systemic lupus erythematosus

NOTE: 室溫儲存

Contraindications: dissecting aortic aneurysm

藥名相似:

外觀相似:

外觀描述: 桃紅色圓形糖衣錠

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1030743

12.10C Miscellaneous

22480 **ɔt be ruled out / Infant risk is**

LONITEN 10MG 洛寧錠10公絲

Minoxidil 10mg tab

Dosage: 1常備品 22480

Adult
·Hypertension: PO, initial 5 mg qd, may be increased at 3-day intervals to 10, 20, then 40 mg/day in single or div. doses if required; Max. 100 mg/day

Pediatric (< 12 yrs)
·Hypertension: PO, initial 0.2 mg/kg/day; usual effective range 0.25-1 mg/kg/day div. qd-bid; Max. 50 mg/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Patients with renal failure or those receiving dialysis may require smaller doses of minoxidil (about 1/3 less than in patients who are not receiving dialysis)

P: Tab: 10mg (22480); Soln: 5%, 60mL/bot (29606)

ADR:

COMMON
Hypotension, Hirsutism, Hypertrichosis, Body fluid retention, Hypernatremia.
SERIOUS
Angina pectoris, Cardiac tamponade, Electrocardiogram abnormal, Pericardial effusion, Pericarditis, Tachyarrhythmia, Stevens-Johnson syndrome, Leukopenia, Thrombocytopenia.

NOTE: 室溫儲存

·《Contraindications》hypersensitivity to minoxidil or any component of the product; Pheochromocytoma ;

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，有U,137及10字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2007538

12.10C Miscellaneous

22533 B / Unsafe

DIPYRIDAMOLE S.C. TABLETS "STANDARD" "生達" 待匹力達糖衣錠

Dipyridamole 25mg SC tab

Dosage: 1常備品 22533

Adult
·Thromboembolism prophylaxis in cardiac valve replacement: PO, ac, 75-100 mg qid as an adjunct to warfarin therapy

Pediatric
Safety and efficacy have not been established
·Mechanical prosthetic heart valves: 2-5 mg/kg/day as an adjunct to warfarin therapy

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 25mg(22533); Inj: 10mg/2mL(32060); Cap: Aggrenox* MR(22550)

ADR:

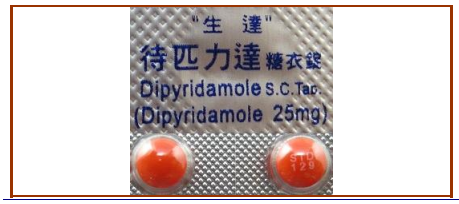
COMMON
abdominal distress, dizziness, ECG changes, headache
SERIOUS
bronchospasm, myocardial infarction, ventricular arrhythmia

NOTE: 室溫儲存

藥名相似: Tab: 25mg(22533); Inj: 10mg/2mL(32060); Ca

外觀相似: Neuquinon* 10mg Tab(26814), Nordazepam

外觀描述: 橘色圓扁糖衣錠,一面有"STD 129"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1013801

12.10C Miscellaneous

22560 demonstrated /

SANYL* TABLETS 暢力糖衣錠

Nicametate citrate 50mg tab

Dosage: 1常備品 22560

Adult
·Peripheral vascular disorders/cerebral insufficiency: PO, 50-100 mg tid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 50mg (22560)

ADR:

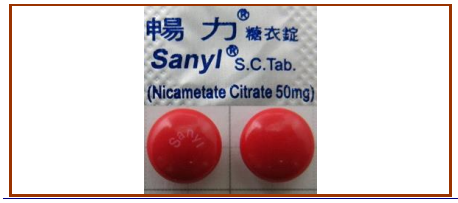
Transient palpitation, flushing

NOTE: 室溫儲存

藥名相似: Tab: 50mg (22560)

外觀相似:

外觀描述: 紅色圓型糖衣錠，一面有"Sanyl"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12009931

12.10C Miscellaneous

27521 X / Caution

TRACLEER FILM COATED TABLETS 62.5MG "全可利"膜衣錠62.5毫克

急用Bosentan 62.5mg tab

Dosage: 2急用藥 27521

Adult
·Pulmonary arterial hypertension (PAH): PO, initial 62.5 mg bid for 4 wks; MD 125 mg bid

Pediatric
Safety and efficacy have not been established
·PAH (Infants ?7 mons and Children): PO,5 -10 kg: Initial: 15.6 mg qd for 4 wks; increase to MD 15.6 mg bid ;10-20 kg: Initial: 31.25 mg qd for 4 wks; increase to MD 31.25 mg bid; 20-40 kg: Initial: 31.25 mg bid for 4 wks; increase to MD 62.5 mg twice daily ; >40 kg: Initial: 62.5 mg bid for 4 wks; increase to MD 125 mg bid

Dosing adjustments in hepatic impairment:

Moderate to severe impairment (Child-Pugh class B and C) and/or baseline transaminase >3 times ULN: contraindication

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 62.5mg(27521), 125mg(27522)

ADR:

COMMON
decreases in hemoglobin, edema, hypotension, palpitations, headache, dyspepsia, nausea, vomiting, flushing
SERIOUS
hepatotoxicity

NOTE: 室溫儲存

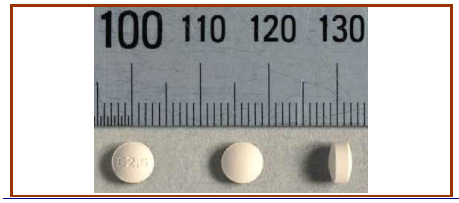
1.Contraindication: concomitant administration with cyclosporine or glyburide, pregnancy,AST/ALT>3ULN
2.When discontinuing treatment, consider a

reduction in dosage to 62.5 mg bid for 3-7 days to avoid clinical deterioration.

藥名相似:

外觀相似:

外觀描述: 淡膚色圓扁錠，有62.5字樣



12.10C Miscellaneous

27522 X / Caution

TRACLEER FILM COATED TABLETS 125MG "全可利" 膜衣錠125毫克

Bosentan 125mg tab

Dosage: 1常備品 27522

Adult
·Pulmonary arterial hypertension (PAH): PO, initial 62.5 mg bid for 4 wks; MD 125 mg bid

Pediatric
Safety and efficacy have not been established
·PAH(Infants ?7 mons and Children): PO,5 -10 kg: Initial: 15.6 mg qd for 4 wks; increase to MD 15.6 mg bid ;10-20 kg: Initial: 31.25 mg qd for 4 wks; increase to MD 31.25 mg bid; 20-40 kg: Initial: 31.25 mg bid for 4 wks; increase to MD 62.5 mg twice daily ; >40 kg: Initial: 62.5 mg bid for 4 wks; increase to MD 125 mg bid

Dosing adjustments in hepatic impairment:

Mild impairment (Child-Pugh class A): No dosage adjustment needed
Moderate to severe impairment (Child-Pugh class B and C) and/or baseline transaminase >3 times ULN: Contraindicated

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 62.5mg(27521), 125mg(27522)

ADR:

COMMON
Edema of lower extremity, hypotension, palpitations, flushing, decreased hemoglobin, headache
SEROIUS
Decreased hemoglobin, cirrhosis of liver, increased liver aminotransferase level, liver failure, angioedema

NOTE: 室溫儲存

1.Contraindication: concomitant administration with cyclosporine or glyburide; pregnancy, AST/ALT>3ULN
2.When discontinuing treatment, consider a reduction in dosage to 62.5 mg bid for 3-7 days to avoid clinical deterioration.

藥名相似:

外觀相似:

外觀描述: 淡膚色長橢圓錠，有125字樣

12.10C Miscellaneous

27555 demonstrated / Infant risk can

Opsumit film-coated tablets 10mg 傲朴舒膜衣錠10毫克

急用Macitentan 10mg tab

Dosage: 2急用藥 27555

Adult
· Pulmonary arterial hypertension： PO, 10 mg qd; max. 10 mg/day.

Pediatric
· Safety and efficacy not established in pediatric patients

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 10mg(27555)(27630)

ADR:

COMMON
Anemia, Influenza, Headache, Urinary tract infectious disease, Bronchitis, Nasopharyngitis, Pharyngitis.
SERIOUS
Hepatitis, Increased liver aminotransferase level.

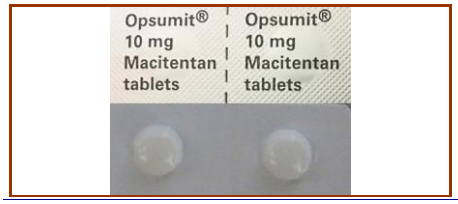
NOTE: 室溫儲存

·《Contraindications》Pregnancy; may cause fetal harm ;
· Adverse effect of Postmarketing: Edema and fluid retention , symptomatic hypotension

藥名相似:

外觀相似:

外觀描述: 白色雙凸膜衣錠，一面有"10"字樣



12.10C Miscellaneous

27563 X / Caution

Adempas film-coated tablets 1.0mg 愛定保肺膜衣錠1.0毫克

急用Riociguat 1.0mg FC tab

Dosage: 2急用藥 27563

Adult
· Chronic thromboembolic pulmonary hypertension (CTEPH), pulmonary arterial hypertension (PAH): PO, initial 1 mg tid, may be increased by 0.5 mg tid no sooner than every 2

weeks to Max 2.5 mg tid if tolerated

Pediatric

· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Severe (Child Pugh C): use not recommended

Dosing adjustments in renal impairment:

Severe (Clcr <15 mL/min): use not recommended
Dialysis: use not recommended

P: P Tab: 0.5mg(27562, 捐贈27975), 1mg(27563, 捐贈27976), 2mg(27565), 2.5mg(27564, 捐贈27977)

ADR:

COMMON
Hypotension, constipation, diarrhea, gastritis, gastroesophageal reflux disease, indigestion, nausea, vomiting, anemia, dizziness, headache
SERIOUS
Bleeding, hemorrhage, hemoptysis

NOTE: 室溫儲存

· Coadministration with nitrates, PDE-5 inhibitors (eg, sildenafil, tadalafil, vardenafil) or nonspecific PDE inhibitors (eg, dipyridamole, theophylline) is contraindicated due to an increased risk of hypotension.

藥名相似:

外觀相似:

外觀描述: 淡黃色圓形雙凸錠，一面有BAYER商標，另一面有1與R字樣

12.10C Miscellaneous

27564 **X / Caution**

Adempas film-coated tablets 2.5mg 愛定保肺膜衣錠2.5毫克

急用Riociguat 2.5mg FC tab

Dosage: 2急用藥 27564

Adult

· Chronic thromboembolic pulmonary hypertension (CTEPH), pulmonary arterial hypertension (PAH): PO, initial 1 mg tid, may be increased by 0.5 mg tid no sooner than every 2 weeks to Max 2.5 mg tid if tolerated

Pediatric

· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Severe (Child Pugh C): use not recommended

Dosing adjustments in renal impairment:

Severe (Clcr <15 mL/min): use not recommended
Dialysis: use not recommended

P: P Tab: 0.5mg(27562, 捐贈27975), 1mg(27563, 捐贈27976), 2mg(27565), 2.5mg(27564, 捐贈27977)

ADR:

COMMON
Hypotension, constipation, diarrhea, gastritis, gastroesophageal reflux disease, indigestion, nausea, vomiting, anemia, dizziness, headache
SERIOUS
Bleeding, hemorrhage, hemoptysis

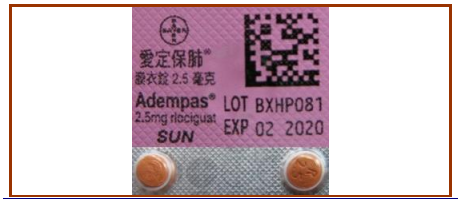
NOTE: 室溫儲存

· Coadministration with nitrates, PDE-5 inhibitors (eg, sildenafil, tadalafil, vardenafil) or nonspecific PDE inhibitors (eg, dipyridamole, theophylline) is contraindicated due to an increased risk of hypotension.

藥名相似:

外觀相似:

外觀描述: 橘紅色圓形雙凸錠，一面有BAYER商標，另一面有2.5與R字樣



12.10C Miscellaneous

27565 **X / Caution**

Adempas film-coated tablets 2.0mg 愛定保肺膜衣錠2.0毫克

急用Riociguat 2mg FC tab

Dosage: 2急用藥 27565

· Chronic thromboembolic pulmonary hypertension (CTEPH), pulmonary arterial hypertension (PAH): PO, initial 1 mg tid, may be increased by 0.5 mg tid no sooner than every 2 weeks to Max 2.5 mg tid if tolerated

· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Severe (Child Pugh C): use not recommended

Dosing adjustments in renal impairment:

Severe (Clcr <15 mL/min): use not recommended

P: P Tab: 0.5mg(27562, 捐贈27975), 1mg(27563, 捐贈27976), 2.5mg(27564, 捐贈27977), 2mg(27565)

ADR:

COMMON
Hypotension, constipation, diarrhea, gastritis, gastroesophageal reflux disease, indigestion, nausea, vomiting, anemia, dizziness, headache
SERIOUS
Bleeding, hemorrhage, hemoptysis

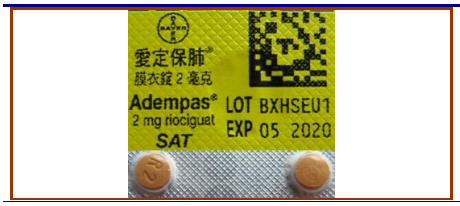
NOTE: 室溫儲存

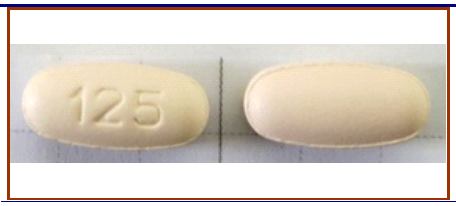
· Coadministration with nitrates, PDE-5 inhibitors (eg, sildenafil, tadalafil, vardenafil) or nonspecific PDE inhibitors (eg, dipyridamole, theophylline) is contraindicated due to an increased risk of hypotension.

藥名相似:

外觀相似:

外觀描述: 淡橘色圓形雙凸錠，一面有BAYER商標，另一面有2與R字樣





12.10C Miscellaneous

27566 X / Caution

TRACLEER Film Coated Tablets 125mg "愛可泰隆"全可利膜衣錠125毫克

急用Bosentan 125mg tab

Dosage: 2急用藥 27566

Adult
·Eisenmenger's syndrome, WHO functional class III PAH: PO 62.5 mg bid for 4 wks, followed by 125 mg bid for an additional 12 wks

Pediatric(?3 yrs)
Safety and efficacy have not been established
·Eisenmenger's syndrome, WHO functional class III PAH : PO, 10-20 kg: Initial: 31.25 mg qd for 4 wks; increase to MD 31.25 mg bid; 20-40 kg: Initial: 31.25 mg bid for 4 wks; increase to MD 62.5 mg twice daily ; >40 kg: Initial: 62.5 mg bid for 4 wks; increase to MD 125 mg bid

Dosing adjustments in hepatic impairment:

Mild impairment (Child-Pugh class A): No dosage adjustment needed
Moderate to severe impairment (Child-Pugh class B and C) and/or baseline transaminase >3 times ULN: Contraindicated

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 62.5mg(27521), 125mg(27522), 125mg(27566, 急用)

ADR:

COMMON
Edema of lower extremity, hypotension, palpitations, flushing, decreased hemoglobin, headache
SEROIUS
Decreased hemoglobin, cirrhosis of liver, increased liver aminotransferase level, liver failure, angioedema

NOTE: 室溫儲存

1.Contraindication: concomitant administration with cyclosporine or glyburide; pregnancy;Moderate to severe impairment (Child-Pugh class B and C) and/or baseline transaminase >3 times ULN
2.When discontinuing treatment, consider a reduction in dosage to 62.5 mg bid for 3-7 days to avoid clinical deterioration.

藥名相似:

外觀相似:

外觀描述: 淡膚色長橢圓錠，有125字樣

12.10C Miscellaneous

27630 demonstrated / Infant risk can

Opsumit*(CM) film-coated tablets 10 mg 奧欣明膜衣錠10毫克

急用Macitentan 10mg tab

Dosage: 2急用藥 27630

Adult
· Pulmonary arterial hypertension： PO, 10 mg qd; max. 10 mg/day

Pediatric
· Safety and efficacy have not established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

COMMON
Anemia, Influenza, Headache, Urinary tract infectious disease, Bronchitis, Nasopharyngitis, Pharyngitis.
SERIOUS
Hepatitis, Increased liver aminotransferase level.

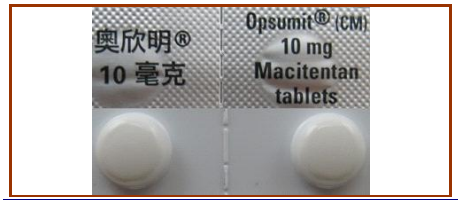
NOTE: 室溫儲存

·《Contraindications》Pregnancy; may cause fetal harm ;
·Adverse effect of Postmarketing: Edema and fluid retention , symptomatic hypotension.

藥名相似:

外觀相似:

外觀描述: 白色雙凸膜衣錠，一面有"10"字樣



12.10C Miscellaneous

27633 ɔt be ruled out / Infant risk can

UPTRAVI* film-coated tablets 800 mcg 尚達利膜衣錠800微克

急用Selexipag 800mcg FC tab

Dosage: 2急用藥 27633

Adult
· Pulmonary arterial hypertension: PO, Initial, 200 mcg bid; increase to the highest tolerated dose in 200-mcg twice-daily increments at weekly intervals, up to 1600 mcg twice daily. If dose is not tolerated,

reduce to the previously tolerated dose

Pediatric
· Safety and efficacy have not been established in pediatric patients

Dosing adjustments in hepatic impairment:

Moderate (Child-Pugh class B): PO, initial, 200 mcg qd and increase in increments of 200 mcg qd at weekly intervals as tolerated
Severe (Child-Pugh class C): Avoid use

Dosing adjustments in renal impairment:

GFR greater than 15 mL/min/1.73 m(2): No adjustments needed

P: P Tab: 200mcg(捐贈27891,急用27631), 600mcg(捐贈27892,急用27632), 800mcg(捐贈27893,急用27633)

ADR:

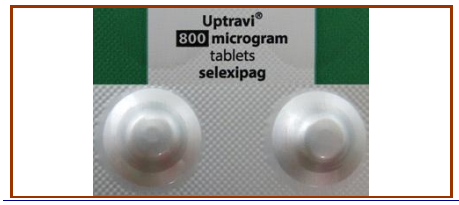
COMMON
Diarrhea, Nausea, Jaw pain, Headache
SERIOUS
Decreased hemoglobin

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 『綠』色圓扁錠，一面有"8"字樣



12.10C Miscellaneous

27975 **X / Caution**

Adempas film-coated tablets 0.5mg 愛定保肺膜衣錠0.5毫克

捐贈急用Riociguat 0.5mg FC tab

Dosage: 2急用藥 27975

Adult
· Chronic thromboembolic pulmonary hypertension (CTEPH), pulmonary arterial hypertension (PAH): PO, initial 1 mg tid, may be increased by 0.5 mg tid no sooner than every 2 weeks to Max 2.5 mg tid if tolerated

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Severe (Child Pugh C): use not recommended

Dosing adjustments in renal impairment:

Severe (Clcr <15 mL/min): use not recommended
Dialysis: use not recommended

P: P Tab: 0.5mg(27562, 捐贈27975), 1mg(27563, 捐贈27976), 2mg(27565), 2.5mg(27564, 捐贈27977)

ADR:

COMMON
Hypotension, constipation, diarrhea, gastritis, gastroesophageal reflux disease, indigestion, nausea, vomiting, anemia, dizziness, headache
SERIOUS
Bleeding, hemorrhage, hemoptysis

NOTE: 室溫儲存

· Coadministration with nitrates, PDE-5 inhibitors (eg, sildenafil, tadalafil, vardenafil) or nonspecific PDE inhibitors (eg, dipyridamole, theophylline) is contraindicated due to an increased risk of hypotension.

藥名相似:

外觀相似:

外觀描述: 白色圓形雙凸錠，一面有BAYER商標，另一面有0.5與R字樣

12.10C Miscellaneous

27976 **X / Caution**

Adempas film-coated tablets 1.0mg 愛定保肺膜衣錠1.0毫克

捐贈急用Riociguat 1.0mg FC tab

Dosage: 2急用藥 27976

Adult
· Chronic thromboembolic pulmonary hypertension (CTEPH), pulmonary arterial hypertension (PAH): PO, initial 1 mg tid, may be increased by 0.5 mg tid no sooner than every 2 weeks to Max 2.5 mg tid if tolerated

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Severe (Child Pugh C): use not recommended

Dosing adjustments in renal impairment:

Severe (Clcr <15 mL/min): use not recommended
Dialysis: use not recommended

P: P Tab: 0.5mg(27562, 捐贈27975), 1mg(27563, 捐贈27976), 2mg(27565), 2.5mg(27564, 捐贈27977)

ADR:

COMMON
Hypotension, constipation, diarrhea, gastritis, gastroesophageal reflux disease, indigestion, nausea, vomiting, anemia, dizziness, headache
SERIOUS
Bleeding, hemorrhage, hemoptysis

NOTE: 室溫儲存

· Coadministration with nitrates, PDE-5 inhibitors (eg, sildenafil, tadalafil, vardenafil) or nonspecific PDE inhibitors (eg, dipyridamole, theophylline) is contraindicated due to an increased risk of hypotension.

藥名相似:

外觀相似:

外觀描述: 淡黃色圓形雙凸錠，一面有BAYER商標，另一面有1與R字樣

12.10C Miscellaneous

29821 C / Unsafe

VENTAVIS NEBULISER SOLUTION 菲塔敏思

急用Iloprost nebuliser soln 20mcg/2mL amp

Dosage: 2急用藥 29821

Adult
·Pulmonary arterial hypertension(PAH): Nebulization, initial 2.5mcg, dose may be increased to 5mcg; administer 6-9 times daily at minimum intervals of 2 hours according to individual need and tolerability; Max. 45mcg/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Initial 2.5mcg given at intervals of at least 3 hours (Max. 6 times daily); use with caution

Dosing adjustments in renal impairment:

no dosage adjustment is necessary in patients not receiving dialysis

P: Nebuliser soln: 20mcg/2mL Amp(29821)

ADR:

COMMON
Vasodilatation, flushing, trismus, headache, increasing frequency of cough
SERIOUS
Hypotension, bronchospasm, pulmonary edema

NOTE: 室溫儲存

·Do not initiate therapy in patients with systolic blood pressure below 85mmHg.
·The duration of one inhalation session is about 4-10 mins.

藥名相似:

外觀相似:

外觀描述: 2mL透明液，透明安瓿瓶頸部有藍點

12.10C Miscellaneous

32060 B / Unsafe

POSINTIN INJECTION 保心丁注射液

Dipyridamole inj 10mg/2mL amp

Dosage: 1常備品 32060

Adult
·Myocardial perfusion imaging: IV infusion, 0.142 mg/kg/min (0.57 mg/kg total) over 4 min prior to thallium; Max. 60 mg

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 25mg(22533); Cap: Aggrenox* MR(22550); Inj: 10mg/2mL(32060)

ADR:

COMMON
dizziness, ECG changes, headache, hypotension, nausea
SERIOUS
bronchospasm, exacerbation of angina pectoris, myocardial infarction, ventricular arrhythmia

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 2mL淡黃色透明注射液透明安瓿，頸部上有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12006489

12.10C Miscellaneous

32135 C / Caution

PROMOSTAN FOR INJECTION 保脈暢注射劑

Alprostadil alfadex inj 666mcg(=20mcg alprostadil) pow in vial

Dosage: 1常備品 32135

Adult
·Peripheral obstructive arterial diesase: Intraarterial: continuous infusion 10-15 mcg/day (0.1-
0.15 ng/kg/min) IV infusion (over 2 hrs): 40-60 mcg in 500 mL IV fluid infused at 5-10 ng/kg/min once to twice daily; dose should not exceed 1.2 mcg/kg/2hrs

Pediatric
·Cyanotic congenital heart disease: IVD, initial 0.05 to 0.1 mcg/kg/min continuous IV, maintenance 0.01 to 0.4 mcg/kg/min
·Patent ductus arteriosus, Palliative: IVD, initial 0.05-0.1 mcg/kg/min,after response is achieved reduce infusion rate to lowest dose needed to maintain response; reduce the dosage incrementally from 0.1 - 0.05- 0.025 - 0.01 mcg/kg/min

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 20mcg (32135)

ADR:

COMMON
bradycardia, fever, hypotension, penile pain, penile fibrosis, ache in penis, testicles and perineum, warmth or burning in urethra,
tachycardia.
SERIOUS
neonatal apnea, seizures, priapism, CHF, second degree heart block, supraventricular tachycardia, ventricular fibrillation,
disseminated intravascular coagulation,
cortical proliferation of long bones.

NOTE: 室溫保存

Contraindication: anatomical deformation of the penis, leukemia, myeloma, neonatal respiratory distress, penile implant, Peyronie's disease, predisposition to priapism, sickle cell anemia or trait

藥名相似:

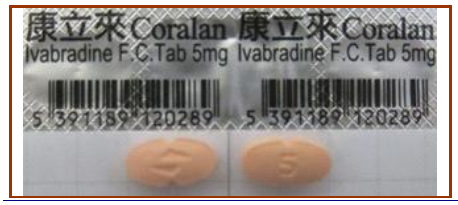
外觀相似:

外觀描述: 白色乾粉，黃蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2018720

字樣，另一面刻有藥廠標誌



12.14 Miscellaneous

22575 **x / Unsafe**

Coralan film-coated tablets 5 mg 康立來 膜衣錠5毫克

Ivabradine 5mg FC tab

Dosage: 1常備品 22575

Adult
·Heart failure, chronic: PO, Initial 5 mg bid. After 2 wks, adjust based on heart rate; for resting rate>60 bpm, 7.5mg bid; HR=50~60 bpm, 5mg bid; HR< 50 bpm, 2.5mg bid ; MAX: 7.5 mg bid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Child-Pugh A and B: No adjustment required.
Child-Pugh C: Contraindicated.

Dosing adjustments in renal impairment:

CrCl > 15 mL/min: No adjustment required.

P: Tab: 5mg(22575)

ADR:

COMMON
Atrial fibrillation, Bradyarrhythmia

NOTE: 室溫儲存

Contraindications: acute decompensated heart failure, concomitant use with strong CYP3A4 inhibitors, pacemaker dependent,resting heart rate below 60 beats per minute before treatment,severe hepatic impairment,severe hypotension

藥名相似:

外觀相似:

外觀描述: 淺橙色橢圓形膜衣錠，雙邊刻痕，一面刻有"5"

14.02A1 Opiate Agonist

22798 C / Unsafe

OxyNorm Immediate Release Capsules 奧諾美5毫克速效膠囊

■Oxycodone HCl 5mg cap

Dosage: 1常備品 22798

Adult
·Pain (Moderate to Severe)
Opioid naive: PO, initial 5-15 mg q4-6 h, adjusted according to response.
Conversion from other opioids: Initial dose should be based on the daily opioid requirement. (10 mg of oxycodone is equivalent to 20 mg of morphine)

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Initiate at one-third to one-half the usual recommended dose and titrate with caution.

Dosing adjustments in renal impairment:

NDA

P: P Cap: 5mg IR cap (22798); Tab: 10mg CR tab (27252)

ADR:

COMMON
Pruritus, sweating, abdominal pain, constipation, nausea, vomiting, xerostomia, asthenia, dizziness, headache, somnolence, fever
SERIOUS
Cardiac arrest, chest pain, heart failure, hypotension, shock, ST segment depression, syncope, bowel obstruction, diverticulitis, exacerbation, hypersensitivity reaction, respiratory depression, drug withdrawal syndrome in neonate of dependent mother, opioid withdrawal

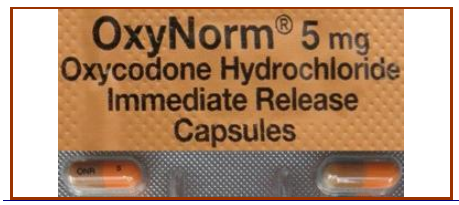
NOTE: 請勿保存於超過 30℃的環境。

·《Contraindications》Acute or severe bronchial asthma; in the absence of resuscitative equipment or in unmonitored settings; Known or suspected gastrointestinal obstruction; Hypercarbia; Hypersensitivity to oxycodone, oxycodone salts, or any product component; Known or suspected paralytic ileus; Significant respiratory depression; in the absence of resuscitative equipment or in unmonitored settings ;

藥名相似:

外觀相似:

外觀描述: 褐色/橘色膠囊，上有ONR、5字樣



14.02A1 Opiate Agonist

22799 C / Caution

PAINKYL fentanyl (buccal soluble films) 600mcg 平舒疼口頰溶片600微公克

■急用Fentanyl 600mcg Buccal Soluble Films

Dosage: 2急用藥 22799

·Breakthrough cancer pain in opioid-tolerant patients: Initial dose: 200 mcg ; If titration required, increase dose in 200 mcg increments once per episode using multiples of the 200 mcg film (for doses up to 1200 mcg) and limit to 4 application per day

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Use with caution.

Dosing adjustments in renal impairment:

Use with caution.

P: P Tab:600mcg(急22799); 200mcg(22816); TTS: 12 mcg/hr(29130), 25mcg/hr(29129), 50mcg/hr(29128); Inj: 0.1mg/2mL Amp(32401), 0.5mg/10mL Amp(32399),1mg/2mL Amp(32412); PCEA: 1mg/500mL(38308), 0.2mg/100mL(38309), 0.5mg/500mL(38306)

ADR:

COMMON
Pruritus, rash, dizziness, nausea, vomiting, abdominal distension, fatigue, malaise, dehydration, decreased appetite, anorexia, anxiety, agitation, hallucination, urinary retention, somnolence, headache, sedation , depression, insomnia, disturbance in attention
SERIOUS
Confusional state, loss of consciousness

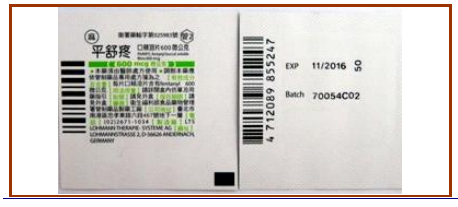
NOTE: 室溫儲存

·《Contraindications》Acute or postoperative pain including use after outpatient or day surgeries, or if analgesia is required for a short time period; risk of life-threatening hypoventilation; Acute or severe bronchial asthma; Known or suspected gastrointestinal obstruction; Hypersensitivity to fentanyl or any components of the product; Mild or intermittent pain management; risk of life-threatening hypoventilation; Opioid non-tolerant patients; Known or suspected paralytic ileus; Significant respiratory depression, especially in unmonitored settings or settings that lack resuscitative equipment ;
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 口頰溶片,白底黑字紙袋包裝,有部分綠色字,有黑字"麻"及黑色六角型"管2"字樣



14.02A1 Opiate Agonist

22800 C / Infant risk has

Codeine Phosphate Tablets 30mg 磷酸可待因錠30毫克

■Codeine phosphate 30mg tab

Dosage: 1常備品 22800

Adult
·Analgesic: PO, 15-60 mg q4-6h as needed, Max. 360mg/day
·Antitussive: PO, 10-20mg q4-6h, Max. 120 mg/day

Pediatric
·Analgesic: PO, 3 mg/kg or 100 mg/m2 daily in 6 divided doses. Alternatively, children may be given 0.5 mg/kg or 15 mg/m2 q4-6h
·Antitussive:
2- 6yrs: PO, 1 mg/kg/day in 4 divided doses, Max. 30 mg/day
6-12yrs: PO, 5-10 mg/dose q4-6h, Max. 60 mg/day

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Clcr 10-50 mL/min: 75% of the usual dose
Clcr <10 mL/min: 50% of the usual dose

P: Tab: 30mg(22800)

ADR:

COMMON
constipation, nausea, vomiting, drowsiness, sedation
SERIOUS
anaphylactoid reactions, convulsions, respiratory depression

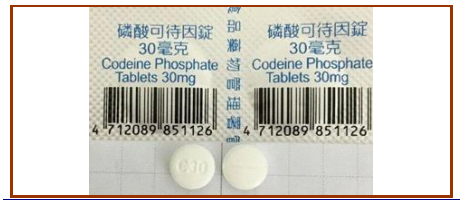
NOTE: 室溫儲存

·《Contraindications》Children younger than 12 years of age; Post-operative management in children younger than 18 years of age following tonsillectomy or adenoidectomy； Significant respiratory depression; Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; Concurrent use of MAO inhibitors or use of MAOIs within the last 14 days; Known or suspected gastrointestinal obstruction, including paralytic ileus; Hypersensitivity to codeine (e.g., anaphylaxis)；
·[D] if used for prolonged peroids or in high doses at term

藥名相似:

外觀相似:

外觀描述: 雙凸面圓錠,一面刻有"C30"字樣,另一面中央有刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1005865

14.02A1 Opiate Agonist

22805 ɔt be ruled out / Infant risk can

MORPHINE SULFATE SUSTAINED-RELEASE* F.C. TABLETS 30MG "PPCD 〝管制藥品廠〞嗎啡長效膜衣錠30毫克

■Morphine sulfate SR 30mg FC tab

Dosage: 1常備品 22805

Adult
·Analgesic: PO, 30mg q12h, dosage can be adjusted by severity of pain, patient's age and previous analgesic requirements

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Dosage adjustment required

P: Tab: 10mg(22804), 30mg(22805), 60mg (22806); Cap: 60mg(22814); Tr: 9.5-10.5mg/mL, 10mL/Bot (28521), 0.38-0.42mg/mL, 25mL/Bot (28522); Inj: 10mg/1mL Amp(32408), 20mg/1mL Amp(32402)

ADR:

COMMON
constipation, nausea, urinary retention, vomiting, dizziness, headache, light-headedness, sedation, weakness
SERIOUS
allergic reaction, confusion, histamine release, hypotension, respiratory depression

NOTE: 室溫儲存

·《Contraindications》Significant respiratory depression; Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; Known or suspected gastrointestinal obstruction, including paralytic ileus; Hypersensitivity (eg, anaphylaxis) to morphine; Neuraxial administration contraindications include: infection at injection microinfusion site, concomitant anticoagulant therapy, uncontrolled bleeding diathesis, or the presence of any other concomitant therapy or medical condition which would render epidural or intrathecal administration of medication especially hazardous；
·Swallow whole, do not crush or chew

藥名相似:

外觀相似:

外觀描述: 深紫色圓扁錠，有30及NNB字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1042534

14.02A1 Opiate Agonist

22809 C / Infant risk has

CAMADOL CAPSULES 50MG (TRAMADOL HCL) 卡莫德膠囊 5 0 公絲

Tramadol HCl 50mg cap

Dosage: 1常備品 22809

Adult
·Moderate to severe chronic pain: PO, initial 25 mg/day, MD 50-100 mg q4-6h, Max. 400mg/day

Pediatric(≧ 17yrs)
·same as adult

Dosing adjustments in hepatic impairment:

Hepatic cirrhosis: 50 mg q12h

Dosing adjustments in renal impairment:

Clcr <30 mL/min: 50-100mg q12h, Max. 200 mg/day
ESRD: 50mg q12h

P: Cap: 50mg(22809);Tab:TRAMACET*(22831); Inj: 100mg/2mL Amp(32413)

ADR:

COMMON
constipation, diarrhea, nausea, vomiting, dizziness, drowsiness, headache, pruritus
SERIOUS
anaphylactoid reactions, cognitive dysfunction, hallucinations, seizures, dyspnea, orthostatic hypotension, syncope, tachycardia

NOTE: 室溫儲存

·《Contraindications》All children younger than 12 years; Postoperative management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy; Significant respiratory depression; Acute or severe bronchial asthma, in unmonitored settings or without resuscitative equipment; Known or suspected gastrointestinal obstruction, including paralytic ileus; Hypersensitivity to traMADol, any other component of the product, or opioids; Concurrent use of MAOIs or use within the last 14 days；

藥名相似:

外觀相似:

外觀描述: 綠色/黃色膠囊

14.02A1 Opiate Agonist

22813 **C / Infant risk can**

MUACTION* SUSTAINED RELEASE TABLETS 100MG "美時" 妙而通持續釋放錠１００公絲（鹽酸妥美度）

Tramadol Hcl 100mg SR TAB

Dosage: 1常備品 22813

Adult
·Moderate to severe chronic pain: PO, 100-200 mg QD-BID; Max. 400 mg QD

Pediatric
Adolescents over 12 years of age:same as adult

Dosing adjustments in hepatic impairment:

Should not be used in patients with severe hepatic impairment (Child-Pugh class C)

Dosing adjustments in renal impairment:

Should not be used in patients with severe renal impairment (Clcr < 30 mL/min)

P: Tab: 100mg(22813); Cap: 50mg(22811); TRAMACET*(22831); Inj: 100mg/2mL Amp(32413)

ADR:

COMMON
Flushing, pruritus, constipation, nausea, vomiting, xerostomia, dizziness, headache, insomnia, somnolence
SERIOUS
Myocardial infarction, pancreatitis, anaphylactoid reaction, dyspnea, respiratory depression, seizures (doses exceeding the recommended range, in patients with epilepsy, a history of seizures, or other risk for seizures). serotonin syndrome (life-threatening, particularly with concomitant use of serotonergic drugs)

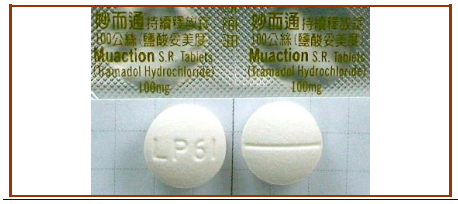
NOTE: 室溫儲存

·《Contraindications》All children younger than 12 years; Postoperative management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy; Significant respiratory depression; Acute or severe bronchial asthma, in unmonitored settings or without resuscitative equipment; Known or suspected gastrointestinal obstruction, including paralytic ileus; Hypersensitivity to traMADol, any other component of the product, or opioids; Concurrent use of MAOIs or use within the last 14 days；
·Swallow whole. Do not crush, break, or chew it.

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠,一面有刻痕,一面有"LP61"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1042770

14.02A1 Opiate Agonist

22814 **X / Unsafe**

MXL* CAPSULES 60MG 默痛舒持續性藥效膠囊60毫克

■Morphine sulfate 60mg cap

Dosage: 1常備品 22814

Adult
·For severe uncontrolled pain: PO, 60 mg qd, dosage can be adjusted by severity of pain, patient's age and previous analgesic requirements

Pediatric
Children aged 1 year and above
·For severe and intractable pain in cancer: PO, 0.4-1.6 mg/kg/day. Doses should be titrared in the normal way as for adults.

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Dosage adjustment required

P: Tab: 10mg(22804), 30mg(22805), 60mg (22806); Cap: 60mg(22814); Tr: 9.5-10.5mg/mL, 10mL/Bot (28521), 0.38-0.42mg/mL, 25mL/Bot (28522); Inj: 10mg/1mL Amp(32408), 20mg/1mL Amp(32402)

ADR:

COMMON
constipation, nausea, urinary retention, vomiting, dizziness, headache, light-headedness, sedation, weakness
SERIOUS
allergic reaction, confusion, histamine release, hypotension, respiratory depression

NOTE: 室溫儲存

·《Contraindications》Significant respiratory depression; Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; Concomitant use with MAOIs, or use of MAOIs within 14 days; Known or suspected gastrointestinal obstruction, including paralytic ileus; Hypersensitivity (eg, anaphylaxis) to morphine; Neuraxial administration contraindications include: infection at injection microinfusion site, concomitant anticoagulant therapy, uncontrolled bleeding diathesis, or the presence of any other concomitant therapy or medical condition which would render epidural or intrathecal administration of medication especially hazardous. ;
·The capsules may be swallowed whole or opened and the contents sprinkled on to soft cold food. The capsules and contents should not be crushed or chewed.

藥名相似:

外觀相似:

外觀描述: 棕色膠囊，有MS OD60字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023779

14.02A1 Opiate Agonist

22816 **C / Caution**

PAINKYL fentanyl (buccal soluble films) 200mcg 平舒疼口頰溶片200微公克

■Fentanyl citrate 0.31mg tab(= fentanyl 200mcg)

Dosage: 1常備品 22816

Adult
·Breakthrough cancer pain in opioid-tolerant patients: starting dose, must begin treatment using one 200 mcg film.
·If adequate pain relief is not achieved after one 200 mcg film, increase the dose by 200 mcg in each subsequent episode until the patient reaches a dose that provides adequate analgesia with tolerate side effects. Do not use more than 4 of the 200 mcg films simultaneously.
·Single doses should be separated by at least 2 hours. Should only be used once per breakthrough cancer pain episode, i.e.,should not be redosed within an episode.
·During any episode of breakthrough cancer pain, if adequate pain relief is not achieved, patient may use a rescue medication (after 30 minutes).

Pediatric
·Safety and efficacy have not been established in patients less than 18 years old.

Dosing adjustments in hepatic impairment:

Use with caution, because of the hepatic metabolismn of fentanyl.

Dosing adjustments in renal impairment:

Use with caution, because of the renal excretion of fentanyl.

P:

ADR:

COMMON
Pruritus, rash, vision blurred, diplopia, dizziness, nausea, vomiting, constipation, diarrhea, dry mouth, abdominal pain, dyspepsia, dysphagia, abdominal distension, intestinal obstruction, flatulence, asthenia, fatigue, malaise, weight decreased, blood pressure increased, dehydration, decreased appetite, anorexia, anxiety, agitation, hallucination, urinary retention, somnolence, headache, lethargy, amnesia, sedation , depression, insomnia, disturbance in attention
SERIOUS
Fall, contusion, tachycardia, confusional state, loss of consciousness, hypotension, hypertension, deep vein thrombosis

NOTE: 室溫儲存

·《Contraindications》Acute or postoperative pain including use after outpatient or day surgeries, or if analgesia is required for a short time period; risk of life-threatening hypoventilation; Acute or severe bronchial asthma; Known or suspected gastrointestinal obstruction; Hypersensitivity to fentanyl or any components of the product; Mild or intermittent pain management; risk of life-threatening hypoventilation; Opioid non-tolerant patients; Known or suspected paralytic ileus; Significant respiratory depression, especially in unmonitored settings or settings that lack resuscitative equipment ;
·Due to the risk of fatal respiratory depression, this product (immediate-release transmucosal fentanyl) is contraindicated in opioid non-tolerant patients and in management of acute or postoperative pain, or use in the emergency room.

藥名相似:

外觀相似:

外觀描述: 口頰溶片,白底黑字紙袋包裝,有部分藍色字,有黑字"麻"及黑色六角型"管2"字樣

14.02A1 Opiate Agonist

22817 **C / Unsafe**

JURNISTA* prolonged-release tab 8mg 釋通緩釋錠8毫克

■Hydromorphone 8mg prolonged-release tab

Dosage: 1常備品 22817

Adult
·Moderate to severe pain (opioid-tolerant): PO, Inital at 50% of the calculated total daily dosage and administered q24h, then titrated upward every 3-4 days as needed.
(1)Conversion from PO opioids: The starting dose should be based on the prior daily opioid dose (the total opioid dose in mg regardless of the dosage form) and a 5:1 conversion ratio of morphine to hydromorphone is recommended
(2)Conversion from transdermal fentanyl: 12mg q24h for each 25mcg/hr fentanyl transdermal dose; initiate 18 hrs following removal of patch

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Moderate impairment: reduce the initial dose to 25% of the normal dose
Severe impairment: use alternative analgesic

Dosing adjustments in renal impairment:

Moderate impairment: reduce initial dose to 50% of the normal dose
Severe impairment: initiate at 25% of the normal dose or consider an alternative analgesic to permit a more flexible dosing interval

P: Tab: 8mg(22817)

ADR:

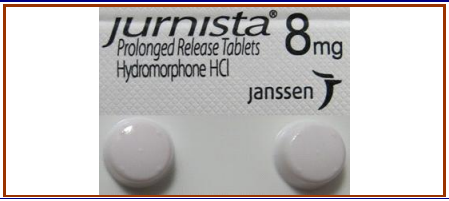
NOTE: 室溫儲存

·《Contraindications》Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; Hypersensitivity to HYDROmorphone, HYDROmorphone salts, or any of component of the products, including sulfites; Known or suspected gastrointestinal obstruction, including paralytic ileus; Opioid non-tolerant patients; increased risk of fatal respiratory depression; Patients with or at increased risk of gastrointestinal narrowing or obstruction due to underlying disease or surgical procedure or who have "blind loops" of the gastrointestinal tract; Significant respiratory depression ;
·Swallow whole, do not break, chew, dissolve or crush.
·All other around-the-clock opioid anagesic medications should be discontinued when when JURNISTA therapy is initiated.
·An opioid-tolerant patient is defined as using at least 60mg of oral morphine/day, 25mcg transdermal fentanyl/hr, 30mg oral oxycodone/day, 8mg oral hydromorphone/day, 25mg oral oxymorphone/day or an equianalgesic dose of another opioid, for a week or longer.
·Gradually titrate downward by 25-50% every 2-3 days to a dose of 8 mg prior to discontinuation.

藥名相似:

外觀相似:

外觀描述: 紅色圓形錠，一面印有HM 8 字樣



14.02A1 Opiate Agonist

22818 ɔt be ruled out / Infant risk can

"PPCD"Morphine Sulfate Tablets 15mg "管制藥品廠"硫酸嗎啡錠15毫克

■Morphine sulfate 15mg tab

Dosage: 1常備品 22818

Adult
·Analgesic: PO, 10-30 mg q4h

Pediatric
·Analgesic: PO, 0.125-0.225 mg/kg q6h(neonate) or 0.2-0.4mg/kg q4-q6h(children)

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Clcr 10-50 mL/min: 75% of the normal dose
Clcr <10 mL/min: 50% of the normal dose

P:

ADR:

COMMON
constipation, nausea, urinary retention, vomiting, dizziness, headache, light-headedness, sedation, weakness
SERIOUS
allergic reaction, confusion, histamine release, hypotension, respiratory depression

NOTE: 室溫儲存

·《Contraindications》Significant respiratory depression; Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; Concomitant use with MAOIs, or use of MAOIs within 14 days; Known or suspected gastrointestinal obstruction, including paralytic ileus; Hypersensitivity (eg, anaphylaxis) to morphine; Neuraxial administration contraindications include: infection at injection microinfusion site, concomitant anticoagulant therapy, uncontrolled bleeding diathesis, or the presence of any other concomitant therapy or medical condition which would render epidural or intrathecal administration of medication especially hazardous. ;
·[D] if used for prolonged periods or in high doses at term

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有"m"字樣，另一面中央有刻痕

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1057779

14.02A1 Opiate Agonist

22831 **B / Infant risk has**

Tramacet F.C. Tablets "五洲"妥美亭膜衣錠

Tramadol 37.5mg & Acetaminophen 325mg Tab

Dosage: 1常備品 22831

Adult
·Analgesia: PO, 1-2 tabs q4-6h as needed, Max. 8 tabs/day

Pediatric(>16 yrs)
·Analgesia: PO, 1-2 tabs q4-6h as needed, Max. 8 tabs/day
·Safety and efficacy have not been established in patients less than 16 years old

Dosing adjustments in hepatic impairment:

Use is not recommended

Dosing adjustments in renal impairment:

Clcr<30mL/min: Increase dosing interval to q12h, Max. 4 tabs/day

P: Tab: Tramacet*(22831); Acetaminophen 80mg(22830)(39313健診), 500mg(22827); Syrup: Acetaminophen 24mg/mL, 60mL/Bot(28531); Cap: Tamadol 50mg, Tab: 100mg, Inj: Tramadol 100mg Amp(32413); Inj: Propacetamol 1 gm(32435) Vial; Cap: 50mg(22809)

ADR:

COMMON
hypothermia, rash
SERIOUS
GI bleeding, hepatotoxicity, nephrotoxicity, pneumonitis

NOTE: 室溫儲存

·《Contraindications》All children younger than 12 years; Postoperative management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy; Significant respiratory depression; Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; Known or suspected gastrointestinal obstruction, including paralytic ileus; Previous hypersensitivity to traMADol, acetaminophen, any other component of the product, or opioids; Concurrent use of monoamine oxidase inhibitors (MAOIs) or use within the last 14 days ;
·Acetylcysteine is the antidote of acetaminophen

藥名相似:

外觀相似:

外觀描述: 米黃色長橢圓錠，有UC 75字樣

14.02A1 Opiate Agonist

27252 **C / Unsafe**

OxyContin Controlled-Release Tablets 10 mg 疼始康定10毫克持續藥效錠

■Oxycodone HCl 10 mg controlled-release tab

Dosage: 1常備品 27252

Adult
·Severe pain requiring around-the-clock long-term opioid therapy: PO, initial
(1) Opioid naive or not opioid-tolerant: 10 mg q12h
(2) Conversion from other oral oxycodone formulations: 1/2 of total daily oxycodone requirement q12h
(3) Conversion from other opioids: 10 mg q12h
(4) Conversion from fentanyl TTS: initiate 18 hrs following removal of patch, 10 mg q12h for 25 mcg/hr of fentanyl TTS
Doses should be titrate by 25-50% dose q1-2 days based on analgesic requirement and tolerance

Pediatric (≧11yrs):
·Severe pain requiring around-the-clock long-term opioid therapy: PO, initial dose administered q12h = (mg/day of current opioid regimen X conversion factor)/ 2
Conversion Factor (only for calculating Initial dose): Oxycodone X 1; Hydrocodone X 0.9; Hydromorphone X 4; Morphine X 0.5; Tramadol X 0.17

Dosing adjustments in hepatic impairment:

Initiate at one-third to one-half the usual recommended dose and titrate with caution.

Dosing adjustments in renal impairment:

NDA

P: P Tab: 10mg CR tab (27552); Cap: 5mg IR cap (22798)

ADR:

COMMON
Pruritus, sweating, abdominal pain, constipation, nausea, vomiting, xerostomia, asthenia, dizziness, headache, somnolence, fever
SERIOUS
Cardiac arrest, chest pain, heart failure, hypotension, shock, ST segment depression, syncope, bowel obstruction, diverticulitis, exacerbation, hypersensitivity reaction, respiratory depression, drug withdrawal syndrome in neonate of dependent mother, opioid withdrawal

NOTE: 室溫儲存

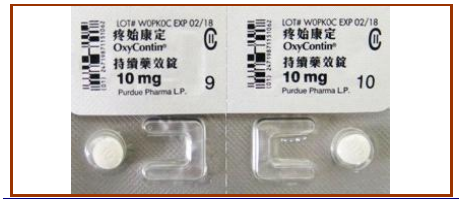
·《Contraindications》Acute or severe bronchial asthma in the absence of resuscitative equipment or in an unmonitored setting; Known or suspected gastrointestinal obstruction, including paralytic ileus; Hypersensitivity to oxycodone; Significant respiratory depression ;

·An opioid-tolerant patient is defined as using at least 60mg of oral morphine/day, 25mcg/hr fentanyl TTS, 30mg oral oxycodone/day, 8mg oral hydromorphone/day, 25mg oral oxymorphone/day or an equianalgesic dose of another opioid, for a week or longer.

藥名相似:

外觀相似:

外觀描述: 白色圓形錠，一面刻有 OP 字樣，另一面刻有 10 字樣



14.02A1 Opiate Agonist

28800 **ɔt be ruled out / Infant risk can**

"PPCD" Morphine Sulfate Oral Solution 2mg/mL "管制藥品廠" 硫酸嗎啡口服液 2 毫克/毫升

急用■管Morphine Sulfate Oral Solution 2mg/mL, 60mL/bot

Dosage: 2急用藥 28800

Adult

·Moderate to severe pain: PO, 10- 20mg Q4H as needed

Pediatric

·Moderate to severe pain (neonate): PO, 0.08 mg/kg/dose Q4~6H

·Moderate to severe pain (pediatric): PO, <= 6 mon, 0.08-0.1 mg/kg/dose Q3~4H; > 6 mon <50 kg, 0.2-0.5 mg/kg/dose Q3~4H as needed, Max initial: 15-20 mg; > 6 mon >50 kg, 15-20 mg Q3~4H as needed

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Clcr 10-50 mL/min (pediatric): reduce dose by 25%
Clcr <10 mL/min (pediatric): reduce dose by 50% or consider alternative opioid analgesic

P: P Soln: 2mg/mL, 60mL/Bot(28800, 急用); Tab: 10mg(22804), 15mg(22818), 30mg(22805), 60mg(22806); Cap: 60mg(22814); Tr: 9.5-10.5mg/mL, 10mL/Bot(28521), 0.38-0.42mg/mL, 25mL/Bot (28522); Inj: 10mg/1mL Amp(32408), 20mg/1mL Amp(32402)

ADR:

COMMON
Pruritus, constipation, nausea, vomiting, dizziness, headache, lightheadedness, somnolence, miosis, urinary retention
SERIOUS
Cardiac arrest, disorder of cardiovascular system, circulatory depression, orthostatic hypotension, shock, syncope, adrenal insufficiency, anaphylaxis, myoclonus, coma, raised intracranial pressure, seizure, dyspnea, respiratory depression, drug dependence, drug withdrawal syndrome in neonate of dependent mother

NOTE: 室溫避光

·《Contraindications》Significant respiratory depression; Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; Concomitant use with MAOIs, or use of MAOIs within 14 days; Known or suspected gastrointestinal obstruction, including paralytic ileus; Hypersensitivity (eg, anaphylaxis) to morphine; Neuraxial administration contraindications include: infection at injection microinfusion site, concomitant anticoagulant therapy, uncontrolled bleeding diathesis, or the presence of any other concomitant therapy or medical condition which would render epidural or intrathecal administration of medication especially hazardous. ;
·When changing routes of administration in chronically treated patients, please note that oral doses are approximately one-half as effective as parenteral dose.

藥名相似:

外觀相似:

外觀描述:

14.02A1 Opiate Agonist

29128 **C / Safe**

Fentanyl Transdermal Patch* 50 µg/hr "PPCD" "管制藥品廠" 吩坦尼穿皮貼片劑50微公克/小時

■Fentanyl 50mcg/hr Transdermal Patch

Dosage: 1常備品 29128

Adult

·Analgesia: Initial 25 mcg/hr/patch, if currently receiving opiates, convert to fentanyl equivalent; dosage titration should be performed in 25 mcg/hr increments every 3 days

Pediatric

·Analgesia: >2yrs: 25 mcg/hr/patch should be opioid-tolerant and receiving at least 45 mg oral morphine equivalents per day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 10-50 mL/min: 75% of the normal fentanyl dose
Clcr <10 mL/min: 50% of the normal fentanyl dose

P: TTS: 12 mcg/hr(29130), 25mcg/hr(29129), 50mcg/hr(29128), 75mcg/hr(急29149), ; Inj: 0.1mg/2mL Amp(32401), 0.5mg/10mL Amp(32399),1mg/2mL Amp(32412); PCEA: 1mg/500mL(38302), 0.2mg/100mL(38303)

ADR:

COMMON
asthenia, confusion, dizziness, sedation,

constipation, dry mouth, nausea, vomiting, pruritus, sweating, urinary retention
SERIOUS
arrhythmias, chest pain, hypertension, hypotension, apnea, hypoventilation, respiratory depression

NOTE: 室溫儲存

·《Contraindications》Acute or postoperative pain including use after outpatient or day surgeries, or if analgesia is required for a short time period; risk of life-threatening hypoventilation; Acute or severe bronchial asthma; Known or suspected gastrointestinal obstruction; Hypersensitivity to fentanyl or any components of the product; Mild or intermittent pain management; risk of life-threatening hypoventilation; Opioid non-tolerant patients; Known or suspected paralytic ileus; Significant respiratory depression, especially in unmonitored settings or settings that lack resuscitative equipment；
·Apply the patch to hairless skin on the upper trunk or upper arm
·A new patch should be applied to a different skin site after removal of the previous patch
·Recommended dose based on daily morphine equivalence dose

IM 24-hour morphine (mg/day)	Oral 24-hour morphine (mg/day)	Durogesic Dose (mcg/h)
<23	<135	25
23-37	135-224	50
38-52	225-314	75
53-67	315-404	100
68-82	405-494	125
83-97	495-584	150
98-112	585-674	175
113-127	675-764	200
128-142	765-854	225
143-157	855-944	250
158-172	945-1034	275
173-187	1035-1124	300

藥名相似:

外觀相似:

外觀描述: 白底黑字紙袋,有綠色"50"及"麻"字樣,黑色六角型與"管2"字,貼片為透明

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1051717

14.02A1 Opiate Agonist

29129 **C / Safe**

Fentanyl Transdermal Patch* 25 μg/hr "PPCD" "管制藥品廠" 吩坦尼穿皮貼片劑 25 微公克/小時

■Fentanyl 25mcg/hr Transdermal Patch

Dosage: 1常備品 29129

Adult
·Analgesia: Initial 25 mcg/hr/patch, if currently receiving opiates, convert to fentanyl equivalent; dosage titration should be performed in 25 mcg/hr increments every 3 days

Pediatric
·Analgesia: >2 yrs: 25 mcg/hr/patch should be opioid-tolerant and receiving at least 45 mg/day oral morphine equivalents

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 10-50 mL/min: 75% of the normal fentanyl dose
Clcr <10 mL/min: 50% of the normal fentanyl dose

P: TTS: 12 mcg/hr(29130), 25mcg/hr(29129), 50mcg/hr(29128), 75mcg/hr(急29149), ; Inj: 0.1mg/2mL Amp(32401), 0.5mg/10mL Amp(32399),1mg/2mL Amp(32412); PCEA: 1mg/500mL(38302), 0.2mg/100mL(38303)

ADR:

COMMON
asthenia, confusion, dizziness, sedation, constipation, dry mouth, nausea, vomiting, pruritus, sweating, urinary retention
SERIOUS
arrhythmias, chest pain, hypertension, hypotension, apnea, hypoventilation, respiratory depression

NOTE: 室溫儲存

·《Contraindications》Acute or postoperative pain including use after outpatient or day surgeries, or if analgesia is required for a short time period; risk of life-threatening hypoventilation; Acute or severe bronchial asthma; Known or suspected gastrointestinal obstruction; Hypersensitivity to fentanyl or any components of the product; Mild or intermittent pain management; risk of life-threatening hypoventilation; Opioid non-tolerant patients; Known or suspected paralytic ileus; Significant respiratory depression, especially in unmonitored settings or settings that lack resuscitative equipment；
·Apply the patch to hairless skin on the upper trunk or upper arm
·A new patch should be applied to a different skin site after removal of the previous patch
·Recommended dose based on daily morphine equivalence dose

IM 24-hour morphine (mg/day)	Oral 24-hour morphine (mg/day)	Durogesic Dose (mcg/h)
<23	<135	25
23-37	135-224	50
38-52	225-314	75
53-67	315-404	100
68-82	405-494	125
83-97	495-584	150
98-112	585-674	175
113-127	675-764	200
128-142	765-854	225
143-157	855-944	250
158-172	945-1034	275
173-187	1035-1124	300

藥名相似:

外觀相似:

外觀描述: 白底黑字紙袋,有粉紅"25"及"麻"字樣,黑色六角型與"管2"字,貼片為透明

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1050018

14.02A1 Opiate Agonist

29130 ɔt be ruled out / Infant risk can

Durogesic D-TRANS Transdermal Patch* 12 μg/h "楊森" 多瑞喜穿皮貼片劑 12 微公克/小時

■Fentanyl 12mcg/hr TTS

Dosage: 1常備品 29130

Adult

·Analgesia: Initial 25 mcg/hr/patch, if currently receiving opiates, convert to fentanyl equivalent; dosage titration should be performed in 12 mcg/hr or 25 mcg/hr increments; replace patch every 3 days

Pediatric (≧2yrs)

·Analgesia: 25 mcg/hr/patch should be opioid-tolerant and receiving at least 60 mg oral morphine equivalents per day; dosage titration should be performed in 12 mcg/hr or 25 mcg/hr increments; replace patch every 3 days

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Clcr 10-50 mL/min: 75% of the normal fentanyl dose

Clcr <10 mL/min: 50% of the normal fentanyl dose

P: TTS: 12 mcg/hr(29130), 25mcg/hr(29129), 50mcg/hr(29128), 75mcg/hr(急29149), ; Inj: 0.1mg/2mL Amp(32401), 0.5mg/10mL Amp(32399),1mg/2mL Amp(32412); PCEA: 1mg/500mL(38302), 0.2mg/100mL(38303)

ADR:

COMMON

Asthenia, confusion, dizziness, sedated, constipation, nausea, vomiting, xerostomia, pruritus, sweating symptom, urinary retention

SERIOUS

Cardiac dysrhythmia, chest pain, hypertension, hypotension, apnea, hypoventilation, respiratory depression

NOTE: 室溫儲存

·《Contraindications》Acute or postoperative pain including use after outpatient or day surgeries, or if analgesia is required for a short time period; risk of life-threatening hypoventilation; Acute or severe bronchial asthma; Known or suspected gastrointestinal obstruction; Hypersensitivity to fentanyl or any components of the product; Mild or intermittent pain management; risk of life-threatening hypoventilation; Opioid non-tolerant patients; Known or suspected paralytic ileus; Significant respiratory depression, especially in unmonitored settings or settings that lack resuscitative equipment ;

·Apply the patch to hairless skin on the upper trunk or upper arm

·A new patch should be applied to a different skin site after removal of the previous patch

·Recommended dose based on daily morphine equivalence dose

IM 24-hour morphine (mg/day)	Oral 24-hour morphine (mg/day)	Durogesic Dose (mcg/h)
	30- 44 (Ped.)	12
	45-134 (Ped.)	25
<23	<135 (Adult)	25
23-37	135-224	50
38-52	225-314	75
53-67	315-404	100
68-82	405-494	125
83-97	495-584	150
98-112	585-674	175
113-127	675-764	200
128-142	765-854	225
143-157	855-944	250
158-172	945-1034	275
173-187	1035-1124	300

·Dosage increments should be based on daily use of opioids using the ratio of 45 mg/day of oral morphine to a 12.5 mcg/hr increase in fentanyl dose

藥名相似:

外觀相似:

外觀描述: 白底深藍字紙袋,有橘底紅字"12μg/h"字,背面六角型"管2",貼片為透明

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024870

14.02A1 Opiate Agonist

29149 ɔt be ruled out / Infant risk can

■◆急用DUROGESIC D-TRANS* transdermal patch 75 μg/h "楊森"多瑞喜穿皮貼片劑 75 微公克/小時

■◆急用Fentanyl 75mcg/hr transdermal therapeutic system

Dosage: 2急用藥 29149

Adult

·Analgesia: Initial 25 mcg/hr/patch, if currently receiving opiates, convert to fentanyl equivalent; dosage titration should be performed in 25 mcg/hr increments every 3 days

Pediatric

·Analgesia: >2yrs: 25 mcg/hr/patch should be opioid-tolerant and receiving at least 45 mg oral morphine equivalents per day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 10-50 mL/min: 75% of the normal fentanyl dose
Clcr <10 mL/min: 50% of the normal fentanyl dose

P: TTS: 12 mcg/hr(29130), 25mcg/hr(29129), 50mcg/hr(29128), 75mcg/hr(29149); Inj: 0.1mg/2mL Amp(32401), 0.5mg/10mL Amp(32399),1mg/2mL Amp(32412); PCEA: 1mg/500mL(38302), 0.2mg/100mL(38303)

ADR:

COMMON
asthenia, confusion, dizziness, sedation, constipation, dry mouth, nausea, vomiting, pruritus, sweating, urinary retention
SERIOUS
arrhythmias, chest pain, hypertension, hypotension, apnea, hypoventilation, respiratory depression

NOTE: 室溫儲存

·《Contraindications》Acute or postoperative pain including use after outpatient or day surgeries, or if analgesia is required for a short time period; risk of life-threatening hypoventilation; Acute or severe bronchial asthma; Known or suspected gastrointestinal obstruction; Hypersensitivity to fentanyl or any components of the product; Mild or intermittent pain management; risk of life-threatening hypoventilation; Opioid non-tolerant patients; Known or suspected paralytic ileus; Significant respiratory depression, especially in unmonitored settings or settings that lack resuscitative equipment ;
·Apply the patch to hairless skin on the upper trunk or upper arm
·A new patch should be applied to a different skin site after removal of the previous patch
·Recommended dose based on daily morphine equivalence dose

IM 24-hour Durogesic Dose (mcg/h)	Oral 24-hour morphine (mg/day)	morphine (mg/day)
<23	<135	25
23-37	135-224	50
38-52	225-314	75
53-67	315-404	100
68-82	405-494	125
83-97	495-584	150
98-112	585-674	175
113-127	675-764	200
128-142	765-854	225
143-157	855-944	250
158-172	945-1034	275
173-187	1035-1124	300

藥名相似:

外觀相似:

外觀描述: 白色深藍色字紙袋包裝,有淺藍底紅字"50μg/h"字樣,背面粉紅管制局標誌,及六角型"管2"字樣,內部貼片為透明

14.02A1 Opiate Agonist

32004 C / Caution

Alfentanil-hameln 0.5mg/ml Injection "哈曼"阿華吩坦尼 0.5毫克/毫升注射液

■Alfentanil inj 1mg/2mL amp

Dosage: 1常備品 32004

Adult
·Primary anesthetic agent: 130-245 mcg/kg induction dose followed by continuous IV infusion of 0.5-1.5 mcg/kg/min
·Analgesic; Adjunct - Surgical procedure:
1.Surgery duration < 30 min; 8-20 mcg/kg IV, then continuous IV infusion of 0.5-1 mcg/kg/min; total dose 8-40 mcg/kg
2.Surgery duration 30-60 min; 20-50 mcg/kg IV, then MD IV 5-15 mcg/kg every 5-20 min; total dose up to 75 mcg/kg
3.Surgery duration > 45 min; 50-75 mcg/kg IV, then continuous IV infusion of 0.5-3 mcg/kg/min

Pediatric
·Safety and efficacy have not been established in patients less than 12 years old.

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Dosage adjustment required

P: TTS: 12 mcg/hr(29130), 25mcg/hr(29129), 50mcg/hr(29128); Inj: 0.1mg/2mL Amp(32401), 0.5mg/10mL Amp(32399),1mg/2mL Amp(32412); PCEA: 1mg/500mL(38302), 0.2mg/100mL(38303)

ADR:

COMMON
nausea, vomiting
SERIOUS
apnea, respiratory depression, arrhythmias, bradycardia, tachycardia, hypertension, hypotension, muscle rigidity, spontaneous skeletal muscle movements

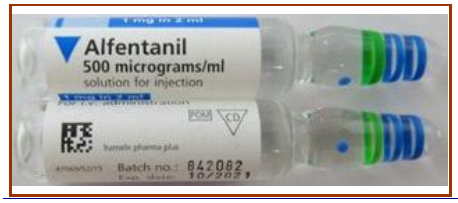
NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to alfentanil ;
■輕中度鎮靜止痛
1. IV use in children <12yrs is not recommended

藥名相似:

外觀相似:

外觀描述: 2mL透明注射液，玻璃安瓿裝，瓶頸有『藍』色圓點及『綠/藍/藍』線條



14.02A1 Opiate Agonist

32008 C / Infant risk can

Remifentanil ALVOGEN* powder for concentrate for

solution for injection or infusion 2mg "艾威群" 瑞吩坦尼凍晶乾燥注射劑2毫克

■Remifentanil inj 2mg pow in vial

Dosage: 1常備品 32008

Adult
·Analgesia for a mechanically ventilated patient
Continuous infu. 0.1-0.15 mcg/kg/min IV initially (IBW), MAX. 0.2-0.4 mcg/kg/min IV.
·General anesthesia; Adjunct
1.Induction, 0.5-1 mcg/kg/min IV; over 30-60 seconds may be used if intubated within 8 minutes of initiation. Administer with a hypnotic or volatile agent.
2.Maintenance, 0.05-2 mcg/kg/min IV plus isoflurane or propofol.
3.Maintenance, 0.1-2 mcg/kg/min IV plus nitrous oxide.
4.CABG, during induction through intubation, 1 mcg/kg/min IV.
5.CABG, during maintenance of anesthesia, 0.125-4 mcg/kg/min IV.
·Monitored anesthesia care sedation, Analgesic component; Adjunct
1.Single dose, 1-0.5 mcg/kg IV injection over 30-60 seconds as single dose 90 seconds before administration of local anesthetic
2.Continuous infusion, 0.05-0.1 mcg/kg/min IV infu. 5 minutes before placement of local or regional block
·Postoperative pain, Immediate postoperative period
1. 0.025-0.2 mcg/kg/min IV, adjust infu. every 5 minutes in 0.025 mcg/kg/min increments to reach desired effect
2.CABG, 0.05-1 mcg/kg/min IV infu.

Pediatric
·Analgesia for a mechanically ventilated patient, ICU
1. Infants: continuous infu. 0.075-0.15 mcg/kg/min IV initially, MAX. 0.5-0.94 mcg/kg/min IV
2.Children: continuous infu. 0.1 mcg/kg/min IV
·General anesthesia; Adjunct
1.Birth to 2 months: Maintenance, 0.4-1 mcg/kg/min IV plus nitrous oxide
2.1-12 years: Maintenance, 0.05-1.3 mcg/kg/min IV plus halothane, sevoflurane, or isoflurane

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Dose adjustment not required

P: Inj: 2mg vial(32008)

ADR:

COMMON
Hypotension, pruritus, nausea, vomiting, muscle rigidity, headache
SERIOUS
Asystole, hemorrhage, anaphylaxis, respiratory depression, serotonin syndrome

NOTE: 室溫儲存

·《Contraindications》Epidural or intrathecal administration; formulation contains glycine; Hypersensitivity to remifentanil；
■輕中度鎮靜止痛

藥名相似:

外觀相似:

外觀描述: 白色乾粉，『綠』蓋透明玻璃小瓶

14.02A1 Opiate Agonist

32400 ɔt be ruled out / Infant risk can

FENTANYL INJECTION 0.05MG/ML "PPCD" "管制藥品廠" 吩坦尼注射液0.05毫克/毫升

■Fentanyl citrate inj 0.5mg/10mL amp

Dosage: 1常備品 32400

Adult
·Preoperative medication: IM, 0.05-0.1mg 30-60 minutes prior to surgery
·Adjunct to general anesthesia Induction: IV, 0.05-0.1mg may be repeated every 2-3 min; MD: 0.025-0.05mg if necessary
·Postoperative analgesic: IM, 0.05-0.1mg q1-2hr if necessary

Pediatric
·Induction and maintenance of general anesthesia: 2-12 yrs: IV, 1.7-3.3mcg/kg

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 10-50 mL/min: 75% of the normal fentanyl dose
Clcr <10 mL/min: 50% of the normal fentanyl dose

P: TTS: 25mcg/hr(29106), 50mcg/hr(29107); Inj: 0.1mg/2mL Amp(32401), 0.5mg/10mL Amp(32400)

ADR:

COMMON
asthenia, confusion, dizziness, sedation, constipation, dry mouth, nausea, vomiting, pruritus, sweating, urinary retention
SERIOUS
arrhythmias, chest pain, hypertension, hypotension, apnea, hypoventilation, respiratory depression

NOTE: 儲存25℃以下

·《Contraindications》Acute or postoperative pain including headache/migraine, dental pain, or use in the emergency room; Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; Hypersensitivity to fentanyl or to any product component; Known or suspected gastrointestinal obstruction, including paralytic ileus; Opioid non-tolerant patients; risk of life-threatening respiratory depression and death; Significant respiratory depression；
■輕中度鎮靜止痛
1.Recommended dose based on daily morphine equivalence dose
IM 24-hour Oral 24-hour
Durogesic Dose

morphine (mg/day)	morphine (mg/day)	(mcg/h)
<23	<135	25
23-37	135-224	50
35-52	225-314	75
53-67	315-404	100
68-82	405-494	125
83-97	495-584	150
98-112	585-674	175
113-127	675-764	200
128-142	765-854	225
143-157	855-944	250
158-172	945-1034	275
173-187	1035-1124	300

藥名相似:

外觀相似:

外觀描述:

14.02A1 Opiate Agonist

32401 **ɔt be ruled out / Infant risk can**

FENTANYL INJECTION* 0.05MG/ML "PPCD" "管制藥品廠" 吩坦尼注射液0.05毫克/毫升

■Fentanyl citrate inj 0.1mg/2mL amp

Dosage: 1常備品 32401

Adult
·Preoperative medication: IM, 0.05-0.1 mg 30-60 min prior to surgery
·Adjunct to general anesthesia:
Low-dose regimen: IV, 0.002 mg/kg
Moderate-dose regimen: initial IV, 0.002-0.020 mg/kg, additional doses of IV, IM, 0.025-0.100 mg may be given as necessary
High-dose regimen: initial IV, 0.020-0.050 mg/kg, additional doses of 0.025 mg to 1/2 the initial dose may be given as necessary
·Postoperative analgesic: IM, 0.05-0.1 mg q1-2hr if necessary

Pediatric
·Induction and maintenance of general anesthesia:
2-12 yrs: IV, 1.7-3.3 mcg/kg

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 10-50 mL/min: 75% of the normal fentanyl dose
Clcr <10 mL/min: 50% of the normal fentanyl dose

P: TTS: 12 mcg/hr(29130), 25mcg/hr(29129), 50mcg/hr(29128); Inj: 0.1mg/2mL Amp(32401), 0.5mg/10mL Amp(32399),1mg/2mL Amp(32412); PCEA: 1mg/500mL(38302), 0.2mg/100mL(38303)

ADR:

COMMON
asthenia, confusion, dizziness, sedation, constipation, dry mouth, nausea, vomiting, pruritus, sweating, urinary retention
SERIOUS
arrhythmias, chest pain, hypertension, hypotension, apnea, hypoventilation, respiratory depression

NOTE: 室溫儲存

·《Contraindications》Acute or postoperative pain including headache/migraine, dental pain, or use in the emergency room; Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; Hypersensitivity to fentanyl or to any product component; Known or suspected gastrointestinal obstruction, including paralytic ileus; Opioid non-tolerant patients; risk of life-threatening respiratory depression and death; Significant respiratory depression ;
■輕中度鎮靜止痛
1.Recommended dose based on daily morphine equivalence dose

IM 24-hour Durogesic Dose morphine (mg/day)	Oral 24-hour morphine (mg/day)	(mcg/h)
<23	<135	25
23-37	135-224	50
38-52	225-314	75
53-67	315-404	100
68-82	405-494	125
83-97	495-584	150
98-112	585-674	175
113-127	675-764	200
128-142	765-854	225
143-157	855-944	250
158-172	945-1034	275
173-187	1035-1124	300

藥名相似:

外觀相似:

外觀描述: 2mL透明注射液，棕色玻璃安瓿，白底橘字標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044332

14.02A1 Opiate Agonist

32402 **ɔt be ruled out / Infant risk can**

MORPHINE HYDROCHLORIDE INJECTION* 20MG/ML 鹽酸嗎啡注射液20毫克/毫升

■Morphine HCl inj 20mg/1mL amp

Dosage: 1常備品 32402

Adult
·Analgesia:
IM, SC, 5-20mg or 10mg q4h as needed
Slow IV, 2-10 mg over 4-5 min, a strength of 2.5-15 mg diluted in 4-5 mL of sterile water for injection
Epidural, Initial 5 mg, careful administration of incremental doses of 1-2 mg at intervals sufficient to assess effectiveness may be given; no more than 10 mg/24 hr
IT, 1/10 epidural dose

Pediatric

·Analgesia:
≧12yrs: IV, 3-4 mg repeated in 5 minutes if needed.
Infants and children : parenteral, 0.1-0.2 mg /kg q2-4h as necessary
Neonates : parenteral, 0.05-0.2 mg /kg q2-4h
Single pediatric doses should not exceed 10mg

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Clcr 10-50 mL/min: 75% of the normal dose
Clcr <10 mL/min: 50% of the normal dose

P: Tab: 10mg(22804), 30mg(22805), 60mg (22806); Cap: 60mg(22814); Tr: 9.5-10.5mg/mL, 10mL/Bot (28521), 0.38-0.42mg/mL, 25mL/Bot (28522); Inj: 10mg/1mL Amp(32408), 20mg/1mL Amp(32402)

ADR:

COMMON
constipation, nausea, urinary retention, vomiting, dizziness, headache, light-headedness, sedation, weakness
SERIOUS
allergic reaction, confusion, histamine release, hypotension, respiratory depression

NOTE: 室溫儲存

·《Contraindications》Significant respiratory depression; Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; Concomitant use with MAOIs, or use of MAOIs within 14 days; Known or suspected gastrointestinal obstruction, including paralytic ileus; Hypersensitivity (eg, anaphylaxis) to morphine; Neuraxial administration contraindications include: infection at injection microinfusion site, concomitant anticoagulant therapy, uncontrolled bleeding diathesis, or the presence of any other concomitant therapy or medical condition which would render epidural or intrathecal administration of medication especially hazardous. ;
■輕中度鎮靜止痛
1.[D] if used for prolonged periods or in high doses at term

藥名相似:

外觀相似:

外觀描述: 1mL注射液，褐色玻璃安瓿，頸部有白點，粉紅底棕色字標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1005886

14.02A1 Opiate Agonist

32406 C / Caution

PETHIDINE HYDROCHLORIDE INJECTION* 50MG/ML 鹽酸配西汀注射液50毫克/毫升

■Pethidine(Meperidine) HCl inj 50mg/1mL amp

Dosage: 1常備品 32406

Adult
·Analgesia: IM, SC, 50-150 mg q3-4h as needed; IV infusion, 15-35 mg/h as needed
·Surgical premedication: IM or SC, 50-100 mg 30-90 mins before the beginning of anesthesia
·Analgesia during labor: IM or SC, 50-100 mg; If necessary, this dose may be repeated at q1-3h

Pediatric
·Analgesia: IM, SC, 1.1-1.8 mg/kg q3-4h as necessary; or 175 mg/m2 daily in 6 divided doses. Max. 100 mg/dose.

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Clcr 10-50 mL/min: 75% of the normal dose
Clcr <10 mL/min: 50% of the normal dose

P: Inj: 50mg/1mL Amp (32406)

ADR:

COMMON
dizziness, lightheadedness, sedation, nausea, vomiting
SERIOUS
cardiac arrest, circulatory depression, hypotension, syncope, respiratory depression, seizures

NOTE: 室溫儲存

■輕中度鎮靜止痛

藥名相似:

外觀相似:

外觀描述: 1mL注射液，棕色玻璃安瓿，頸部有白點，黃底綠字標簽

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1005874

14.02A1 Opiate Agonist

32408 ɔt be ruled out / Infant risk can

Morphine* Hydrochloride Injection 10mg/mL 鹽酸嗎啡注射液１０毫克/毫升

■Morphine HCl inj 10mg/1mL amp

Dosage: 1常備品 32408

Adult
·Analgesia:
IM, SC, 5-20mg or 10mg q4h as needed
Slow IV, 2-10 mg over 4-5 min, a strength of 2.5-15 mg diluted in 4-5 mL of sterile water for injection
Epidural, Initial 5 mg, careful administration of incremental doses of 1-2 mg at intervals sufficient to assess effectiveness may be given; no more than 10 mg/24 hr
IT, 1/10 epidural dose

Pediatric
·Analgesia:
≧12yrs: IV, 3-4 mg repeated in 5 minutes if needed.
Infants and children : parenteral, 0.1-0.2 mg /kg q2-

4h as necessary
Neonates : parenteral, 0.05-0.2 mg /kg q2-4h
Single pediatric doses should not exceed 10mg

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Clcr 10-50 mL/min: 75% of the normal dose
Clcr <10 mL/min: 50% of the normal dose

P: Tab: 10mg(22804), 30mg(22805), 60mg (22806); Cap: 60mg(22814); Tr: 9.5-10.5mg/mL, 10mL/Bot (28521), 0.38-0.42mg/mL, 25mL/Bot (28522); Inj: 10mg/1mL Amp(32408), 20mg/1mL Amp(32402)

ADR:

COMMON
constipation, nausea, urinary retention, vomiting, dizziness, headache, light-headedness, sedation, weakness
SERIOUS
allergic reaction, confusion, histamine release, hypotension, respiratory depression

NOTE: 室溫儲存

·《Contraindications》Significant respiratory depression; Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; Concomitant use with MAOIs, or use of MAOIs within 14 days; Known or suspected gastrointestinal obstruction, including paralytic ileus; Hypersensitivity (eg, anaphylaxis) to morphine; Neuraxial administration contraindications include: infection at injection microinfusion site, concomitant anticoagulant therapy, uncontrolled bleeding diathesis, or the presence of any other concomitant therapy or medical condition which would render epidural or intrathecal administration of medication especially hazardous. ;
■輕中度鎮靜止痛

藥名相似:

外觀相似:

外觀描述: 1mL注射液，褐色玻璃安瓿，頸部有『藍』點，白底紫字標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1005891

14.02A1 Opiate Agonist

32413 C / Infant risk has

TRAMTOR INJECTION* 50MG/ML (TRAMADOL HYDROCHLORIDE) 頓痛特注射液 5 0 毫克/毫升（鹽酸妥美度）

Tramadol Inj 100mg/2mL

Dosage: 1常備品 32413

Adult
Cancer pain: IM, 300 mg/day in div. doses
Labor pain: IM, 100 mg single dose
Postoperative pain: IM, IV, 50-100 mg q4-6h, Max. 400 mg/day

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Hepatic cirrhosis: 50 mg q12h

Dosing adjustments in renal impairment:

Clcr <30 mL/min: 50-100mg q12h, Max. 200 mg/day
ESRD: 50mg q12h

P: Inj: 100mg/2mL(32413); Tab: 100mg(22813); Cap: 50mg(22811); TRAMACET*(22831)

ADR:

COMMON
Flushing, pruritus, constipation, nausea, vomiting, xerostomia, dizziness, headache, insomnia, somnolence
SERIOUS
Myocardial infarction, pancreatitis, anaphylactoid reaction, dyspnea, respiratory depression, seizures (doses exceeding the recommended range, in patients with epilepsy, a history of seizures, or other risk for seizures). serotonin syndrome (life-threatening, particularly with concomitant use of serotonergic drugs)

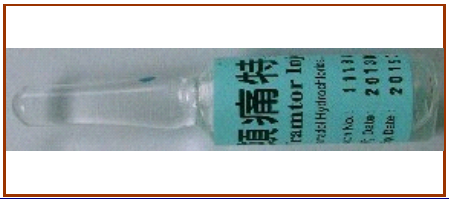
NOTE: 室溫儲存

《Contraindications》All children younger than 12 years; Postoperative management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy; Significant respiratory depression; Acute or severe bronchial asthma, in unmonitored settings or without resuscitative equipment; Known or suspected gastrointestinal obstruction, including paralytic ileus; Hypersensitivity to traMADol, any other component of the product, or opioids; Concurrent use of MAOIs or use within the last 14 days ;

藥名相似:

外觀相似:

外觀描述: 2mL透明注射液透明安瓿頸部有藍點



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1038145

14.02A2 Opiate Partial Agonist

22801 C / Unsafe

TEMGESIC SUBLINGUAL TABLETS 0.2MG 丁基原啡因舌下錠 0 · 2 毫克

■Buprenorphine HCl 0.2mg tab

Dosage: 1常備品 22801

Adult
·Pain (Moderate to Severe): Sublingual, 1-2 tab q6-8h or as needed

Pediatric
·Pain (Moderate to Severe):≧12yrs: Same as adult
< 12yrs: Sublingual,
15-25kg: 0.1 mg q6-8h or as needed
25-37kg: 0.1-0.2 mg q6-8h or as needed

37.5-50kg: 0.2-0.3 mg q6-8h or as needed

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Sublingual: 0.2mg(22801)

ADR:

COMMON
nausea, vomiting, dizziness, drowsiness, sedation, vertigo
SERIOUS
hypotension, bradycardia, tachycardia, hypertension, cyanosis, dyspnea, respiratory depression

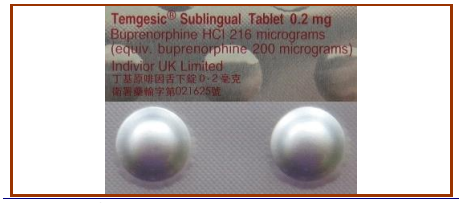
NOTE: 室溫儲存

·《Contraindications》Significant respiratory depression; Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; Known or suspected gastrointestinal obstruction, including paralytic ileus; Hypersensitivity to buprenorphine or any other component of the product ;
·The tab should not be chewed or swallowed as this will reduce efficacy
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，有L字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021625

14.02A2 Opiate Partial Agonist

22815 **C / Unsafe**

Desud* Plus Sublingual Tablets 解佳益 舌下錠

■Buprenorphine 8mg, Naloxone 2mg tab

Dosage: 1常備品 22815

Adult
·Opioid dependence: Sublingual, 12-16 mg (buprenorphine) qd, adjust dosage in 2-4 mg increments/decrements each day, typical dose range 4-24 mg/day.

Pediatric
·Opioid dependence: >16 yr, maintenance, Sublingual,12-16 mg (buprenorphine) qd, adjust dosage in 2-4 mg increments/decrements each day, typical dose range 4-24 mg/day.

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

NDA

P: Sublingual: 8mg+2mg(22815)

ADR:

·Buprenorphine :
COMMON
Sweating, Abdominal pain, Constipation, Nausea, Vomiting, Infectious disease, Dizziness, Headache, Insomnia, Sedated, Somnolence, Vertigo, Miosis.
SERIOUS
Hypotension, Myocardial infarction, Prolonged QT interval, Adrenal insufficiency, Hepatitis, Anaphylaxis, Seizure, Respiratory depression, Drug dependence.
·Naloxone :
COMMON
Dizziness, Headache.
SERIOUS
Cardiac arrest, Hypertension, Hypotension, Tachycardia, Ventricular fibrillation, Ventricular tachycardia, Sweating, Nausea, Vomiting, Coma, Encephalopathy, Seizure, Tremor, Pulmonary edema, Opioid withdrawal.

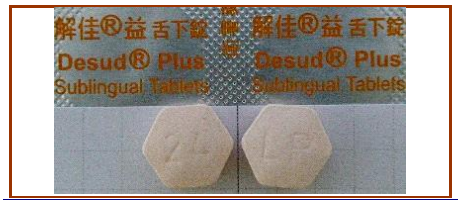
NOTE: 室溫儲存

·《Contraindications》Significant respiratory depression; Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; Known or suspected gastrointestinal obstruction, including paralytic ileus; Hypersensitivity to buprenorphine or naloxone ;
·The tab should not be chewed or swallowed as this will reduce efficacy
·Buprenorphine:naloxone=4:1
·Induction with buprenorphine (without naloxone) sublingual tablets recommended prior to initiation of buprenorphine/naloxone products.
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 淡橘色六角形錠，一面有LP字樣，另一面有24字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1050251

14.02A2 Opiate Partial Agonist

29150 **C / Unsafe**

SOVENOR 5 micrograms/hour transdermal patches 舒免疼穿皮貼片劑5微公克/小時

急用■Buprenorphine 5mcg/hr transdermal patch

Dosage: 2急用藥 29150

Adult
·Moderate to severe chronic pain: Transdermal,
(1) Opioid-naive: Initial 5 mcg/hr replace patch every 7 days
(2) Prior daily dose <30 mg of oral morphine equivalents: Discontinue opioid drugs; initiate 5 mcg/hr at next dosing interval, replace patch every 7 days
(3) Prior daily dose 30-80 mg of oral morphine equivalents: Taper opioids for up to 7 days to <30 mg; then discontinue opioids and initiate 10 mcg/hr at next dosing interval; replace patch every 7 days;

short-acting analgesics may be used as needed until efficacy is attained
(4) Prior daily dose ≥80 mg of oral morphine equivalents: Consider an alternative analgesic
Doses should be titrate at a min interval of q72hrs, Max 20 mcg/hr

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Severe hepatic impairment: Consider alternate analgesic therapy

Dosing adjustments in renal impairment:

NDA

P: Tab: Sublingual 0.2mg(22801); TTS: 5mcg/hr(29150)

ADR:

COMMON
Application site erythema, irritation, rash or pruritus. Constipation, diarrhea, nausea, vomiting, xerostomia, dizziness, headache, somnolence, upper respiratory infection, fatigue
SERIOUS
Hypotension, prolonged QT interval, application site severe reaction, bowel obstruction, hepatic encephalopathy, hepatic necrosis, hepatitis, hepatorenal syndrome, liver failure, anaphylaxis, hypersensitivity reaction, cerebrovascular accident, coma, sedated, respiratory depression, respiratory failure, drug dependence, drug withdrawal

NOTE: 室溫儲存

·《Contraindications》Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; Known or suspected gastrointestinal obstruction, including paralytic ileus; Hypersensitivity to buprenorphine or any component of the product or delivery system; Significant respiratory depression ;

藥名相似:

外觀相似:

外觀描述:

14.02A2 Opiate Partial Agonist

29157 ɔt be ruled out / Infant risk can

TRANSTEC* 35ug/h, transdermal patch 全克痛穿皮貼片劑35微克/小時

急用■Buprenorphine 35mcg/hr transdermal patch

Dosage: 2急用藥 29157

Adult
·Moderate to severe chronic pain: Transdermal, 35 mcg/hr/patch q96h. Alternatively, 1 patch BIW at regular intervals . No more than 1 patch should be applied at the same time.
· previously treated with higher daily dosages of a strong opioid (approximately 120 mg oral morphine) : may start with 52.5mcg/hr/patch

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Hepatic impairment, severe: Consider alternate analgesic therapy.

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: P Tab: Sublingual 0.2mg(22801),8mg+2mg(22815); TTS: 5mcg/hr(29150), 35mcg/hr(29157)

ADR:

COMMON
Application site erythema, irritation, rash or pruritus. Constipation, diarrhea, nausea, vomiting, xerostomia, dizziness, headache, somnolence, upper respiratory infection, fatigue
SERIOUS
Hypotension, prolonged QT interval, application site severe reaction, bowel obstruction, hepatic encephalopathy, hepatic necrosis, hepatitis, hepatorenal syndrome, liver failure, anaphylaxis, hypersensitivity reaction, cerebrovascular accident, coma, sedated, respiratory depression, respiratory failure, drug dependence, drug withdrawal, serotonin syndrome

NOTE: 室溫儲存

·《Contraindications》Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; Known or suspected gastrointestinal obstruction, including paralytic ileus; Hypersensitivity to buprenorphine or any component of the product or delivery system; Significant respiratory depression ;

藥名相似:

外觀相似:

外觀描述: 白底黑字紙袋包裝,有深/淺藍色區塊,紅色"麻"字樣及六角型"管3"字樣

14.02A2 Opiate Partial Agonist

32415 **B / Caution**

Bain Injection* 10mg/ml 芯奔注射液10毫克

■Nalbuphine HCl 10mg/1mL amp

Dosage: 1常備品 32415

Adult
·General anesthesia; Adjunct: induction, 0.3-3 mg/kg IV over 10-15 min; maintenance, 0.25-0.5 mg/kg in single IV administrations, as needed.
·Analgesia: 10 mg SC, IM or IV for a 70 kg individual q 3-6 hs as needed; MAX single dose 20 mg/dose; MAX total daily dose 160 mg/day
·Shivering, Postanesthesia: 0.08 mg/kg IV

Pediatric
·Safety and effectiveness not established in patients

under 18 years of age

Dosing adjustments in hepatic impairment:

Administered with caution and in reduced doses in the presence of hepatic dysfunction

Dosing adjustments in renal impairment:

No dosage adjustment necessary

P: Inj: 10mg/1mL Amp(32415)

ADR:

COMMON
Diaphoresis,N/V, xerostomia,dizziness, headache, sedated,vertigo
SERIOUS
Immune hypersensitivity reaction, loss of consciousness, seizure, pulmonary edema, respiratory depression

NOTE: 室溫儲存

·《Contraindications》Significant respiratory depression; Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; Known or suspected gastrointestinal obstruction, including paralytic ileus; Hypersensitivity to nalbuphine or to any component of the product；

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液，透明安瓿頸部有紅點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048167

14.02B1 Salicylate

22833 **D / Unsafe**

BOKEY ENTERIC-MICROENCAPSULATED CAPSULES 100MG(ASPIRIN) 伯基腸溶微粒膠囊１００毫克（乙醯水楊酸）

Aspirin (Acetylsalicylic acid)100mg cap

Dosage: 1常備品 22833

Adult
·TIA: PO, 100 mg qd
·Prophylaxis of myocardial infarction & cardiogenic thromboembolism: PO, 100 mg qd
·Minor aches and pains: PO, 325-650 mg q4h as needed

Pediatric
·Analgesia, antipyretic: PO, 40-60 mg/kg/day div.q4-6h, Max. 4g/day
·Kawasaki disease(AHA and AAP recommendations): PO, high-dose (acute phase), 80-100 mg/kg/day (div.q6h); continue therapy until afebrile for 48 to 72 hs, or until day 14 of illness and afebrile for at least 48 hs; then low-dose, 3 to 5 mg/kg/day until no evidence of coronary changes, usually 6 to 8 weeks after onset of illness; continue low-dose aspirin indefinitely for patients with underlying coronary abnormalities

Dosing adjustments in hepatic impairment:

Aspirin should be avoided in severe hepatic insufficiency

Dosing adjustments in renal impairment:

Clcr <10 mL/min should avoid aspirin

P: Cap: 100mg(22833); Tab: 100mg(22841)

ADR:

COMMON
dyspepsia, N/V
SERIOUS
bleeding, gastrointestinal ulcers, Reye's syndrome, tinnitus, angioedema, bronchospasm

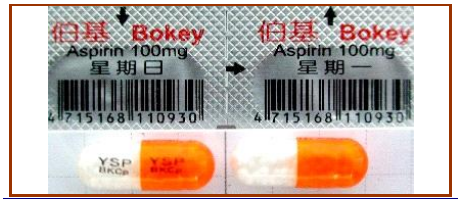
NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to NSAIDs; Syndrome of asthma, rhinitis, and nasal polyps; severe urticaria, angioedema, or bronchospasm may occur；
·Capsule: do not crush but can open

藥名相似:

外觀相似:

外觀描述: 橙色/透明膠囊，有"YSP"及"BKCp"字樣)



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1037344

14.02B1 Salicylate

22841 **D / Unsafe**

ROPAL TABLETS (ASPIRIN) "ROYAL" "皇佳" 熱痛寧錠（阿斯匹林）

Aspirin(Acetylsalicylic acid) 100mg tab

Dosage: 1常備品 22841

Adult
·TIA: PO, 100 mg qd
·Prophylaxis of myocardial infarction & cardiogenic thromboembolism: PO, 100 mg qd
·Minor aches and pains: PO, 325-650 mg q4h as needed

Pediatric
·Analgesia, antipyretic: PO, 40-60 mg/kg/day div.q4-6h, Max. 4g/day
·Kawasaki disease(AHA and AAP recommendations): PO, high-dose (acute phase), 80-100 mg/kg/day (div.q6h); continue therapy until afebrile for 48 to 72 hs, or until day 14 of illness and afebrile for at least 48 hs; then low-dose, 3 to 5 mg/kg/day until no evidence of coronary changes, usually 6 to 8 weeks after onset of illness; continue low-dose aspirin indefinitely for patients with underlying coronary abnormalities

Dosing adjustments in hepatic impairment:

Aspirin should be avoided in severe hepatic insufficiency

Dosing adjustments in renal impairment:

Clcr <10 mL/min should avoid aspirin

P: Tab: 100mg(22841); EC Tab: 100mg(22829); Cap:

Aggrenox* MR(22550)

ADR:

COMMON
dyspepsia, N/V
SERIOUS
bleeding, gastrointestinal ulcers, Reye's syndrome, tinnitus, angioedema, bronchospasm, tinnitus

NOTE: 室溫儲存25℃以下

·《Contraindications》Hypersensitivity to NSAIDs; Syndrome of asthma, rhinitis, and nasal polyps; severe urticaria, angioedema, or bronchospasm may occur ;
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 淺黃色圓扁錠，一面有刻痕

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1023534

14.02B2 Non-Selective NSAID

22828 **C / Caution**

Pinton SR Tablets 400mg "C.H." "正和"平痛持續性藥效錠400毫克

Etodolac 400mg SR tab

Dosage: 1常備品 22828

Adult
·Osteoarthritis, Rheumatoid arthritis: PO, 400-1000 mg qd, Max.1200 mg/day

Pediatric (6-16 yrs)
·Juvenile rheumatoid arthritis:
20-30kg: PO, 400mg qd
31-45kg: PO, 600mg qd
46-60kg: PO, 800mg qd
>60kg: PO, 1000mg qd

Dosing adjustments in hepatic impairment:

Severe hepatic failure: Dosage adjustment is required

Dosing adjustments in renal impairment:

Mild-to-moderate renal failure: no adjustment required
Severe renal dysfunction: use with caution

P: SR Tab: 400mg(22828)

ADR:

COMMON
abdominal pain, diarrhea, dyspepsia, flatulence, nausea, dizziness, malaise
SERIOUS
melena, allergic reaction, hypertension, CHF, elevated LFTs, hepatitis, jaundice, anemia, thrombocytopenia, agranulocytosis, neutopenia, renal failure, renal papillary necrosis, GI bleeding, GI perforation

NOTE: 室溫儲存

·《Contraindications》asthma, urticaria, or allergic-type reaction following aspirin or other NSAID administration; severe, even fatal anaphylactic-like reactions have been reported; CABG surgery, treatment of perioperative pain; hypersensitivity to etodolac ;
·Swallow whole; do not crush or chew

藥名相似:

外觀相似: actosMET* Tab (25720)

外觀描述: 紅色長橢圓扁錠，一面有CH，另一面有 71 字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1057966

14.02B2 Non-Selective NSAID

22840 **c / Infant risk can**

INDOY* CAPSULES 炎達益膠囊

Indomethacin 25mg cap

Dosage: 1常備品 22840

Adult
·Acute gouty arthritis, ankylosing spondylitis, OA, RA: PO, 25-50 mg 2-3 times/day, Max. 200 mg/day

Pediatric
·Safety and efficacy have not been established in patients less than 14 years old.
·If use is warranted, PO; initiate 1-2 mg/kg/day in divided doses; do not exceed 3 mg/kg/day or 150-200 mg/day, whichever is less. After observing initial response, adjust dose and frequency to meet individual patient's needs .

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed;
Not recommended in patients with advanced renal disease.

P: Cap: 25mg(22840); Supp: 50mg(29006); Inj: 1mg Vial(32410, 專案用藥)

ADR:

COMMON
nausea, vomiting, abdominal pain, constipation, diarrhea, dyspepsia, depression, dizziness, headache, fatigue
somnolence, tinnitus, tenesmus
SERIOUS
anaphylaxis, asthma, pulmonary edema, GI ulceration, GI perforation, edema, arrhythmias, chest pain, CHF, hypertension, agranulocytosis, anemia, leukopenia, thrombocytopenic purpura, hepatitis, jaundice, asthma, bronchospasm, dyspnea, erythema multiforme, rash, Stevens-Johnson syndrome, toxic epidermal ecrolysis, hematuria, interstitial nephritis, nephrotic syndrome, renal failure, renal dysfunction, pulmonary hypertension, hyponatremia, hyperkalemia, aggravation of epilepsy or parkinsonism, convulsion, peripheral neuropathy, psychic disturbances, blurred vision, corneal

deposits, deafness, retinal disturbances

NOTE: 室溫儲存

·《Contraindications》Asthma, urticaria, or other allergic-type reactions following aspirin or other NSAID administration; severe and sometimes fatal, anaphylactic reactions have been reported; History of proctitis or recent rectal bleeding; Hypersensitivity or serious skin reactions to indomethacin or any components of the product; Use in the setting of CABG surgery ;

藥名相似:

外觀相似:

外觀描述: 紅/白色膠囊，有STD及505字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1001154

14.02B2 Non-Selective NSAID

22843 ɔt be ruled out / Infant risk can

POTARLON* FILM COATED TABLETS 500MG (MEFENAMIC ACID) 保痛樂膜衣錠 5 0 0 公絲（每非那）

Mefenamic acid 500mg FC tab

Dosage: 1常備品 22843

Adult
·Pain: PO, initial 500 mg then 250 mg q6h as needed. For acute pain, drug should not be administered for longer than 1 week.
·Dysmenorrhea: PO, initial 500 mg then 250 mg q6h as needed. Therapy should not be necessary for more than 2-3 days.

Pediatric (>14yrs)
·Pain, Dysmenorrhea: same as adult.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Not recommended for use.

P: Tab: 500mg(22843)

ADR:

COMMON
diarrhea, GI upset, rash, dizziness

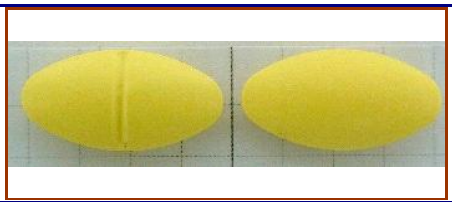
NOTE: 儲存25℃以下

·《Contraindications》Known hypersensitivity to mefenamic acid or any component of the product; History of asthma, urticaria, or allergic-type reaction following aspirin or other NSAID administration; In the setting of CABG surgery ;

藥名相似:

外觀相似:

外觀描述: 黃色長橢圓形錠，一面有一刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1030119

14.02B2 Non-Selective NSAID

22845 ɔt be ruled out / Infant risk can

DEFLAM-K F.C. TABLETS 25MG "KINGDOM" (DICLOFENAC POTASSIUM) "景德" 驅炎寧膜衣錠 2 5 毫克(二克氣吩鉀)

Diclofenac potassium 25mg tab

Dosage: 1常備品 22845

Adult
·Osteoarthritis: PO, 100-150 mg/day div. 2-3 doses
·Rheumatoid arthritis: PO, 150-200 mg/day div. 3-4 doses
·Ankylosing spondylitis: PO, 100-125 mg/day div. 4-5 doses
·Analgesia or primary dysmenorrhea: PO, 50 mg tid

Pediatric(<14yrs)
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Dosage reductions may be necessary.

Dosing adjustments in renal impairment:

No dosage adjustment needed. however, should be monitored closely.

P: Tab: 25mg(22845), 100mg(22860); Supp: 12.5mg (29012); Inj: 75mg/3mL

ADR:

COMMON
abdominal pain, constipation, diarrhea, dyspepsia, flatulence, nausea, rash, pruritus, tinnitus, dizziness, headache, edema, elevations in liver function tests
SERIOUS
GI ulceration, GI perforation, melena, vomiting, jaundice, hepatitis, hepatic necrosis, cirrhosis, anaphylaxis, leukopenia, hypertension, CHF, anemia, purpura, thrombocytopenia, aseptic meningitis, seizures, angioedema, erythema multiforme, Stevens-Johnson syndrome, proteinuria, acute renal failure, interstitial nephritis, nephrotic syndrome, blurred vision, hearing loss

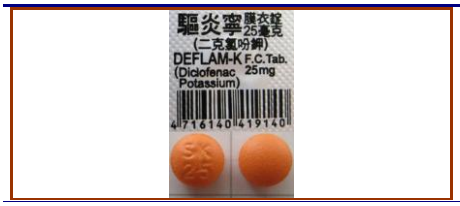
NOTE: 儲存25℃以下

·《Contraindications》Asthma, urticaria, or allergic-type reaction following aspirin or other NSAID administration; severe and rarely fatal anaphylactic-like reactions have been reported; Hypersensitivity to bovine protein (liquid-filled capsules); Hypersensitivity to diclofenac potassium or any component of the product; Use in the setting of CABG surgery ;
·FDA Pregnancy Category: Category C (1st trimester), C (2nd trimester), D (3rd trimester)

藥名相似:

外觀相似:

外觀描述: 橘色圓扁錠，一面有SK 25字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045358

14.02B2 Non-Selective NSAID

22847 **C / Caution**

LABUTON* F.C. TABLETS 500MG "WEIDAR" "衛達" 樂不痛膜衣錠500公絲

Nabumetone 500mg Tab

Dosage: 1常備品 22847

Adult
·Osteoarthritis, rheumatoid arthritis: PO, 1000 mg/day div. into 1-2 doses, Max. 2 g/day

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Should be used cautiously in severe hepatic impairment patients.

Dosing adjustments in renal impairment:

Clcr 30-49 mL/min: initial dose should not exceed 750 mg/day, Max. 1500 mg/day
Clcr <30 mL/min: initial dose should not exceed 500 mg/day, Max. 1000 mg/day

P: Tab: 500mg(22847)

ADR:

COMMON
edema, dizziness, headache, insomnia, abdominal pain, constipation, diarrhea, dyspepsia, flatulence, nausea, positive stool guaiac, pruritus, rash, tinnitus
SERIOUS
GI bleeding, GI perforation, melena, LFT abnormalities, hepatic failure, allergic reactions, erythema multiforme, albuminuria, azotemia, interstitial nephritis, renal failure, anemia, thrombocytopenia

NOTE: 室溫儲存

·《Contraindications》Asthma, urticaria, or allergic-type reaction following aspirin or other NSAID administration; severe and rarely fatal anaphylactic-like reactions have been reported; Hypersensitivity to nabumetone or product excipients; Use in the setting of CABG surgery；
·Swallow whole; do not crush or chew

藥名相似:

外觀相似:

外觀描述: 深桃紅色長橢圓錠，一面有WEIDAR字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044916

14.02B2 Non-Selective NSAID

22849 **C / Caution**

MOBIC* (R) Tablets 15mg 骨敏捷(R)錠15毫克(希臘廠)

Meloxicam 15mg tab

Dosage: 1常備品 22849

Adult
· Rheumatoid arthritis, osteoarthritis: PO, 7.5-15 mg qd, Max. 15 mg/day

Pediatric (2 yrs and older)
· Juvenile rheumatoid arthritis, pauciarticular-polyarticular juvenile rheumatoid arthritis: PO, 0.125 mg/kg once daily; Max. 7.5 mg/day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed in mild-to-moderate hepatic impairment.

Dosing adjustments in renal impairment:

No dosage adjustment needed in mild-to-moderate renal impairment.
Use in severe renal impairment (CrCl < 15 mL/min) is not recommended.

P: Tab: 15mg(22849)

ADR:

COMMON
abdominal pain, diarrhea, dyspepsia, flatulence, nausea, edema, dizziness, headache, insomnia, pharyngitis, URI, UTI
pruritus, rash, anemia, arthralgia, back pain
SERIOUS
allergic reaction, anaphylaxis, angina, CHF, hypertension, MI, vasculitis, GI ulceration, GI perforation, melena, pancreatitis, arrhythmias, agranulocytosis, leukopenia, purpura, thrombocytopenia, liver function test abnormalities, hepatitis, jaundice, liver failure, asthma, bronchospasm, dyspnea, erythema multiforme, Stevens-Johnson syndrom, toxic epidermal necrolysis, interstitial nephritis, renal failure

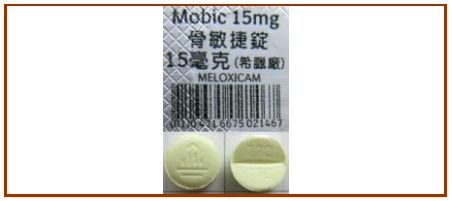
NOTE: 室溫儲存

·《Contraindications》History of asthma, urticaria, or allergic-type reaction following aspirin or other NSAID administration; severe and sometimes fatal anaphylactic reactions have been reported; Known hypersensitivity to meloxicam or the product components, including anaphylactic reactions and serious skin reactions; In the setting of coronary artery bypass graft (CABG) surgery; Moderate to severe renal insufficiency patients who are risk for renal failure due to volume depletion; Patients with phenylketonuria; 7.5-mg and 15-mg orally disintegrating tablets contain 0.3 mg and 0.59 mg of phenylalanine, respectively；

藥名相似:

外觀相似:

外觀描述: 淺黃色圓扁錠，一面有刻痕雙側77C字樣，一面有商標圖案



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025747

14.02B2 Non-Selective NSAID

22853 UK / Caution

ACEMET CAPSULES 60MG 艾斯美特膠囊60毫克

Acemetacin 60mg cap

Dosage: 1常備品 22853

ADULT
·Inflammatory and rheumatic disorders: PO, 60 mg qd-tid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Cap: 60mg(22853)

ADR:

Blood dyscrasias, gastric or duodenal ulcers, ulcerative colitis, renal insufficiency, hepatic insufficiency, high blood pressure, congestive heart failure

NOTE: 儲存30℃以下

1.不可咬碎
2.Contraindications: blood dyscrasias, hypersensitivity to acemetacin or other non-steroidal anti- inflammatory drugs, current gastric and duodenal ulcer, children under 14 years of age, the third trimester of pregnancy
3.仿單新增列之警語
(1)心血管栓塞事件-儘可能使用最短治療時間及最小有效劑量。用藥期間應注意心血管不良事件之發生。
(2)冠狀動脈繞道手術(CABG)後-進行冠狀動脈繞道手術之後14 天內禁用本藥。
(3)最近發生心肌梗塞的病人-應避免使用。若使用於近期發生心肌梗塞者，應嚴密監視是否出現心肌缺血之症狀。
(4)心臟衰竭與水腫-應避免使用。若使用於嚴重心臟衰竭者，應嚴密監視是否出現心臟衰竭惡化之症狀。

藥名相似:

外觀相似:

外觀描述: 橘/白膠囊，有Acemet字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1040011

14.02B2 Non-Selective NSAID

22855 ɔt be ruled out / Infant risk can

NAPROXEN* TABLETS "SINPHAR" 那普洛先錠

Naproxen 250mg tab

Dosage: 1常備品 22855

Adult
·Rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, pain & dysmenorrhea, fever: PO, 250-500 mg bid, may increased to 1.5g/day
·Acute gouty arthritis: PO, 750 mg initially, then 250 mg q8h until the attack subsides

Pediatric
·Juvenile rheumatoid arthritis: PO, 10 mg/kg/day in 2 divided doses, Max. 15-20 mg/kg
·The safety and efficacy of naproxen have not been established in pediatric patients younger than 2 years of age

Dosing adjustments in hepatic impairment:

Reduce dose by 50%

Dosing adjustments in renal impairment:

Clcr <30 mL/min: use is not recommended

P: Tab: 250 mg(22855)

ADR:

COMMON
Edema, Ecchymosis, Pruritus, Rash, Abdominal pain, Constipation, Heartburn, Nausea, Dizziness, Headache, Somnolence, Ototoxicity, Tinnitus, Dyspnea.
SERIOUS
Body fluid retention, Congestive heart failure, Hypertension, Myocardial infarction, Vasculitis, Erythema multiforme, Erythroderma, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Hyperkalemia, Gastrointestinal hemorrhage, Gastrointestinal perforation, Gastrointestinal ulcer, Hematemesis, Inflammatory bowel disease, Pancreatitis, Agranulocytosis, Anemia, Aplastic anemia, Granulocytopenic disorder, Hemolytic anemia, Hemorrhage, Thrombocytopenia, Thrombosis, Hepatitis, Hepatotoxicity, Increased liver function test, Jaundice, Liver failure, Anaphylaxis, Aseptic meningitis, Cerebrovascular accident, Seizure, Acute renal failure, Nephritis, Nephrotic syndrome, Nephrotoxicity, Renal failure, Bronchospasm, Pulmonary edema, Angioedema.

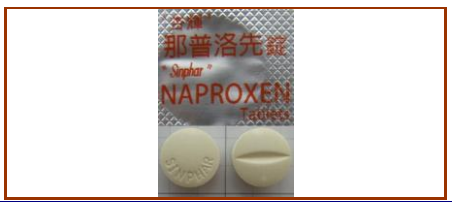
NOTE: 室溫儲存

·《Contraindications》Asthma, urticaria, or allergic-type reaction following aspirin or other NSAID administration; severe, even fatal anaphylactic-like reactions have been reported; Hypersensitivity to naproxen or any component of the product; Use in the setting of CABG surgery ;

藥名相似:

外觀相似:

外觀描述: 米白色圓凸錠，一面中央有刻痕，另一面有"SINPHAR"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1019620

14.02B2 Non-Selective NSAID

22860 B / Caution

VOTAN* SR F.C. TABLETS 100MG "信東" 莫痛緩釋膜衣錠１００毫克

Diclofenac sodium 100mg SR FC tab

Dosage: 1常備品 22860

Adult
·Osteoarthritis: PO, 100-200 mg qd, Max. 200mg/day
·Rheumatoid arthritis: PO, 100-200 mg qd-bid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Dosage reductions may be necessary.

Dosing adjustments in renal impairment:

No adjustment needed. however, should be monitored closely.

P: Tab: 25mg(22845), 100mg(22860); Supp: 12.5mg (29012); Inj: 75mg/3mL Amp(32437)

ADR:

COMMON
abdominal pain, constipation, diarrhea, dyspepsia, flatulence, nausea, rash, pruritus, tinnitus, dizziness, headache, edema, elevations in liver function tests
SERIOUS
GI ulceration, GI perforation, melena, vomiting, jaundice, hepatitis, hepatic necrosis, cirrhosis, anaphylaxis, hypertension, CHF, anemia, leukopenia, thrombocytopenia, purpura, aseptic meningitis, seizures, angioedema, erythema multiforme, Stevens-Johnson syndrome, proteinuria, acute renal failure, interstitial nephritis, nephrotic syndrome, blurred vision, hearing loss

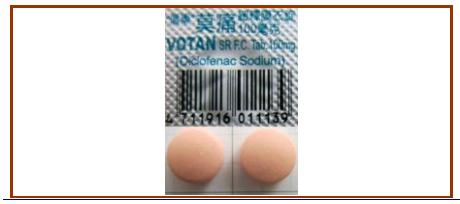
NOTE: 室溫儲存

·《Contraindications》History of asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs; severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported; In the setting of coronary artery bypass graft (CABG) surgery; Hypersensitivity to diclofenac or any component of the product; Mild or severe renal insufficiency and at risk for volume depletion during perioperative period；
·SR tab should be swallow whole, do not crush or chew
·FDA Pregnancy Category: Category C (1st trimester), C (2nd trimester), D (3rd trimester)

藥名相似:

外觀相似:

外觀描述: 淺橘色圓扁錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044478

14.02B2 Non-Selective NSAID

22891 UK / Caution

ASCOFEN* F.C. TABLETS 100MG "STANDARD" (ACECLOFENAC) "生達"炎立消膜衣錠100毫克

Aceclofenac 100mg tab

Dosage: 1常備品 22891

Adult
·Osteoarthritis, rheumatoid arthritis, ankylosing spondylitis：PO, 100 mg bid.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

The initial dose should be reduced to 100 mg daily in patients with hepatic impairment.

Dosing adjustments in renal impairment:

Should be avoided in patients with moderate to severe renal impairment.

P: Tab: 100mg(22891)

ADR:

COMMON
Abdominal pain, constipation, diarrhea, dyspepsia, flatulence, nausea, rash, pruritus, tinnitus, dizziness, headache, edema, elevations in liver function tests
SERIOUS
GI ulceration, GI perforation, melena, vomiting, jaundice, hepatitis, hepatic necrosis, cirrhosis, anaphylaxis, leukopenia, hypertension, CHF, anemia, purpura, thrombocytopenia, aseptic meningitis, seizures, angioedema, erythema multiforme, Stevens-Johnson syndrome, proteinuria, acute renal failure, interstitial nephritis, nephrotic syndrome, blurred vision, hearing loss.

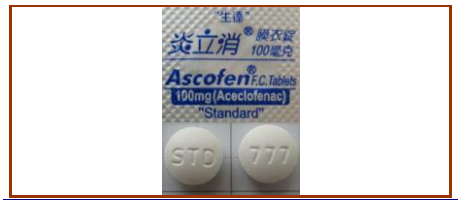
NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to aceclofenac or diclofenac; Rhinitis, urticaria, asthma, or allergic reactions to aspirin or other anti-inflammatory agents；

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有"777"字樣，另一面有"STD"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1057798

14.02B2 Non-Selective NSAID

28532 ɔt be ruled out / Infant risk can

IBUPROFEN* ORAL SUSPENSION 20MG/ML "CENTER" "晟德"依普芬口服懸液劑20毫克/毫升

Ibuprofen Susp 1200mg/60mL, 60mL/ Bot

Dosage: 1常備品 28532

Pediatric
·Analgesic: PO, 4-10 mg/kg/dose q6-8h
·Antipyretic(6mons-12yrs): PO, 5 mg/kg/dose q6-8h(<39℃) or 10 mg/kg/dose q6-8h(>39℃), Max. 40 mg/kg/day
·Juvenile rheumatoid arthritis: PO, 30-50 mg/kg/day div. into 4 doses, Max. 2.4 g/day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Susp: 20mg/mL, 60mL/Bot(28532)

ADR:

COMMON
abdominal pain, constipation, diarrhea, dyspepsia, heartburn, nausea, stomatitis, vomiting, dizziness, drowsiness, headache
edema, tinnitus, rash
SERIOUS
liver function test abnormalities, hepatitis, jaundice, GI bleeding, GI perforation, melena, pancreatitis, acute renal failure, azotemia, hematuria, agranulocytosis, anemia, thrombocytopenia, neutropenia, hypertension, CHF, anaphylaxis, depression, insomnia, confusion, aseptic meningitis, erythema multiforme, Stevens-Johnson syndrome, hearing loss, amblyopia

NOTE: 室溫儲存

·《Contraindications》Asthma, urticaria, or other allergic-type reaction following aspirin or other NSAID administration (severe and sometimes fatal anaphylactic reactions have been reported); In the setting of coronary artery bypass graft (CABG) surgery; Hypersensitivity to ibuprofen or any component of the product；

· Due to known effects on the fetal cardiovascular system (closure of ductus arteriosus), use during late pregnancy should be avoided
· FDA Pregnancy Category: Category C (1st trimester), C (2nd trimester), D (3rd trimester)

藥名相似:

外觀相似:

外觀描述: 白色瓶蓋,60mL塑膠瓶，內有紫色藥水

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043152

14.02B2 Non-Selective NSAID

29012 **c / Caution**

VOREN* SUPPOSITORIES 12.5MG (DICLOFENAC) 非炎栓劑１２．５毫克（待克菲那）

Diclofenac sodium 12.5mg Supp

Dosage: 1常備品 29012

Pediatric
·Fever, pain: Rectal, 2-5 yrs: 25 mg; 6-10 yrs: 50 mg
·Rheumatoid arthritis: Rectal, 25 mg or 50 mg

Dosing adjustments in hepatic impairment:

Dosage reductions may be necessary.

Dosing adjustments in renal impairment:

No dosage adjustment needed. however, should be monitored closely.

P: Tab: 25mg(22845), 100mg(22860); Supp: 12.5mg (29012); Inj: 75mg/3mL Amp(32437)

ADR:

COMMON
abdominal pain, constipation, diarrhea, rash, dyspepsia, flatulence, nausea, edema, pruritus, tinnitus, dizziness, headache, elevations in liver function tests
SERIOUS
GI ulceration, GI perforation, melena, vomiting, jaundice, hepatitis, hepatic necrosis, cirrhosis, anaphylaxis, hypertension, CHF, anemia, leukopenia, thrombocytopenia, purpura, aseptic meningitis, seizures, angioedema, erythema multiforme, Stevens-Johnson syndrome, proteinuria, acute renal failure, interstitial nephritis, nephrotic syndrome, blurred vision, hearing loss

NOTE: 室溫儲存

·《Contraindications》History of asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs; severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported; In the setting of coronary artery bypass graft (CABG) surgery; Hypersensitivity to diclofenac or any component of the product; Mild or severe renal insufficiency and at risk for volume depletion during perioperative period；
· FDA Pregnancy Category: Category C (1st trimester), C (2nd trimester), D (3rd trimester)

藥名相似:

外觀相似:

外觀描述: 子彈型臘質栓劑,白色塑膠膜,白底橘色字印刷

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1028656

14.02B2 Non-Selective NSAID

32437 **B / Caution**

VOREN INJECTION* (DICLOFENAC) "YUNG SHIN" "永信" 非炎注射液（待克菲那）

Diclofenac sodium inj 75mg/3mL amp

Dosage: 1常備品 32437

Adult
·Pain, rheumatoid arthritis, osteoarthritis: IM, 75 mg 1-2 times/day.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Dosage reductions may be necessary.

Dosing adjustments in renal impairment:

No dosage adjustment needed. however, should be monitored closely.

P: Tab: 25mg(22845), 100mg(22860); Supp: 12.5mg (29012); Inj: 75mg/3mL Amp(32437)

ADR:

COMMON
abdominal pain, constipation, diarrhea, dyspepsia, flatulence, nausea, rash, pruritus, tinnitus, dizziness,

headache, edema, elevations in liver function tests
SERIOUS
GI ulceration, GI perforation, melena, vomiting, jaundice, hepatitis, hepatic necrosis, cirrhosis, anaphylaxis, hypertension, CHF, anemia, leukopenia, thrombocytopenia, purpura, aseptic meningitis, seizures, angioedema, erythema multiforme, Stevens-Johnson syndrome, proteinuria, acute renal failure, interstitial nephritis, nephrotic syndrome, blurred vision, hearing loss

NOTE: 室溫儲存

·《Contraindications》History of asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs; severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported; In the setting of coronary artery bypass graft (CABG) surgery; Hypersensitivity to diclofenac or any component of the product; Mild or severe renal insufficiency and at risk for volume depletion during perioperative period ;
·FDA Pregnancy Category: Category C (1st trimester), C (2nd trimester), D (3rd trimester)

藥名相似:

外觀相似:

外觀描述: 3mL透明注射液,透明安瓿頸部有藍點,白底綠字有綠色區塊印刷

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1020785

14.02B2 Non-Selective NSAID

32438 **B / Caution**

Laston Injection 30 mg/ml (Ketorolac Tromethamine) "信東" 克痛解注射液30 毫克/毫升

■Ketorolac tromethamine inj 30mg/1mL amp

Dosage: 1常備品 32438

Adult
·Analgesic:
Single-dose treatment: IM, 60 mg; IV, 30 mg
Multiple-dose treatment: IV, IM, 30 mg q6h, Max. 120 mg/day

Pediatric
·Analgesic(2-16yrs): Single-dose treatment: IM, 1 mg/kg, Max. 30 mg; IV, 0.5 mg/kg, Max.15 mg

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Single IM, 30mg or IV, 15mg
Multiple-dose, 15 mg q6h, Max. 60mg daily

P: Oph soln: 0.5% 5mL/B (29197); Inj: 30mg/1mL Amp(32438)

ADR:

COMMON
abdominal pain, constipation, diarrhea, dyspepsia, flatulence, nausea, stomatitis, vomiting, edema, hypertension, pruritus, rash, purpura, injection site pain, dizziness, drowsiness, headache, sweating
SERIOUS
bleeding complications, epithelial breakdown, palpitations, pallor, syncope, liver function test abnormalities, hepatitis, jaundice, GI bleeding, GI perforation, melena, pancreatitis, hematuria, proteinuria, anemia, interstitial nephritis, renal failure, leukopenia, thrombocytopenia, angioedema, asthma, anaphylaxis, Stevens-Johnson syndrome, hearing loss, dyspnea, pulmonary edema, bronchospasm, aseptic meningitis, convulsions, psychosis

NOTE: 室溫避光

·《Contraindications》Allergic-type reaction, asthma, or urticaria in response to exposure to aspirin or other NSAIDs; severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported; Bleeding risk, suspected or confirmed; CABG surgery, perioperative pain treatment or any use in the setting of CABG surgery; suspected or confirmed Cerebrovascular bleeding ; Concomitant aspirin or NSAID use; Concomitant pentoxifylline use; Concomitant probenecid use; recent or history of Gastrointestinal bleeding/perforation; suspected or confirmed Hemorrhagic diathesis; incomplete, suspected or confirmed Hemostasis; Hypersensitivity to aspirin or to other NSAIDs; Hypersensitivity to EDTA; Hypersensitivity or serious skin reactions ketorolac tromethamine or to any product component; Labor and delivery; increased risk of uterine hemorrhage and risk for adversely affecting fetal circulation; Neuraxial (epidural or intrathecal) administration; Nursing mothers; increased risk of adverse events in the neonate; Peptic ulcer disease, active or history; Renal impairment, advanced, or risk of renal failure due to volume depletion; Use of ketorolac tromethamine as a prophylactic analgesic prior to major surgery ;
·The total duration of ketorolac therapy should not exceed 5 days.
·IV bolus doses should be administered over at least 15 seconds.

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液，透明安瓿頸部有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1047551

14.02B3 Selective Cox-2 Inhibitors

22819 **UK / Unsafe**

ARCOXIA* TABLET 60MG 萬克適錠60毫克

Etoricoxib 60mg tab

Dosage: 1常備品 22819

Adult
· Osteoarthritis: PO, 60 mg once daily
· Rheumatoid arthritis: PO, 90 mg once daily
· Acute gouty arthritis, primary dysmenorrhea: PO,

120 mg once daily for a maximum of 8 days

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Mild hepatic impairment (Child-Pugh score 5-6): <60 mg qd
Moderate hepatic impairment (Child-Pugh score 7-9): <60 mg qod
Severe hepatic impairment (Child-Pugh score >9): Not recommended

Dosing adjustments in renal impairment:

Clcr > 30mL/min: No dosage adjustment need
Clcr < 30mL/min: Not recommended

P: Tab: 60mg(22819)

ADR:

Asthenia, fatigue, dizziness, lower extremity edema, hypertension, dyspepsia, heartburn, nausea, headache, ALT/AST increased

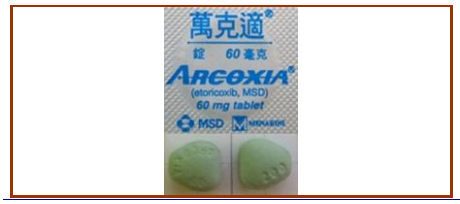
NOTE: 室溫儲存

·《Contraindications》Previous hypersensitivity to etoricoxib; Acute peptic ulcer disease or GI bleeding; Patients with a history of bronchospasm with rhinoconjunctivitis or urticaria/angioedema associated with aspirin or other nonsteroidal antiinflammatory agents (adult-onset asthma, chronic rhinitis, nasal polyps, and chronic urticaria/angioedema predispose to these reactions) (risk of anaphylactic-like reactions; Severe renal or hepatic disease ;
· Etoricoxib 120mg should be used only for the acute symptomatic period, limited to a maximum of 8 days treatment

藥名相似:

外觀相似:

外觀描述: 綠色三角形錠，有200及ARCOXIA 60字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023983

14.02B3 Selective Cox-2 Inhibitors

22856 C / Caution

CELEBREX* CAPSULE 200MG 希樂葆膠囊２００毫克

Celecoxib 200mg Cap

Dosage: 1常備品 22856

Adult
·Osteoarthritis: PO, 100mg bid or 200mg qd
·Rheumatoid arthritis: PO, 100mg-200mg bid
·Acute pain, primary dysmenorrhea: PO, initial 400 mg, followed by an additional 200 mg dose if needed on the first day. On subsequent days, 200 mg bid as needed.

Pediatric
·Safety and efficacy have not been established in patients less than 2 years old.
·Juvenile rheumatoid arthritis(≥2yrs), 10-25 kg : PO, 50 mg bid.
·Juvenile rheumatoid arthritis(≥2yrs), >25 kg : PO, 100 mg bid.

Dosing adjustments in hepatic impairment:

Moderate hepatic impairment (Child-Pugh Class B): decrease dose by 50%

Dosing adjustments in renal impairment:

Severe renal impairment: not recommended

P: Cap: 200mg(22856)

ADR:

COMMON
Hypertension, Diarrhea, Nausea, Headache
SERIOUS
Myocardial infarction, Torsades de pointes, Ventricular hypertrophy, Erythema multiforme, Erythroderma, Generalized exanthematous pustulosis, acute, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Hyperkalemia, Gastrointestinal hemorrhage, Gastrointestinal perforation, Gastrointestinal ulcer, Inflammatory disorder of digestive tract, Hemorrhage, Thrombosis, Fulminant hepatitis, Hepatotoxicity (Rare), Increased liver enzymes, Liver failure, Anaphylactoid reaction, Drug reaction with eosinophilia and systemic symptoms, Cerebrovascular accident, Acute renal failure, Injury of kidney, Asthma, Bronchospasm.

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity (eg, anaphylactic reactions and serious skin reactions) to celecoxib or any components of the drug product; History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs; severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported; In the setting of CABG surgery; In patients who have demonstrated allergic-type reactions to sulfonamides ;
1.FDA Pregnancy Category: Category C (1st trimester), C (2nd trimester), D (3rd trimester)
2.禁忌症：(A)進行冠狀動脈繞道手術後14天內禁用本藥。(B)曾對磺醯胺(sulfonamides)產生過敏反應者。(C)曾於服用aspirin或其它NSAIDs之後出現氣喘、蕁麻疹、或其他過敏反應的病人。
3.應避免使用本藥於近期發生心肌梗塞者、嚴重心臟衰竭者、有aspirin敏感性者、孕婦從妊娠30週開始(第三孕期)-胎兒動脈導管過早閉合。
4.嚴重心血管事件：
·剛開始使用該 類藥品的幾周內，即可能出現嚴重心血管栓塞事件，而且隨著使用劑量增加，其心血管栓塞事件之風險亦隨之增加。為減少心血管栓塞事件潛在風險，建議儘可能使用最短治療時間及最小有效劑量。
·沒有一致的證據證明同時使用aspirin會緩和使用NSAID伴隨的嚴重心血管栓塞性事件的危險性增加。而同時使用aspirin和NSAID (如CELEBREX)確實會增加嚴重胃腸道。
(GI)事件的危險性
5.胃腸道(GI)事件：
·胃腸道(GI)出血、潰瘍及穿孔-老年人及先前有消化性潰瘍病史或胃腸道(GI)出血的病人有較高的危險會出現嚴重事件。

藥名相似:

外觀相似:

外觀描述: 白色黃條紋膠囊，有7767及200字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023177

14.02B3 Selective Cox-2 Inhibitors

32445 C / Infant risk can

DYNASTAT 40MG POWDER FOR SOLUTION FOR INJECTION 得術泰注射劑40毫克

Parecoxib inj 40mg pow in vial

Dosage: 1常備品 32445

Adult

· Short-term treatment (not more than 4 days) of postoperative pain: IV or IM 40mg, followed q6-12 hours by 20 mg or 40mg as required; Max. 80mg/day

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Child-Pugh score 5-6 : No dosage adjustment is generally required.
Child-Pugh score 7-9 : 1/2 of the usual recommended dose; Max. 40mg/day.
Child-Pugh score≧10 : contraindicated.

Dosing adjustments in renal impairment:

Mild to moderate renal impairment : No dosage adjustment needed
Severe renal impairment: initiated at the lowest recommended dose and closely monitored.

P: P Inj: 40mg vial(32445)

ADR:

COMMON
Hypertension, peripheral edema, rash, abdominal pain, diarrhea, flatulence, indigestion, nausea, backache, myalgia, dizziness, headache, sinusitis, upper respiratory infection
SERIOUS
Angina, cardiac dysrhythmia, congestive heart failure, coronary arteriosclerosis, deep venous thrombosis, hypertension, aggravated, myocardial infarction, unstable angina, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, esophageal perforation, gastrointestinal hemorrhage, melena, thrombocytopenia, hepatitis, increased liver function test, anaphylaxis, hypersensitivity reaction, cerebrovascular accident, acute renal failure, pulmonary embolism

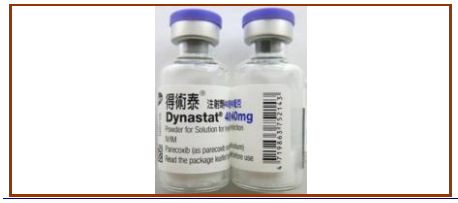
NOTE: 室溫儲存

· There is limited clinical experience with treatment beyond 3 day.
(1)進行冠狀動脈繞道手術之後14天內禁用本藥。
(2)最近發生心肌梗塞的病人-應避免使用。若使用，應嚴密監視是否出現心肌缺血之症狀。
(3)心臟衰竭與水腫-應避免使用。若使用，應嚴密監視是否出現心臟衰竭惡化之症狀。
(4)NSAIDs藥品會增加嚴重心血管栓塞事件之風險，包括心肌梗塞和中風，且可能致命。此風險可能發生在使用藥品的初期，且時間越長，風險越大。

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『紫』蓋透明玻璃小瓶



14.02C Analgesics, Non-Narcotic

22827 ɔt be ruled out / Infant risk is

DEPYRETIN TABLETS 500mg(ACETAMINOPHEN) "榮民" 得百利寧錠500毫克

Acetaminophen 500mg tab

Dosage: 1常備品 22827

Adult

·Fever, pain, headache, dysmenorrhea: PO, 500 mg-1g q4-6 h as needed, max 4 g/day.

Pediatric

·Analgesia, antipyresis: PO, <12 yrs: 10-15 mg/kg/dose q4-6h, Max. 5 doses/day.
Age(Weight)-related dosing: PO, q4-6h as needed
Up to 3 mons(2.7-5 kg): 40 mg/dose
4-11mons (5-8 kg): 80 mg/dose
12-23mons (8-11 kg):120 mg/dose
2-3yrs (11-16 kg): 160 mg/dose
4-5yrs (16-21.5 kg): 240 mg/dose
6-8yrs (21.5-27 kg): 320 mg/dose
9-10yrs (27-32.5 kg): 400 mg/dose
11yrs (32.5-43 kg): 480 mg/dose
>12yrs: same as adult

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Clcr 10-50 mL/min: administer q6h
Clcr <10 mL/min: administer q8h

P: Tab: 80mg(22830)(39313健診), 500mg(22827), TRAMACET*(22831); Syrup: 24mg/mL, 60mL/Bot (28531); Inj: 1 gm(32435) Vial

ADR:

COMMON
Pruritus, Constipation, Nausea, Vomiting, Headache, Insomnia, Agitation, Atelectasis.
SERIOUS
Acute generalized exanthematous pustulosis, , Stevens-Johnson syndrome, Toxic epidermal necrolysis, Liver failure, Pneumonitis.

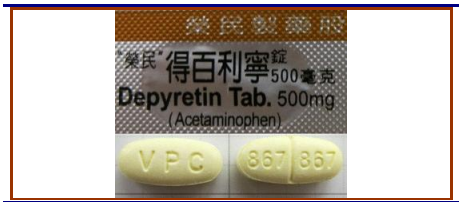
NOTE: 室溫儲存

·《Contraindications》Active and severe hepatic disease; Hypersensitivity to acetaminophen or any other components of the product; Severe hepatic impairment ;
·Acetylcysteine is the antidote of acetaminophen

藥名相似:

外觀相似:

外觀描述: 黃色長橢圓扁錠，中間有刻痕，有"867"及"VPC"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1020707

14.02C Analgesics, Non-Narcotic

22830 **ɔt be ruled out / Infant risk is**

BUBDEL* TABLETS 80MG (ACETAMINOPHEN)"WINSTON" "溫士頓"普德錠 8 0 毫克（對位乙醯氨基酚）

Acetaminophen 80mg tab

Dosage: 1常備品 22830

Pediatric
·Analgesia, antipyresis: PO, <12 yrs: 10-15 mg/kg/dose q4-6h, Max. 5 doses/day.
Age(Weight)-related dosing: PO, q4-6h as needed
Up to 3 mons(2.7-5 kg): 40 mg/dose
4-11mons (5-8 kg): 80 mg/dose
12-23mons (8-11 kg):120 mg/dose
2-3yrs (11-16 kg): 160 mg/dose
4-5yrs (16-21.5 kg): 240 mg/dose
6-8yrs (21.5-27 kg): 320 mg/dose
9-10yrs (27-32.5 kg): 400 mg/dose
11yrs (32.5-43 kg): 480 mg/dose
>12yrs: same as adult

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Clcr 10-50 mL/min: administer q6h
Clcr <10 mL/min: administer q8h

P: Tab: 80mg(22830)(39313健診), 500mg(22827), TRAMACET*(22831); Syrup: 24mg/mL, 60mL/Bot (28531); Inj: 1 gm(32435) Vial

ADR:

COMMON
hypothermia, rash
SERIOUS
GI bleeding, hepatotoxicity, nephrotoxicity, pneumonitis

NOTE: 室溫儲存

·《Contraindications》Active and severe hepatic disease; Hypersensitivity to acetaminophen or any other components of the product; Severe hepatic impairment ;
·Acetylcysteine is the antidote of acetaminophen
·含阿斯巴甜，苯酮尿症者不宜使用。

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有W字樣，另一面有刻痕

14.02C Analgesics, Non-Narcotic

28531 **ɔt be ruled out / Infant risk is**

ANTI-PHEN SYRUP 24MG/ML"CENTER" "晟德" 安佳熱糖漿 2 4 毫克/毫升

Acetaminophen syrup 24mg/mL, 60mL/Bot

Dosage: 1常備品 28531

Adult
·

Pediatric
·Analgesia, antipyresis: PO, <12 yrs:10-15 mg/kg/dose q4-6h, Max. 5 doses/day.
Age(Weight)-related dosing: PO, q4-6h as needed
Up to 3 mons(2.7-5 kg): 40 mg/dose
4-11mons (5-8 kg): 80 mg/dose
12-23mons (8-11 kg):120 mg/dose
2-3yrs (11-16 kg): 160 mg/dose
4-5yrs (16-21.5 kg): 240 mg/dose
6-8yrs (21.5-27 kg): 320 mg/dose
9-10yrs (27-32.5 kg): 400 mg/dose
11yrs (32.5-43 kg): 480 mg/dose
>12yrs: same as adult

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Clcr 10-50 mL/min: administer q6h
Clcr <10 mL/min: administer q8h

P: Tab: 80mg(22830)(39313健診), 500mg(22827), TRAMACET*(22831); Syrup: 24mg/mL, 60mL/Bot (28531); Inj: 1 gm(32435) Vial

ADR:

COMMON
hypothermia, rash
SERIOUS
GI bleeding, hepatotoxicity, nephrotoxicity, pneumonitis

NOTE: 室溫儲存

·《Contraindications》Active and severe hepatic disease; Hypersensitivity to acetaminophen or any other components of the product; Severe hepatic impairment ;
·含阿斯巴甜，苯酮尿症者不宜使用。(1.25mg/mL)
·Acetylcysteine is the antidote of acetaminophen

藥名相似:

外觀相似:

外觀描述: 60mL淡紅色澄清液體，半透明塑膠瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1040164

14.02C Analgesics, Non-Narcotic

32435 **UK / No report(毫**

Acetamol Injection 1g "Standard" "生達" 舒疼消熱注射劑 1 公克

Propacetamol HCl 1g Vial with 5mL solvent (sodium citrate 100mg)

Dosage: 1常備品 32435

Adult
·Analgesia, antipyresis: IV, 1 to 2 g q4h up to 4 times daily if necessary, Max. 8 g/day

Pediatric (>4 yrs or >17 kg)
·Analgesia, antipyresis: IV, 20-30 mg/kg over 15 minutes up to 4 times daily, Max. 120 mg/kg

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 80mg(22830)(39313健診), 500mg(22827), TRAMACET*(22831); Syrup: 24mg/mL, 60mL/Bot (28531); Inj: 1g Vial with 5mL solvent (32435)

ADR:

COMMON
Hypothermia, rash
SERIOUS
GI bleeding, hepatotoxicity, nephrotoxicity, pneumonitis

NOTE: 室溫儲存

·《Contraindications》Active and severe hepatic disease; Hypersensitivity to acetaminophen or any other components of the product; Severe hepatic impairment ;
·Propacetamol is hydrolysed to paracetamol(ACT) in the plasma. Propacetamol 1g is equivalent to ACT 0.5g.
·配製本藥時必須穿戴手套(曾有醫療人員因對propacetamol過敏，在操作後發生接觸性濕疹)

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『紅』蓋透明玻璃小瓶，附5mL調配專用溶劑

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049126

14.02D Analgesics, Urinary

21265 **B / Caution**

UROPRIN SUGAR COATED TABLETS 100MG 攸汝琳路必淨糖衣錠100毫克

Phenazopyridine HCl 100mg Tab

Dosage: 1常備品 21265

Adult
·Urinary tract discomfort: PO, 200 mg tid

Pediatric
·Urinary tract discomfort: PO, 12 mg/kg/day in 3 div. doses

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr >50 mL/min: administer q8-16h.
Clcr <50 mL/min: not recommened

P: Tab: 100mg(21265)

ADR:

COMMON
gastrointestinal disturbance, headache, rash, pruritus, anaphylactoid reactions
SERIOUS
hemolytic anemia, nephrotoxicity, hepatotoxicity

NOTE: 室溫儲存

·《Contraindications》hypersensitivity to phenazopyridine products; renal insufficiency ;

藥名相似:

外觀相似:

外觀描述: 紫色圓扁錠

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12000102

14.02D Analgesics, Urinary

21266 **B / Caution**

Urosan Capsules 優而順膠囊

Pentosan polysulfate Sod 100mg cap

Dosage: 1常備品 21266

Adult
·Interstitial cystitis, chronic, relief of bladder pain or discomfort: PO, 100 mg tid ac

Pediatric
·Safety and efficacy in patients <16 y/o have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: 100 mg (21266)

ADR:

COMMON
Alopecia, rash, abdominal pain, diarrhea, indigestion, nausea, increased liver enzymes, dizziness, headache
SERIOUS
Proctitis, rectal hemorrhage, thrombocytopenia

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to pentosan polysulfate sodium; any structurally related compound, or excipients ;
Administer 1hr before or 2hrs after meals.

藥名相似:

外觀相似:

外觀描述:

14.04A Antirheumatic Agents (disease-modifying)

22822 X / Infant risk can

Arheuma* 20mg tab "美時" 雅努麻錠 2 0 毫克

Leflunomide 20mg tab

Dosage: 1常備品 22822

Adult
·Rheumatoid arthritis: PO, LD 100 mg daily for 3 days; MD 20 mg daily, may reduce dose to 10 mg daily if higher dose not tolerated

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

1. Hepatitis B or C infection: Not recommended
2. ALT > 2X upper limits of normal (ULN): reduction to 10 mg/day
3. ALT >3X ULN: discontinue and initiate the drug elimination process

Dosing adjustments in renal impairment:

Use with caution

P: Tab: 20 mg(22822), 10 mg(22821)

ADR:

COMMON
alopecia, rash, diarrhea, ulcer of mouth, dizziness, headache.
SERIOUS
increased liver enzymes, hypertension, Stevens-Johnson syndrome (rare), toxic epidermal necrolysis (rare), hepatic necrosis (rare), hepatotoxicity (rare), liver failure (rare), anaphylaxis, sepsis (rare), iInterstitial lung disease (rare), agranulocytosis, pancytopenia, thrombocytopenia, ALT/SGPT level raised, drug reaction with eosinophilia and systemic symptoms, infectious disease, opportunistic infection, tuberculosis, peripheral neuropathy, pneumocystis pneumonia, respiratory tract infection.

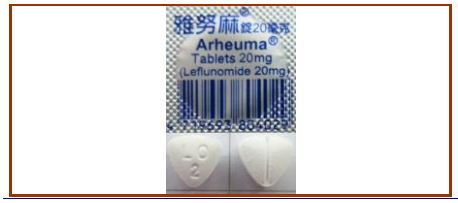
NOTE: 室溫儲存

·《Contraindications》Concomitant treatment with teriflunomide; Hypersensitivity to leflunomide or any components of the product; Pregnancyor women who may become pregnant; Severe hepatic impairment or evidence of hepatitis B or C infection; severe immunodeficiency; bone marrow dysplasia; severe/uncontrolled infection
·Monitoring: ALT, WBC, Platelet, Hb, Hct at baseline and monthly first 6 months, then q6~8 wks thereafter
·Drug elimination process: cholestyramine 8 g q8h for 11 days or activated charcoal 50 g q6h for 11 days.

藥名相似:

外觀相似:

外觀描述: 白色三角形錠,有LO及2字樣



14.04A Antirheumatic Agents (disease-modifying)

27212 D / Unsafe

DP-AZATHIOPRINE* Film Coated Tablets 50mg 雅迅靈膜衣錠50毫克

Azathioprine 50mg tab

Dosage: 1常備品 27212

Adult
·Renal Allotransplantation: PO, 3-5 mg/kg/day on the day of (or 1-3 days before) transplantation, then MD 1-3 mg/kg/day
·Rheumatoid arthritis: PO, initial 1 mg/kg/day for 6-8 weeks, increase by 0.5 mg/kg/day every 4 weeks to Max. 2.5 mg/kg/day
·Crohn's disease (unlabeled use): 2-4 mg/kg/day

Pediatric
·Renal Allotransplantation (unlabled used): refere to adult
·Heart transplantation (unlabeled use): PO, 4 mg/kg/day
·Inflammatory bowel disease (unlabeled use): PO, 1.5-2 mg/kg/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr >50 mL/min: No dosage adjustment needed
Clcr 10-50 mL/min: 75% of normal dose
Clcr <10 mL/min: 50% of normal dose

P: Tab: 50mg(27212)

ADR:

COMMON
gastrointestinal hypersensitivity, nausea, vomiting
SERIOUS
cancer, hepatotoxicity, infection, leukopenia, thrombocytopenia, megaloblastic anemia, pancreatitis

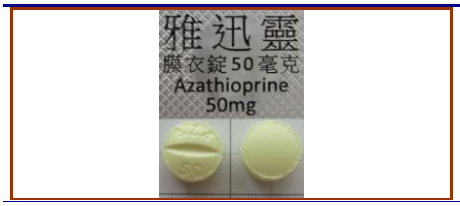
NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to the drug; Treatment of rheumatoid arthritis in pregnant women; Patients with rheumatoid arthritis previously treated with alkylating agents ;

藥名相似: Imigran* 50mg FDT tab(22104)

外觀相似:

外觀描述: 黃色圓扁錠,一面中央有刻痕及"AZA | 50"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025754

14.04A Antirheumatic Agents (disease-modifying)

27214 C / Unsafe

■SANDIMMUN NEORAL* SOFT GELATIN CAP. 25MG 新體睦軟膠囊25毫克

■Ciclosporine (cyclosporine) 25mg soft gelatin cap

Dosage: 1常備品 27214

Adult
·Aplastic anemia: PO, 5 mg/kg/day div. 2 doses
·Atopic dermatitis: PO, initial 2.5 mg/kg/day div. 2 doses; in severe cases, therapy may be started at 5 mg/kg/day. Dose may be increased by 1 mg/kg/day to Max. 5 mg/kg/day. After 8 weeks, slow tapering is recommended
·Organ rejection prophylaxis: PO, 15 mg/kg/day single dose 4-12 hr before transplantation. Postoperatively, 14-18 mg/kg/day qd for 1-2 wks. Then tapered by 5%/wk(over 6-8 wks) to MD 5-10 mg/kg/day
·Psoriasis: PO, initial 2.5 mg/kg/day div. 2 doses, increase by 0.5 mg/kg/day q2w, Max. 4 mg/kg/day
·RA: PO, initial 2.5 mg/kg/day div. 2 doses, Max. 4 mg/kg/day

Pediatric
·Organ rejection prophylaxis: Refer to adult dosing, children may require & tolerate, larger doses than adult.
·Bone marrow transplant: PO, 6.25 mg q12h
·Autoimmune disease: PO, 1-3 mg/kg/day; psoriasis patients may require doses up to 5-7 mg/kg/day

Dosing adjustments in hepatic impairment:

Probably necessary, monitor level closely

Dosing adjustments in renal impairment:

In RA, Scr> 30% baseline on at least two occasions one week apart: daily dose should be reduce in decrements of 0.5-0.75 mg/kg/day. If Scr returns to </=30% of baseline, therapy can be continued. If Scr remains >30% above baseline, discontinue for 1 m & resume cyclosporine therapy if Scr returns to </= 15% of baseline. Consideration should be given to reducing or discontinuing other nonsteroidal antiinflammatory drugs if Scr remains >30% above baseline following cyclosporine dosage adjustment

P: Cap: 25mg(27214)(27239, 急用藥),100mg(27234); Inj: 50mg/1mL Amp(37602); Soln: 50mL/B (28701, 急用藥)

ADR:

COMMON
headache, hirsutism, N/V, diarrhea, tremor
SERIOUS
convulsion, gum hyperplasia, hepatotoxicity, hyperkalemia, hypomagnesemia, hypertension, infection, nephrotoxicity, hemolytic-uremic syndrome, pancreatitis, paresthesia, post-transplant lymphoproliferative disorder

NOTE: 室溫儲存

·《Contraindications》Active ocular infections (ophthalmic emulsion); Hypersensitivity to cycloSPORINE or any of ingredient in the formulation of the product , including polyoxyethylated castor oil (Cremophor(R) EL) in Sandimmune(R) injection ;
·Neoral are not bioequivalent to Sandimmune
·Neoral cap should be swallow whole; do not crush or chew

藥名相似:

外觀相似:

外觀描述: 灰色橢圓軟膠囊，印有商標字樣及25mg字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021189

14.04A Antirheumatic Agents (disease-modifying)

27234 C / Unsafe

■SANDIMMUN NEORAL* SOFT GELATIN CAP. 100MG 新體睦軟膠囊１００毫克

■Ciclosporin (Cyclosporine) 100mg cap

Dosage: 1常備品 27234

Adult
·Aplastic anemia: PO, 5 mg/kg/day div. 2 doses
·Atopic dermatitis: PO, initial 2.5 mg/kg/day div. 2 doses; in severe cases, therapy may be started at 5 mg/kg/day. Dose may be increased by 1 mg/kg/day to Max. 5 mg/kg/day. After 8 weeks, slow tapering is recommended
·Organ rejection prophylaxis: PO, 15 mg/kg/day single dose 4-12 hr before transplantation. Postoperatively, 14-18 mg/kg/day qd for 1-2 wks. Then tapered by 5%/wk(over 6-8 wks) to MD 5-10 mg/kg/day
·Psoriasis: PO, initial 2.5 mg/kg/day div. 2 doses, increase by 0.5 mg/kg/day q2w, Max. 4 mg/kg/day
·RA: PO, initial 2.5 mg/kg/day div. 2 doses, Max. 4 mg/kg/day

Pediatric
·Organ rejection prophylaxis: Refer to adult dosing, children may require & tolerate, larger doses than adult.
·Bone marrow transplant: PO, 6.25 mg q12h
·Autoimmune disease: PO, 1-3 mg/kg/day; psoriasis patients may require doses up to 5-7 mg/kg/day

Dosing adjustments in hepatic impairment:

Probably necessary; monitor levels closely

Dosing adjustments in renal impairment:

In RA, Scr> 30% baseline on at least two occasions one week apart: daily dose should be reduce in decrements of 0.5-0.75 mg/kg/day. If Scr returns to </=30% of baseline, therapy can be continued. If Scr remains >30% above baseline, discontinue for 1 m & resume cyclosporine therapy if Scr returns to

</= 15% of baseline. Consideration should be given to reducing or discontinuing other nonsteroidal antiinflammatory drugs if Scr remains >30% above baseline following cyclosporine dosage adjustment

P: Cap: 25mg(27214)(27239, 急用藥),100mg(27234); Inj: 50mg/1mL Amp(37602); Soln: 50mL/B (28701, 急用藥)

ADR:

COMMON
headache, hirsutism, N/V, diarrhea, tremor
SERIOUS
convulsion, gum hyperplasia, hepatotoxicity, hyperkalemia, hypomagnesemia, hypertension, infection, nephrotoxicity, hemolytic-uremic syndrome, pancreatitis, paresthesia, post-transplant lymphoproliferative disorder

NOTE: 室溫儲存

·《Contraindications》Active ocular infections (ophthalmic emulsion); Hypersensitivity to cycloSPORINE or any of ingredient in the formulation of the product , including polyoxyethylated castor oil (Cremophor(R) EL) in Sandimmune(R) injection ;
·Should be swallow whole; do not crush or chew
·Monitor blood pressure and serum creatinine after any cyclosporine dosage changes or addition other medications.

藥名相似:

外觀相似:

外觀描述: 灰色長橢圓形軟膠囊，有NVR及100mg字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021188

14.04A Antirheumatic Agents (disease-modifying)

27250 ɔt be ruled out / Infant risk can

XELJANZ Film-Coated Tablets 5mg 捷抑炎 膜衣錠 5毫克

Tofacitinib 5mg tab

Dosage: 1常備品 27250

·Rheumatoid arthritis: PO, 5 mg bid as monotherapy or in combination with methotrexate or other nonbiologic DMARDs.
·Psoriatic arthritis: PO, 5 mg bid in combination with methotrexate or other nonbiologic DMARDs.
·Ulcerative colitis : PO,
-Induction dose: 10mg bid for 8 wks. If the patient' s symptoms do not improve after 16 wks, the induction therapy should be stopped.
-Maintenance dose: 5mg bid or 10 mg bid, the choice of maintenance dose should be based on the patient' s clinical reaction. The lowest effective dose should be used as the maintenance dose.

·Safety and effectiveness have not been established.

Dosing adjustments in hepatic impairment:

Mild impairment: No dosage adjustment needed
Moderate impairment: 5 mg qd
Severe impairment: Use is not recommended

Dosing adjustments in renal impairment:

Mild impairment: No dosage adjustment needed
Moderate or severe impairment: 5 mg qd

P: P Tab: 5 mg(27250)

ADR:

COMMON
Increased HDL level, raised LDL, headache, UTI, nasopharyngitis, URI
SERIOUS
Non-melanoma skin cancer, gastrointestinal perforation, anemia, decreased lymphocyte count, neutropenia, injury of liver, infectious disease, opportunistic infection, Epstein Barr virus-associated post-transplant lymphoproliferative disorder, tuberculosis, cancer

NOTE: 室溫儲存30℃以下

·《Contraindications》Specific contraindications have not been determined ;
·Do not initiate tofacitinib in patients with an ANC less than 1000 cells/mm(3), a lymphocyte count less than 500 cells/mm(3), or an Hb level less than 9 g/dL. Test for latent or active TB and screen for viral hepatitis before starting treatment.
·Use with biologic DMARDs or potent immunosuppressants (eg, cyclosporine, azathioprine) is not recommended.
·治療期間與治療之後，應密切監測病人是否出現感染的徵兆與症狀。如果病人發生嚴重感染、伺機性感染或敗血症，即應停用。
·有慢性肺部疾病史或患有間質性肺部疾病者，可能更易發生感染。
·感染風險可能隨淋巴球細胞減少程度的增加而提高，應考量以淋巴球細胞計數評估感染的風險。
·活性疫苗應避免同時投予。活性疫苗接種與開始tofacitinib治療之間的間隔應符合現行關於免疫抑制劑的疫苗接種準則。開始治療前應先瞭解病人依現行免疫接種指引接種疫苗的最新狀態。
·在合適的情況下，也要向病人與主要照顧者說明治療風險：
(1)嚴重感染：
A.治療時，嚴重感染(導致住院或死亡)的風險會升高，包括活動性結核病、侵入性黴菌感染、細菌、病毒或其他伺機性病原體的感染症。
B.治療前，應接受完整結核病篩檢評估，若為活動性結核病人，應先接受結核病藥物治療；若為潛伏性結核感染，須先接受結核病藥物治療連續達9個月。
C.治療前，應進行病毒性肝炎篩檢。
(2)惡性腫瘤與淋巴增生疾病：已患有惡性腫瘤的病人，應權衡治療的風險與效益。在臨床試驗研究中，曾發生淋巴瘤及其他惡性腫瘤的報告。
(3)應監測淋巴球、嗜中性白血球、血紅素及血脂值，因為第3期臨床試驗曾出現這些異常現象。
·接受10mg每日兩次者有較高的風險：嚴重感染、伺機性帶狀皰疹感染、惡性腫瘤(包括實質固態瘤及淋巴瘤)、非黑色素瘤皮膚癌等。

藥名相似:

外觀相似:

外觀描述: 白色圓形錠，一面有 Pfizer 字樣，另一面有 JKI 5 字樣

14.04A Antirheumatic Agents (disease-modifying)

32450 ɔt be ruled out / Infant risk can

Actemra* Solution for Infusion 安挺樂 靜脈點滴注射劑

Tocilizumab inj 80mg/4mL vial

Dosage: 1常備品 32450

· Moderate to severe active rheumatoid arthritis: IV infusion over 60mins, 4mg/kg every 4 weeks in combination with methotrexate or as monotherapy, dose may be increased to 8mg/kg every 4 weeks; Max. 800mg/dose

·Safety and efficacy have not been established in patients less than 2 years old.
·Juvenile idiopathic arthritis(<30 kg) : IV infusion, 12 mg/kg over 1 hr once every 2 weeks.
·Juvenile idiopathic arthritis(≧30 kg) : IV infusion, 8 mg/kg over 1 hr once every 2 weeks.
·Polyarticular juvenile rheumatoid arthritis(< 30 kg) : IV infusion, 10 mg/kg over 1 hr once every 4 weeks
·Polyarticular juvenile rheumatoid arthritis(≧30 kg) : IV infusion, 8 mg/kg over 1 hr once every 4 weeks.

Dosing adjustments in hepatic impairment:

· Greater than 1 to 3X ULN: Modify dosage of MTX as appropriate. For persistent elevations within this range, reduce dosage to 4mg/kg or interrupt therapy until liver enzymes normalize.
· Greater than 3 to 5X ULN: Interrupt dosing until liver enzymes less than 3X ULN and follow recommendations above for greater than 1 to 3X ULN. For persistent elevations greater than 3X ULN, discontinue therapy.
· Greater than 5X ULN: Discontinue therapy

Dosing adjustments in renal impairment:

Mild renal impairment: No dosage adjustment needed
Moderate to severe renal impairment: Use has not been evaluated

P: Inj: 200mg/10mL vial(37792), 80mg/4mL vial(32450)

ADR:

COMMON
Hypertension, Injection site reaction, Rash, Diarrhea, Upper abdominal pain, ALT/SGPT level raised, AST/SGOT level raised, Dizziness, Headache, Nasopharyngitis, Infusion reaction.
SERIOUS
Gastrointestinal perforation, Pancreatitis, Decreased platelet count, Neutropenia, Hepatotoxicity, Anaphylaxis, Hypersensitivity reaction, Opportunistic infection, Tuberculosis, Upper respiratory infection, Cancer, Severe infectious disease.

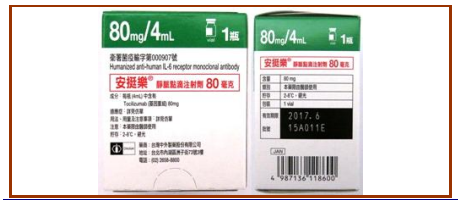
NOTE: 冰箱冷藏，不可冷凍

·《Contraindications》Known hypersensitivity to tocilizumab ;
·Concomitant use with other biological DMARDs (eg, TNF blockers, IL-1 receptor blockers, anti-CD20 monoclonal antibodies, selective costimulation modulators) should be avoided due to the increased risk of infection.
·Do not initiate therapy in patients with an absolute neutrophil count below 2000/mm(3), platelet count below 100,000/mm(3) or ALT/AST above 1.5 X ULN.
·Latent tuberculosis screening should be performed prior to initiation of treatment to rule out the possibility of active tuberculosis (including extrapulmonary tuberculosis) or latent tuberculosis infection. If the test result is positive, patients should receive TB medication before starting to use the drug.
·Even if the screening for latent tuberculosis is negative before treatment, it should be continuously monitored for tuberculosis infection during the medication.
·The clinical safety of this drug and vaccination has not been established. Since the inhibition of IL-6 pathway may interfere with the normal immune response to new antigens, it is recommended that all patients, especially children or elderly patients, be vaccinated with all the vaccines recommended by current immunization guidelines before receiving this medication.
·Tocilizumab為一種人類化重組抗人類介白素-6 (IL-6)受體之單株抗體，於哺乳類動物(中國倉鼠卵巢)細胞中製造而得。
·給予本藥時，應考慮病人是否曾經有復發或慢性感染病史，或其他潛在之病症(如：憩室炎、糖尿病、間質性肺病等可能使病人易受感染之病症)。
·間質性肺病-肺功能受損可能會增加感染的風險。有關間質性肺病(包括肺炎和肺纖維化)的上市後報告中，其中部分案件後果為死亡。
·肝毒性-曾觀察到嚴重肝損傷病例。發生時間從開始使用本藥治療後數月至數年不等。治療前應先取得肝功能檢查結果；治療後最初6個月應每4至8週檢查一次，之後應每3個月檢查一次。

藥名相似:

外觀相似:

外觀描述: 紙盒包裝，白底黑/紅字，有『綠』色區塊



14.04A Antirheumatic Agents (disease-modifying)

37612 ɔt be ruled out / Infant risk can

HUMIRA* 40MG SOLUTION FOR INJECTION, PRE-FILLED SYRINGE "艾伯維"復邁針筒裝注射劑

Adalimumab inj 40mg/0.4mL/syringe

Dosage: 1常備品 37612

Adult
·Ankylosing spondylitis, psoriatic arthritis: SC, 40 mg

every other week
·Rheumatoid arthritis: SC, 40 mg every other week; may increase to 40 mg every week in patients not taking methotrexate

Pediatric
·Juvenile idiopathic arthritis(4-17 yrs), 15-<30 kg : SC, 20 mg every other week.
·Juvenile idiopathic arthritis(4-17 yrs), ≥30 kg : SC, 40 mg every other week.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 40 mg/0.8 mL/Syringe(37612)

ADR:

COMMON
Hypertension, injection site reaction, rash, antibody development to adalimumab, antinuclear antibody positive, headache
SERIOUS
Skin cancer, aplastic anemia, erythrocytosis, leukopenia, pancytopenia, immune hypersensitivity reaction, infectious disease, malignant lymphoma(rare), demyelinating disease of central nervous system(rare), multiple sclerosis, paresthesia, subdural hematoma, tuberculosis(rare), cancer

NOTE: 冰箱儲存

·Methotrexate, glucocorticoids, salicylates, NSAIDs, analgesics or other DMARDs may be continued during trearment with Humira*
·Patients should be evaluated for latent tuberculosis prior to therapy. Treatment of latent tuberculosis should be started prior to Humira* therapy

藥名相似:

外觀相似:

外觀描述: 鋁箔包內含0.8mL含藥透明溶液注射器 ，灰色蓋頭『紅』色推進器固定於『棕』色裝置，附一個酒精棉片

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000776

14.04A Antirheumatic Agents (disease-modifying)

37617 ɔt be ruled out / Infant risk can

Simponi (golimumab),Solution for Injection 欣普尼 注射液

Golimumab inj 50mg/0.5mL syringe

Dosage: 1常備品 37617

· Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis: SC, 50mg once monthly
· Moderate to severe active Ulcerative colitis: SC, Moderate to severe active ulcerative colitis:
BW< 80 Kg
induction, 200 mg at week 0, then 100 mg at week 2, If a clinical response is achieved, MD 50 mg Q4W; If a clinical response is not achieved, MD 100 mg Q4W.
BW≧ 80 Kg
induction, 200 mg at week 0, followed by 100 mg at week 2, MD 100 mg Q4W.

·Safety and efficacy have not been established in patients less than 18 years old.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: inj: 50mg/0.5mL syringe (37617)

ADR:

COMMON
Hypertension, Injection site reaction, Rash, ALT/SGPT level raised, AST/SGOT level raised, Viral disease, Dizziness, Paresthesia, Bronchitis, Sinusitis, Upper respiratory infection.
SERIOUS
Congestive heart failure, Malignant melanoma, Merkel cell carcinoma, Sarcoidosis, Non-melanoma Skin cancer, Leukemia, Reactivation of hepatitis B viral hepatitis, Anaphylaxis, Hypersensitivity reaction, Lupus erythematosus and erythema multiforme-like syndrome, Malignant lymphoma, Mycosis, Invasive, Opportunistic infection, Septic shock, Tuberculosis, Demyelinating disease of central nervous system, Guillain-Barre syndrome, Peripheral demyelinating neuropathy, Optic neuritis, Legionnaires disease, Pneumonia, Cancer, Infectious disease, Listeriosis.

NOTE: 冰箱冷藏，不可冷凍

·《Contraindications》Specific contraindications have not been determined；
·It should be administered in conjunction with methotrexate in rheumatoid arthritis; may administer with or without methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs) in psoriatic arthritis or ankylosing spondylitis.
·上市後的使用經驗(仿單)：皮膚及皮下組織疾患：皮膚剝落、苔癬樣反應、疹、大皰性皮膚反應。。
·《仿單禁忌》
1.對本品主成份或任何一賦型劑過敏者
2.活動性肺結核(active tuberculosis)或其他嚴重感染者
，如敗血症及伺機性感染
3.中度或重度心衰竭者(NYHA class III/IV)
，中度至嚴重活動性潰瘍性結腸炎，通常接受治療的12至14週內(4個劑量之後)可達到臨床反應。對於這段期間內未顯示有治療效益的病人，應考慮是否仍持續進行治療。
，錯過劑量，延遲2週以內，應注射原劑量，並依照原本的時程；延遲超過2週，應注射原劑量，並當日開始一個新的注射時程。

藥名相似:

外觀相似:

外觀描述: 單劑裝預充玻璃針筒[27號1/2吋針頭]裝有0.5毫升注射溶液

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000911

14.04A Antirheumatic Agents (disease-modifying)

37655 **ɔt be ruled out / Infant risk can**

CIMZIA* 200 mg/ml solution for injection 欣膝亞 200毫克/毫升注射液

急用Certolizumab 200mg/1mL pre-filled syringe

Dosage: 2急用藥 37655

Adult
· initial dose : 400mg SC at weeks 0,2 and 4
· maintenance dose
Rheumatoid arthritis,Ankylosing spondylitis,Psoriatic arthritis,Psoriasis : 200 mg SC every 2 weeks or 400 mg once every 4 weeks.
Psoriasis : 200 mg SC every 2 weeks, or 400 mg every 2 weeks.

Pediatric
· Safety and effectiveness have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 200mg/1mL syringe(37655)

ADR:

COMMON
Upper respiratory infection,Arthralgia,Urinary tract infectious disease
SERIOUS
Cardiac dysrhythmia, Congestive heart failure, Hypertensive heart disease, Myocardial infarction, Pericardial effusion, Pericarditis,Erythema,SJS/TEN, urticaria,Bowel obstruction,Cytopenia,Hypersensitivity reaction (rare), Lupus erythematosus (rare), Malignant lymphoma, Opportunistic infection,Demyelinating disease of central nervous system (rare), Seizure,At risk for suicide,Nephrotic syndrome, Renal failur,Cancer, Infectious disease, Listeriosis

NOTE: 冰箱冷藏，不可冷凍

·《Contraindications》Hypersensitivity to certolizumab pegol or any component of the product；
Avoid live vaccines during therapy due to drug-induced immunosuppression.

藥名相似:

外觀相似:

外觀描述:

14.04A Antirheumatic Agents (disease-modifying)

37788 **ɔt be ruled out / Infant risk can**

Enbrel 25mg solution for injection in pre-filled syringe 恩博針筒裝注射劑 25毫克

Etanercept inj 25mg/Syringe

Dosage: 1常備品 37788

·Ankylosing spondylitis, psoriatic arthritis (PsRA), rheumatoid arthritis (RA): SC, 50 mg QW or 25 mg BIW given 72-96 hours apart
·Plaque psoriasis: SC, 50 mg BIW given 3 or 4 days apart for 3 mons, followed by 50 mg QW or 25 mg BIW given 72-96 hours apart

·Polyarticular Juvenile idiopathic arthritis(≥2 yrs): SC, 0.4 mg/kg (Max. 25 mg/dose) BIW with an interval of 3-4 days between doses, , or 0.8 mg/kg (Max. 50 mg/dose) QW.
·Pediatric plaque psoriasis (≥6 yrs) : SC, 0.8 mg/kg (Max. 50 mg/dose) QW.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 25mg/Syringe(37788)

ADR:

COMMON
Injection site reaction, Upper respiratory infection.
SERIOUS
Congestive heart failure, Erythema multiforme, Malignant melanoma, Necrotizing fasciitis, Primary cutaneous vasculitis, Skin cancer, Squamous cell carcinoma of skin, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Aplastic anemia, Leukemia, Pancytopenia, Reactivation of hepatitis B viral hepatitis, Autoimmune hepatitis, Cancer, Hepatosplenic T-cell lymphoma, Hypersensitivity reaction, Malignant lymphoma, Demyelinating disease of central nervous system, Multiple sclerosis, Peripheral demyelinating neuropathy, Seizure, acute Transverse myelitis, Optic neuritis, Tuberculosis, Infectious disease.

NOTE: 冰箱冷藏，不可冷凍

·《Contraindications》Sepsis；
·It is not recommended for pediatric patients weighing less than 31 kg
·建議幼年型病人在接受治療前，應依據現行預防接種的基準，完成當時所需之所有免疫接種。
·仿單警語
1.可能會增加侵入性黴菌感染之風險。
2.兒童及青少年使用抗腫瘤壞死因子製劑(anti-tumor necrosis factor (TNF agents) (etanercept)可能會增加

淋巴癌(lymphoma)及其他癌症風險。

藥名相似:

外觀相似:

外觀描述: 0.5mL透明藥液預充注射針筒 ，『灰』蓋頭 『白』推進器固定於『白』色裝置

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000851

14.04A Antirheumatic Agents (disease-modifying)

37792 ɔt be ruled out / Infant risk can

Actemra* Solution for Infusion 安挺樂 靜脈點滴注射劑

Tocilizumab inj 200mg/10mL vial

Dosage: 1常備品 37792

· Moderate to severe active rheumatoid arthritis: IV infusion over 60mins, 4mg/kg every 4 weeks in combination with methotrexate or as monotherapy, dose may be increased to 8mg/kg every 4 weeks; Max. 800mg/dose

·Safety and efficacy have not been established in patients less than 2 years old.
·Juvenile idiopathic arthritis(<30 kg) : IV infusion, 12 mg/kg over 1 hr once every 2 weeks.
·Juvenile idiopathic arthritis(≧30 kg) : IV infusion, 8 mg/kg over 1 hr once every 2 weeks.
·Polyarticular juvenile rheumatoid arthritis(< 30 kg) : IV infusion, 10 mg/kg over 1 hr once every 4 weeks
·Polyarticular juvenile rheumatoid arthritis(≧30 kg) : IV infusion, 8 mg/kg over 1 hr once every 4 weeks.

Dosing adjustments in hepatic impairment:

· Greater than 1 to 3X ULN: Modify dosage of MTX as appropriate. For persistent elevations within this range, reduce dosage to 4mg/kg or interrupt therapy until liver enzymes normalize.
· Greater than 3 to 5X ULN: Interrupt dosing until liver enzymes less than 3X ULN and follow recommendations above for greater than 1 to 3X ULN. For persistent elevations greater than 3X ULN, discontinue therapy.
· Greater than 5X ULN: Discontinue therapy

Dosing adjustments in renal impairment:

Mild renal impairment: No dosage adjustment needed
Moderate to severe renal impairment: Use has not been evaluated

P: Inj: 200mg/10mL vial(37792), 80mg/4mL vial(32450)

ADR:

COMMON
Hypertension, Injection site reaction, Rash, Diarrhea, Upper abdominal pain, ALT/SGPT level raised, AST/SGOT level raised, Dizziness, Headache, Nasopharyngitis, Infusion reaction.
SERIOUS
Gastrointestinal perforation, Pancreatitis, Decreased platelet count, Neutropenia, Hepatotoxicity, Anaphylaxis, Hypersensitivity reaction, Opportunistic infection, Tuberculosis, Upper respiratory infection, Cancer, Severe infectious disease.

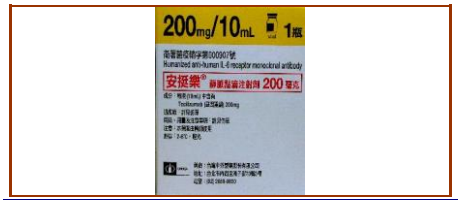
NOTE: 冰箱冷藏，不可冷凍

·《Contraindications》Known hypersensitivity to tocilizumab；
· Concomitant use with other biological DMARDs (eg, TNF blockers, IL-1 receptor blockers, anti-CD20 monoclonal antibodies, selective costimulation modulators) should be avoided due to the increased risk of infection.
· Do not initiate therapy in patients with an absolute neutrophil count below 2000/mm(3), platelet count below 100,000/mm(3) or ALT/AST above 1.5 X ULN.
· Latent tuberculosis screening should be performed prior to initiation of treatment to rule out the possibility of active tuberculosis (including extrapulmonary tuberculosis) or latent tuberculosis infection. If the test result is positive, patients should receive TB medication before starting to use the drug.
· Even if the screening for latent tuberculosis is negative before treatment, it should be continuously monitored for tuberculosis infection during the medication.
· The clinical safety of this drug and vaccination has not been established. Since the inhibition of IL-6 pathway may interfere with the normal immune response to new antigens, it is recommended that all patients, especially children or elderly patients, be vaccinated with all the vaccines recommended by current immunization guidelines before receiving this medication.
· Tocilizumab為一種人類化重組抗人類介白素-6 (IL-6)受體之單株抗體，於哺乳類動物(中國倉鼠卵巢)細胞中製造而得。
·給予本藥時，應考慮病人是否曾經有復發或慢性感染病史，或其他潛在之病症(如：憩室炎、糖尿病、間質性肺病等可能使病人易受感染之病症)。
·間質性肺病-肺功能受損可能會增加感染的風險。有關間質性肺病(包括肺炎和肺纖維化)的上市後報告中，其中部分案件後果為死亡。
·肝毒性-曾觀察到嚴重肝損傷病例。發生時間從開始使用本藥治療後數月至數年不等。治療前應先取得肝功能檢查結果；治療後最初6個月應每4至8週檢查一次，之後應每3個月檢查一次。

藥名相似:

外觀相似:

外觀描述: 紙盒包裝，白底黑/紅字，有『黃』色區塊



14.04A Antirheumatic Agents (disease-modifying)

37793 C / Caution

Orencia* Lyophilized Powder for IV Infusion 250mg 恩瑞舒凍晶注射劑250毫克

Abatacept inj 250mg vial

Dosage: 1常備品 37793

Adult
· Moderate to severe active rheumatoid arthritis: IV infusion over 30 mins, the initial 3 doses are administered at 0, 2 and 4 weeks, then every 4 weeks thereafter
<60kg: 500mg ; 60-100kg: 750mg ; >100kg: 1000mg

Pediatric (≧6yrs)
· Safety and efficacy have not been established in patients less than 6 years old.
· Moderate to severe active juvenile idiopathic arthritis: IV infusion over 30 mins, the initial 3 doses are administered at 0, 2 and 4 weeks, then every 4 weeks thereafter
<75kg: 10mg/kg
≧75kg: Same as adult; Max 1000mg/dose

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 250mg vial(37793)

ADR:

COMMON
Nausea, infectious disease, headache, urinary tract infectious disease, acute exacerbation of chronic obstructive pulmonary disease, nasopharyngitis, upper respiratory infection
SERIOUS
Cellulitis, sepsis, acute pyelonephritis, pneumonia, cancer

NOTE: 冰箱冷藏，不可冷凍

·《Contraindications》Specific contraindications have not been determined ;
· Administer through a 0.2-1.2 micron low protein-binding filter.
· Concomitant use with other biologic antirheumatic drugs is not recommended.
· Live vaccines should not be given concurrently or within 3 months of discontinuation of therapy.

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『白』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000897

14.04B Antigout Agents & Uricosuric Agents

22834 C / Infant risk is

COLCHICINE TABLETS 0.5MG "SYNMOSA" "健喬"秋水仙鹼片0.5毫克

Colchicine 0.5mg tab

Dosage: 1常備品 22834

Adult
·Gout: Children >16 yr and adult
Flare treatment: Initial 1.2 mg at the first sign of a flare, followed in 1 hr with a single dose of 0.6 mg; MAX 1.8 mg within 1 hr. Patients receiving prophylaxis therapy may receive dosing; wait 12 hr before resuming prophylaxis dose.
Prophylaxis: 0.6 mg once or twice daily, MAX 1.2 mg/day

·Familial Mediterranean fever: 1.2-2.4 mg/day, increase or decrease in increments of 0.3 mg/day
Max 2.4 mg/day

Pediatric
·Familial Mediterranean fever:
4-6 yr: 0.3-1.8 mg/day in 1-2 divided doses
6-12 yr: 0.9-1.8 mg/day in 1-2 divided doses
> 12 yr: 1.2-2.4 mg/day in 1-2 divided doses, increase or decrease in increments of 0.3 mg/day
Max 2.4 mg/day

·Gout:
Prophylaxis: adolescents greater than age 16 years, 0.6 mg once or twice daily, MAX 1.2 mg/day

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Clcr 10 to 50 mL/min: not more than 0.6 mg daily to every other day
Clcr <10 mL/min: contraindicated

P: Tab: 0.5mg(22834)

ADR:

COMMON
epigastric pain, diarrhea, nausea, vomiting
SERIOUS
myelosuppression, myoneuropathy

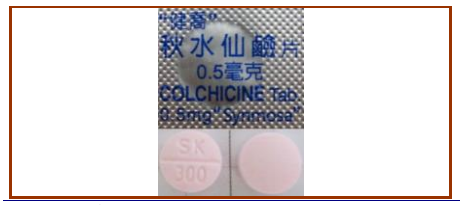
NOTE: 室溫儲存

·《Contraindications》Concomitant use of drugs that are both P-glycoprotein and CYP3A4 inhibitors in patients with renal or hepatic impairment has resulted in life-threatening or fatal colchicine toxicity (oral solution); Concomitant use of P-glycoprotein or CYP3A4 inhibitors, including all protease inhibitors except fosamprenavir, in patients with hepatic or renal impairment; life-threatening and fatal colchicine toxicity has been reported (tablets, capsules); Patients with both renal and hepatic impairment ;

藥名相似:

外觀相似: Diazepam 2mg Tab (23009), Furide* 40 mg (2

外觀描述: 淡粉紅色圓扁錠，一面有中央刻痕，並有SK及300字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12006271

14.04B Antigout Agents & Uricosuric Agents

23731 C / Infant risk is

SYNORID TABLETS 100MG 欣律錠100毫克

Allopurinol 100mg tab

Dosage: 1常備品 23731

Adult
·Gout: PO, 100-200 mg bid-tid, Max. 800 mg/day
·Chemotherapy-induced hyperuricemia: PO, 600-800 mg/day for 2-3 days, begin 1-2 days before initiating chemotherapy or radiation therapy

Pediatric
·Chemotherapy-induced hyperuricemia:
<6yrs: PO, 150 mg/day
6-10 yrs: PO, 300 mg/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Alternative dosing scheme based on GFR and 300 mg/24 h for normal renal function:
GFR >50 ml/min: 75% normal dose
GFR 10-50 ml/min: 50% normal dose
GFR< 10 ml/min: 25% normal dose

P: Tab: 100mg(23731)

ADR:

COMMON
nausea, vomiting, pruritus, rash, renal failure, renal insufficiency
SERIOUS
agranulocytosis, anemia, bone marrow suppression, hepatotoxicity, Stevens-Johnson syndrome

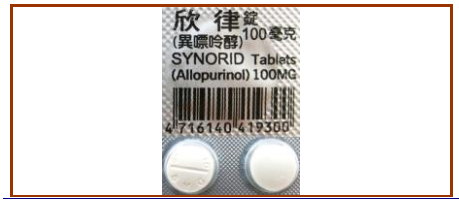
NOTE:

·《Contraindications》Concomitant use with didanosine; Severe reaction to allopurinol; Carriers of HLA-B*58:01 allele due to significant increased risk of severe cutaneous adverse reaction ;

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面中間有一刻痕及SYNORID、SYG字樣)



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1040106

14.04B Antigout Agents & Uricosuric Agents

23734 demonstrated / Infant risk has

EURICON* TABLETS 50MG 優力康錠5 0毫克

Benzbromarone 50mg tab

Dosage: 1常備品 23734

Adult
·Gout: PO, 50-200 mg/day

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr <20 mL/min: Not recommended

P: Tab: 50mg(23734)

ADR:

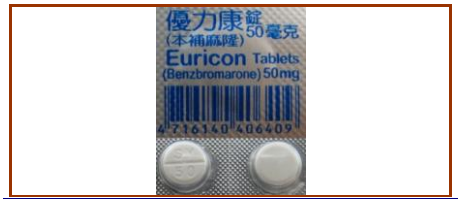
diarrhea, skin rash, liver failure

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面中間有一刻痕並有SY及50字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1042754

14.04B Antigout Agents & Uricosuric Agents

23735 b2 / Caution

SULFIN* TABLETS 100MG (SULFINPYRAZONE) "TTY" "台灣東洋" 速復利錠100毫克(賜芬匹拉隆)

Sulfinpyrazone 100mg tab

Dosage: 1常備品 23735

Adult
·Gout: PO, initial 100-200 mg bid, titration to 200-400 mg bid. Doses may be reduced as low as 200 mg daily after serum urate concentrations have been controlled
·Prophylactic treatment of thromboembolic disorders: PO, 600-800 mg/day

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr<50 mL/min: should be avoided(AHFS)
Clcr<10 mL/min: should be avoided(MICROMEDEX)

P: Tab: 100mg(23735)

ADR:

Granulocytopenia, inhibition of platelet aggregation, nausea, vomiting, interstitial nephritis, renal failure, skin rash

NOTE: 室溫儲存

·《Contraindications》Acute attack of gout; Peptic ulcer or symptoms of gastrointestinal inflammation or ulceration; History of renal or uric acid calculi, or urate nephropathy; Radiation therapy for malignancy; Cancer chemotherapy with rapid cytolytic agents; Hypersensitivity to aspirin, oxyphenbutazone, phenylbutazone or other pyrazoles; Blood dyscrasias ;
一.禁忌症：1.活動性消化性潰瘍, 2.對本藥或其他pyrazole類過敏, 3.嚴重肝功能不良, 4.嚴重腎功能不良, 5.尿酸性腎臟結石。
二.警語及注意事項：1.急性痛風發作時不要使用本藥, 2.水楊酸藥物會拮抗本藥之促尿酸排泄作用,故本藥不要併

用水楊酸藥物。

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠,有TTY及SF字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1041673

14.04B Antigout Agents & Uricosuric Agents

23738 C / Caution

Feburic 80 mg Film Coated Tablets 福避痛膜衣錠80毫克

Febuxostat 80mg FC tab

Dosage: 1常備品 23738

Adult
·Gout：Hyperuricemia: PO, 40 mg qd, may be increased to 80 mg qd if serum uric acid levels of less than 6 mg/dL are not achieved after 2 weeks.
·Gout：Hyperuricemia: gout flare prophylaxis with a NSAID or colchicine is recommended when initiating therapy.
·Tumor lysis syndrome: Hyperuricemia: PO,starting 2 days prior to chemotherapy, 80 mg qd at least 7 days, according to clinical judgment, can be extended to 9 days.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

·Mild to moderate hepatic impairment (Child Pugh A and B): No dosage adjustment needed.
·Severe hepatic impairment (Child Pugh C): Use with caution.

Dosing adjustments in renal impairment:

·CrCl 30-89 mL/min: no dosage adjustment necessary.
·CrCl 15-29 mL/min: 40 mg QD.
·CrCl <15 mL/min: safety and efficacy have not been established.

P: Tab: 80mg(23738)

ADR:

COMMON
Rash, diarrhea, nausea, arthralgia.
SERIOUS
Cardiovascular death, myocardial infarction, drug reaction with eosinophilia and systemic symptoms, Stevens-Johnson syndrome, toxic epidermal necrolysis, Abnormal liver function, ALT/SGPT level raised, AST/SGOT level raised, acute gout, myositis, rhabdomyolysis, cerebrovascular accident.

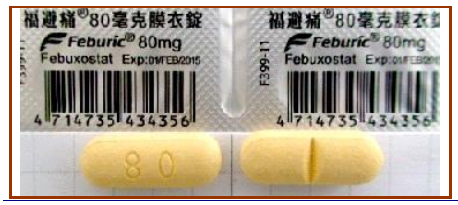
NOTE: 室溫儲存

·《Contraindications》Concomitant use of azathioprine or mercaptopurine；
·Cardiac monitoring should be appropriate for patients with hematologic malignancies who receive chemotherapy and have a moderate to high risk of developing tumor lysis.
·A similar skin reaction to allopurinol has been reported previously and should be used with caution in these patients.
·心血管相關死亡-具有心血管疾病的痛風病人使用本藥相較於使用allopurinol，會有較高的心血管相關死亡發生率。建議於處方或持續使用本藥時須考量其風險及效益，醫師及病人應注意是否出現心血管相關不良反應症狀或徵候。病人應被告知嚴重心血管事件的症狀及事件發生時應立即尋求緊急醫療協助。

藥名相似:

外觀相似:

外觀描述: 淺黃色膜衣錠，一面刻上"80")



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025427

14.04B Antigout Agents & Uricosuric Agents

27561 B /

PROCID* TABLETS 彼洛喜錠

急用Probenecid 500mg tab

Dosage: 2急用藥 27561

Adult
·Hyperuricemia: PO, Initial 250mg bid for 1 wk, followed by 500mg bid; Max. 2g/day
·Adjunct to antibiotic therapy: PO, 2g/day in divided doses
·Prevention of cidofovir nephrotoxicity: PO, 2g administered 3 hrs prior to cidofovir, followed by 1g given 2 and 8 hrs after cidofovir infusion

Pediatric
·Prevention of cidofovir nephrotoxicity(小兒血液腫瘤科): PO, 1000mg/m(2) administered 3 hrs prior to cidofovir, followed by 500mg/m(2) given 2 and 8 hrs after cidofovir infusion
·Adjunct to antibiotic therapy: PO,
≦50kg: Initial 25mg/kg, followed by 40mg/kg/day div q6h
>50kg: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr <30 mL/min: Avoid use

P: Tab: 500mg(27561)

ADR:

SERIOUS
Stevens-Johnson syndrome, aplastic anemia, leukopenia, neutropenia, thrombocytopenia, hepatic necrosis, anaphylaxis, hypersensitivity reaction, nephrotic syndrome (rare)

NOTE: 室溫儲存

·《Contraindications》blood dyscrasias; children younger than 2 years of age; concomitant use with salicylates, small or large doses; gouty attack, acute; initiate therapy once attack has subsided; hypersensitivity to probenecid; uric acid kidney stones;

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面印有J字樣

14.06A Barbiturates

22873 **D / Caution**

L.A.* TABLETS "JOHNSON" "強生" 樂安錠

Phenobarbital 20mg & diphenylhydantoin 50mg Tab

Dosage: 1常備品 22873

Adult
·Seizure: PO, 1-2 tab tid

Pediatric
·Seizure:
5-10yrs: PO, 1-4 tab/day
>10 yrs: PO, 1-2 tab tid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: Epilepsin(22873), Luminal(22865); Tab: Phenytoin(22863); Inj: Aleviatin(32461), Phenobital(32463)

ADR:

COMMON
anxiety, nervousness, insomnia, irritability clumsiness, unsteadiness, dizziness, lightheadedness, constipation, nausea, vomiting, drowsiness, hangover effect, headache, gingival hyperplasia, pruritus, rash
SERIOUS
agranulocytosis, megaloblastic anemia, hrombocytopenia, exfoliative dermatitis, Stevens-Johnson syndrome, hepatic damage, osteopenia or rickets, thrombophlebitis

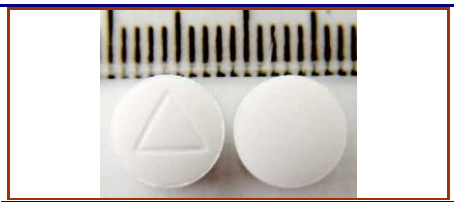
NOTE: 室溫儲存

PHENOBARBITAL
·《Contraindications》Hypersensitivity to barbiturates; History of manifest or latent porphyria; Marked liver impairment; Respiratory disease with evidence of dyspnea or obstruction; Concomitant use with rilpivirine；
PHENYTOIN
·《Contraindications》History of hypersensitivity to phenytoin, any component of the product, or to other hydantoins; reactions have included angioedema; History of prior acute hepatotoxicity attributable to phenytoin; Concomitant use with delavirdine; Concomitant use with rilpivirine；

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12003667

14.06A Barbiturates

22879 **D / Caution**

PHENOBARBITAL* TABLETS 30MG "JOHNSON" "強生" 苯巴比特魯錠 3 0 毫克

■Phenobarbital 30mg tab

Dosage: 1常備品 22879

Adult
·Anticonvulsant: PO, 100-300 mg/day
·Hypnotic: PO, 100-320 mg hs
·Sedation: PO, 30-120 mg/day in 2-3 div. doses

Pediatric
·Anticonvulsant: PO, 3-5 mg/kg/day or 125 mg/m2/day
·Prevention of febrile seizures: PO, MD 3-4 mg/kg/day
·Sedation: PO, 2 mg/kg tid
·Preoperative sedation: PO, 1-3 mg/kg 1-1.5 hr before procedure
·Hyperbilirubinemia in neonates (unlabeled use): PO, 5-10 mg/kg/day for the first few days after birth

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Clcr >10 mL/min: No dosage adjustment needed
Clcr <10 mL/min: q12-16h

P: Tab: 30mg(22879), Epilepsin(22873); Inj: 100mg/1mL Amp(32463)

ADR:

COMMON
anxiety, nervousness, insomnia, irritability, clumsiness, unsteadiness, dizziness, lightheadednes, constipation, nausea, vomiting, drowsiness, hangover effect, headache
SERIOUS
agranulocytosis, megaloblastic anemia, thrombocytopenia, exfoliative dermatitis, Stevens-Johnson syndrome, hepatic damage, osteopenia or rickets, thrombophlebitis

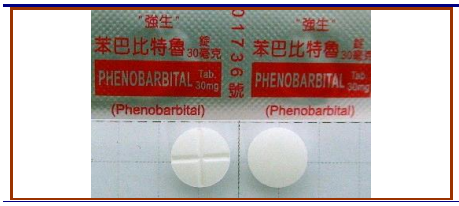
NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to barbiturates; History of manifest or latent porphyria; Marked liver impairment; Respiratory disease with evidence of dyspnea or obstruction; Concomitant use with rilpivirine；

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有十字刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12001736

14.06A Barbiturates

32463 D / Caution

PHENOBITAL INJECTION* 100MG/ML "T.F." "大豐"惠腦必達注射液１００毫克/毫升

■Phenobarbital inj 100mg/1mL

Dosage: 1常備品 32463

Adult
·Status epilepticus & other acute seizure states: IM, 200-600 mg
·Sedation: IM, 30-120 mg/day in 2-3 div. doses
·Hypnotic: IM, 100-320 mg hs
·Preoperative sedation: IM, 100-200 mg 1-1.5 hr before procedure

Pediatric
·Status epilepticus & other acute seizure states: IM, 100-400 mg
·Hypnotic: IM, 3-5 mg/kg hs
·Preoperative sedation: IM, 1-3 mg/kg 1-1.5 hr before procedure
·Hyperbilirubinemia in neonates (unlabeled use): IM, 5-10 mg/kg/day for the first few days after birth

Dosing adjustments in hepatic impairment:

Cautiously, initial doses should be reduced. Marked impairment –contraindicated.

Dosing adjustments in renal impairment:

Clcr >10 mL/min: No dosage adjustment needed
Clcr <10 mL/min: q12-16h

P: Tab: Epilepsin(22873), 30mg(22865); Inj: 100mg/1mL Amp(32463)

ADR:

COMMON
anxiety, nervousness, insomnia, irritability, clumsiness, unsteadiness, dizziness, lightheadedness, constipation, nausea, vomiting, drowsiness, hangover effect, headache
SERIOUS
agranulocytosis, megaloblastic anemia, thrombocytopenia, exfoliative dermatitis, Stevens-Johnson syndrome, hepatic damage, osteopenia or rickets, thrombophlebitis

NOTE: 室溫儲存

·《Contraindications》History of manifest or latent porphyria; Intraarterial administration; adverse reactions ranging from transient pain to gangrene may occur; History of addiction to sedative-hypnotic medications; normal doses may be ineffective and contribute to further addiction; Large doses in patients with nephritic syndrome; Marked hepatic impairment; Severe respiratory distress with dyspnea or obstruction; Sensitivity to barbiturates; Subcutaneous administration; tissue irritation ranging from tenderness and redness to necrosis may occur ;

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液透明安瓿頸部有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1033920

14.06B Benzodiazepines

22880 D / Caution

RIVOTRIL* 0.5MG TABLET "羅氏" 利福全0.5毫克錠

Clonazepam 0.5mg tab

Dosage: 1常備品 22880

Adult
·Seizure: PO, initial dose should not exceed 1.5 mg/day div. 3 doses, increase in increments of 0.5-1 mg every 3 days, MD individualize, Max. 20 mg/day
·Panic disorder: PO, initial 0.25 mg bid, dose may be increased after 3 days, MD 1 mg/day, Max.1-4mg/day

Pediatric
·Seizure:
<10yrs or BW <30 kg : initial 0.01-0.03 mg/kg/day, may increase by 0.25-0.5 mg every 3 days, MD 0.1-0.2 mg/kg/day, not to exceed 0.2 mg/kg/day

Dosing adjustments in hepatic impairment:

Liver disease: decrease usual dose by 50% LORAZEPAM, OXAZEPAM, and TEMAZEPAM may be the benzodiazepines of choice for patients with liver disease. Dosage or dosing interval may need to altered to compensate for impaired hepatic metabolism

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 0.5mg(22880), 2mg(22881), 2mg(22883 限精神科使用)

ADR:

COMMON
aggravation of seizures, ataxia, dizziness, behavior problems, nervousness, drowsiness, depression, decreased intellectual ability, increased salivation, respiratory depression

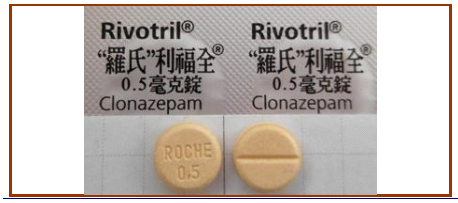
NOTE: 室溫儲存

·《Contraindications》Acute narrow angle glaucoma; Hypersensitivity to benzodiazepines; Significant liver disease ;

藥名相似:

外觀相似:

外觀描述: 淺橙色圓扁錠，有ROCHE 0,5字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2003077

14.06B Benzodiazepines

22881 D / Caution

RIVOTRIL* 2MG TABLET "羅氏" 利福全 2 毫克錠

Clonazepam 2mg tab

Dosage: 1常備品 22881

Adult
·Seizure: PO, initial dose should not exceed 1.5 mg/day div. Into 3 doses, increase in increments of 0.5-1 mg every 3 days, MD individualize, Max. 20 mg/day
·Panic disorder: PO, initial 0.25 mg bid, dose may be increased after 3 days, MD 1 mg/day, Max.1-4mg/day

Pediatric
·Seizure:
<10yrs or BW <30 kg : initial 0.01-0.03 mg/kg/day, may increase by 0.25-0.5 mg every 3 days, MD 0.1-0.2 mg/kg/day, not to exceed 0.2 mg/kg/day

Dosing adjustments in hepatic impairment:

Liver disease: decrease usual dose by 50%
LORAZEPAM, OXAZEPAM, and TEMAZEPAM may be the benzodiazepines of choice for patients with liver disease. Dosage or dosing interval may need to altered to compensate for impaired hepatic metabolism

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 0.5mg(22880), 2mg(22881), 2mg(22883 限精神科使用)

ADR:

COMMON
aggravation of seizures, ataxia, dizziness, behavior problems, nervousness, drowsiness, depression, decreased intellectual ability, increased salivation, respiratory depression

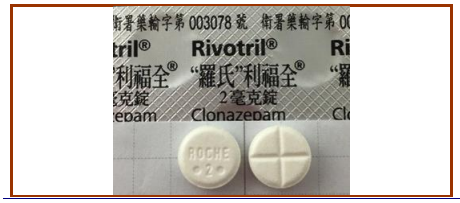
NOTE: 室溫儲存

·《Contraindications》Acute narrow angle glaucoma; Hypersensitivity to benzodiazepines; Significant liver disease ;

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，有ROCHE .2.字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2003078

14.06B Benzodiazepines

23009 D /

Diapin Tablets 2mg (Diazepam) "Pine Lawer" "柏理" 當立平錠 2 毫克（二氮平）

Diazepam 2mg tab

Dosage: 1常備品 23009

Adult
·Anxiety: PO, 2-10 mg bid-qid
·Agitation associated with acute alcohol withdrawal: PO, 10 mg tid-qid for 1 day, followed by 5mg tid-qid
·Adjunct to other anticonvulsant & skeletal muscle relaxant: PO, 2-10 mg bid-qid

Pediatric
>6 mons: PO, 1-2.5 mg tid-qid, alternatively, 0.12-0.8 mg/kg/day in 3-4 divided doses
·Adjunct in epilepsy: PO, 6-15 mg/day, Max. 30 mg/day

Dosing adjustments in hepatic impairment:

Cirrhosis: reduced dose by 50%

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 2mg(23009); Rectal soln: 10mg/2.5mL(29310); Inj: 10mg/2mL Amp (32604)

ADR:

COMMON
ataxia, drowsiness, fatigue, hypotension, respiratory depression, sedation

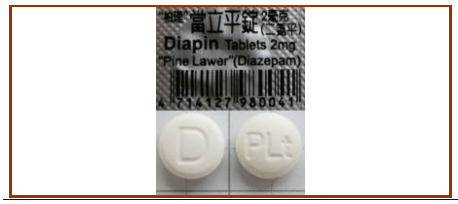
NOTE: 室溫儲存15-30℃

·《Contraindications》Acute narrow-angle glaucoma; Hypersensitivity to diazepam; Myasthenia gravis; Pediatric patients less than 6 months of age; Severe hepatic insufficiency; Severe respiratory insufficiency; Sleep apnea syndrome ;
·Patients receiving> 15 mg/day should be under observation, due to an accumulation of active metabolites which are excreted by the kidneys

藥名相似: Tab: 2mg(23009); Rectal soln: 10mg/2.5mL(2

外觀相似: Colchicine 0.5mg Tab (22834), Furide* 40 mg

外觀描述: 白色圓扁錠，一面有"PLt"字樣，另一面有"D"字樣



14.06B Benzodiazepines

23013 B / Caution

FRISIUM* TABLET 10MG "漢德克" 服利寧錠１０公絲

Clobazam 10mg tab

Dosage: 1常備品 23013

Adult
·Anxiety: PO,20-80mg/day(single or divided doses)
·Epilepsy; Adjunct:PO, initial, 5-15 mg/day, gradually increasing to maximum daily dose of about 80 mg.

Pediatric
·Safety and efficacy not established in patients younger than 2 years.
·Anxiety(>3 yrs): PO,10 -15 mg/day (single or divided doses).

Dosing adjustments in hepatic impairment:

Hepatic impairment (Child-Pugh score 5 to 9): initial, 5 mg ORALLY once daily, titrated no faster

than every 7 days to 10 to 20 mg/day in 2 divided doses depending on weight; if tolerated may titrate to max dose of 20 to 40 mg/day depending on weight starting on day 21.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 10mg(23013)

ADR:

COMMON
Constipation, Drooling, Ataxia, Dysarthria, Insomnia, Lethargy, Sedated, Somnolence, Aggressive behavior, Urinary tract infectious disease, Cough, Fever
SERIOUS
Stevens-Johnson syndrome, Toxic epidermal necrolysis

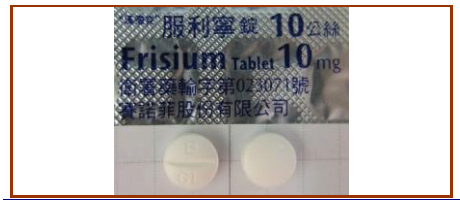
NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to clobazam or any component of the product；

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，中間有一刻痕有"B"及"GL"字樣)



14.06B Benzodiazepines

29310 **D / Unsafe**

STESOLID* Rectal soln 10mg/2.5mL 疏痙直腸用液劑

Diazepam Rectal soln 10mg/2.5mL tube

Dosage: 1常備品 29310

Adult
·Status epilepticus: Rectal, 0.2 mg/kg (not exceed 20 mg). May be repeated 4-12 hours after the initial dose. Third dose currently is not recommended

Pediatric
·Status epilepticus:
2-5 yrs: Rectal, 0.5 mg/kg
6-11yrs: Rectal, 0.3 mg/kg
>12 yrs: Rectal, 0.2 mg/kg

Dosing adjustments in hepatic impairment:

Cirrhosis: reduced dose by 50%

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 2mg(23009); Rectal soln: 10mg/2.5mL(29310); Inj: 10mg/2mL Amp (32604)

ADR:

NOTE: 室溫儲存

· 《Contraindications》Acute narrow-angle glaucoma; Hypersensitivity to diazepam; Myasthenia gravis; Pediatric patients less than 6 months of age; Severe hepatic insufficiency; Severe respiratory insufficiency; Sleep apnea syndrome；

藥名相似:

外觀相似:

外觀描述:

14.06B Benzodiazepines

32601 **D / Unknown(有**

ANXICAM INJECTION* 2MG/ML (LORAZEPAM) "SWISS" "瑞士"安心平注射液2毫克/毫升(樂必寧)

■Lorazepam 2mg/1mL amp

Dosage: 1常備品 32601

Adult
· Preoperative sedation: IM, 0.05mg/kg (Max. 4mg) 2 hrs before surgery; IV, 0.044mg/kg (Max. 2mg) 15-20 mins before surgery
· Status epilepticus: IV, 4mg/dose, dose may be repeated after 10-15 mins if needed; Max. 8mg
· Sedation in critical-care: IV, 0.02-0.06mg/kg every 2-6 hours. Continuous IV infusion, an infusion rate of 0.01-0.1mg/kg/hr
· Chemotherapy-induced nausea and vomiting: A single dose of 0.025- 0.05 mg/kg (max 4 mg) injected slowly IV, 30-35 min prior to receiving chemotherapy is recommended in combination with other antiemetics

Pediatric
· Status epilepticus: <18 y/o safety not been established
· Sedation in critical-care: <18 y/o insufficient data

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed; caution should be exercised with multiple doses over a short period of time

P: Tab: 0.5mg(23015), 2mg(23005); Inj: 2mg/1mL Amp(32601)

ADR:

COMMON
Asthenia, dizziness, sedated, unsteadiness, vertigo, depression
SERIOUS
Acidosis, delirium

NOTE: 冰箱避光儲存

·《Contraindications》Hypersensitivity to benzodiazepines or any component of the product (oral and injection), polyethylene glycol, propylene glycol, or benzyl alcohol (injection); Intraarterial administration; may produce arteriospasm resulting in gangrene (injection); Narrow-angle glaucoma, acute; Premature infants; injection formulation contains benzyl alcohol; Respiratory insufficiency, severe; in the absence of resuscitative equipment (injection); Sleep apnea syndrome (injection)；

■輕中度鎮靜止痛
· 不可直接IV注射，以等量之注射用水或N.S.稀釋。注射速率不能超過2mg/min。
· IV infusion，以N.S.或D5W稀釋至1mg/mL或更低的濃度。注射速率不能超過2mg/min。

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液『棕』色安瓿頸部有黃點及一條黃線

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1039626

14.06B Benzodiazepines

32604 **D / Unsafe**

DIANLIN* INJECTION "N.K." "南光" 得安寧注射液

■Diazepam inj 10mg/2mL amp

Dosage: 1常備品 32604

Adult
·Anxiety: Slow IV, 2-10 mg
·Agitation associated with acute alcohol withdrawal: Slow IV, initial 10 mg followed by 5-10 mg as needed
·Preoperative sedation: IM, Slow IV , 5-10 mg
·Anticonvulsant: Slow IV, initial 5-10 mg may be repeated at 10-15min intervals, Max. total dose 30mg

Pediatric
·Seizure:
1mon-5yrs: severe recurrent convulsive seizures, IV, initial 0.2-0.5 mg, repeat q2-5 min as needed, Max. 5mg. Treatment may be repeated in 2 to 4 hours if necessary
>5yrs: IV, initial 1 mg, repeat q2 - 5 min as needed, Max. 10 mg
·Tetanus:
1mon-5yrs: Slow IV , 1-2 mg q3-4 hr as needed
>5yrs: Slow IV, 5-10 mg q3-4 hr as needed
·Preoperative sedation: IM, 0.4 mg/kg
·Neonates opiate withdrawal: IM, 0.5-2 mg q8h

Dosing adjustments in hepatic impairment:

Cirrhosis: reduced dose by 50%

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 2mg(23009); Rectal soln: 10mg/2.5mL(29310); Inj:10mg/2mL Amp (32604)

ADR:

COMMON
ataxia, drowsiness, fatigue, hypotension, respiratory depression, sedation

NOTE: 室溫儲存

·《Contraindications》Acute narrow-angle glaucoma; Hypersensitivity to diazepam; Myasthenia gravis; Pediatric patients less than 6 months of age; Severe hepatic insufficiency; Severe respiratory insufficiency; Sleep apnea syndrome；

■輕中度鎮靜止痛
IV infusion is not recommended by the manufacturer.

藥名相似:

外觀相似:

外觀描述: 2CC注射液，棕色玻璃安瓿，頸部有藍點

14.06C Hydantoins

22863 **ɔt be ruled out / Infant risk can**

ALEVIATIN* TABLETS 阿雷彼阿慶錠

Phenytoin (Diphenylhydantoin) 100mg Tab

Dosage: 1常備品 22863

Adult
·Seizure disorders: PO, initial 100 mg tid, gradually increased by 100 mg q 2-4weeks until the desired response is obtained, MD 300-600 mg/day

Pediatric
·Seizure disorders: PO, initial 5 mg/kg or 250 mg/m2/day div. 2-3 doses, MD 4-8mg/kg/day, Max. 300 mg/day

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No specific dose adjustment is necessary. However, serum phenytoin protein binding is altered in uremia which can effect proper interpretation/evaluation of serum phenytoin concentrations

P: Tab: 100mg(22863), Epilepsin (22873); Inj: 250mg/5mL Amp(32461)

ADR:

COMMON
ataxia, dizziness, decreased coordination, slurred speech, choreoathetosis, encephalopathy, gingival hyperplasia, mental confusion, headache, nervousness, insomnia, nausea, vomiting, constipation, osteomalacia, nephrotoxicity, hepatotoxicity, pruritus, rash, paresthesia
SERIOUS
bullous, exfoliative or purpuric dermatitis, lupus erythematosus, Stevens-Johnson syndrome, toxic epidermal necrolysis, thrombocytopenia, leukopenia, granulocytopenia, agranulocytosis, pancytopenia, toxic hepatitis, liver damage

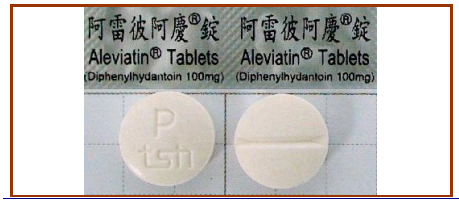
NOTE: 室溫儲存

·《Contraindications》History of hypersensitivity to phenytoin, any component of the product, or to other hydantoins; reactions have included angioedema; History of prior acute hepatotoxicity attributable to phenytoin; Concomitant use with delavirdine; Concomitant use with rilpivirine；

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有"P"及"tsh"字樣，另一面中央有刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1002320

14.06C Hydantoins

32461 ɔt be ruled out / Infant risk can

ALEVIATIN* INJECTION 阿雷彼阿慶注射液

Phenytoin sodium 250mg/5mL

Dosage: 1常備品 32461

Adult
·Status epilepticus: IV, initial 10-15 mg/kg at a rate not exceeding 50 mg/min; MD 100 mg q6-8h
·Prophylactic control of seizures during neurosurgery: IV, 100-200 mg q4h during surgery and immediate postoperative period

Pediatric
·Status epilepticus: IV, initial 15-20 mg/kg at a rate not exceeding 1-3 mg/kg/min

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No specific dose adjustment is necessary. However, serum phenytoin protein binding is altered in uremia which can effect proper interpretation/evaluation of serum phenytoin concentrations

P: Cap: 100mg(22871); Tab: Epilepsin (22873); Inj: 250mg/5mL Amp(32461)

ADR:

COMMON
ataxia, dizziness, decreased coordination, slurred speech, choreoathetosis, encephalopathy, gingival hyperplasia, mental confusion, headache, nervousness, insomnia, nausea, vomiting, constipation, osteomalacia, nephrotoxicity, hepatotoxicity, pruritus, rash, paresthesia
SERIOUS
bullous, exfoliative or purpuric dermatitis, lupus erythematosus, Stevens-Johnson syndrome, toxic epidermal necrolysis, thrombocytopenia, leukopenia, granulocytopenia, agranulocytosis, pancytopenia, toxic hepatitis, liver damage

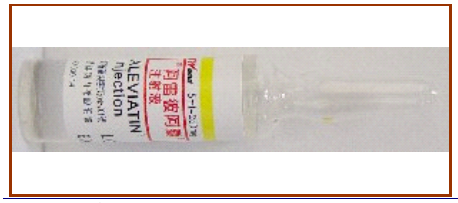
NOTE: 室溫儲存

·《Contraindications》Adams-Stokes syndrome; Concomitant use with delavirdine; History of hypersensitivity to phenytoin, other hydantoins, or any component of the product; Second- or third-degree atrioventricular block; Sinus bradycardia; Sino-atrial block ;
·Administration rate of IV should not exceed 50 mg/min

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液透明安瓿，頸部有黃點



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045701

14.06D Miscellaneous

22864 demonstrated / Infant risk can

TOPAMAX* FILM-COATED TABLETS 100MG 妥泰膜衣錠１００毫克

Topiramate 100mg FC tab

Dosage: 1常備品 22864

Adult:
·Seizures-adjunct therapy: PO, initial 25-50 mg/day, increase by 25-50 mg/day at 1 week intervals to target dose of 200-400 mg/day in 2 div.dose, Max. 1600 mg/day

Pediatric:
·Seizures-adjunct therapy(2-16yrs): PO, initial 25 mg (or less, base on range of 1-3 mg/kg/day) hs for one week, the dosage should be increased at 1-2 week intervals by increments of 1-3 mg/kg/day to target dose of 5-9 mg/kg/day in 2 div.dose

Dosing adjustments in hepatic impairment:

Dosage adjustment required.

Dosing adjustments in renal impairment:

Clcr <70 mL/min: daily dosage decreased by 50%

P: Cap: 25mg(22876); Tab: 100mg(22864)

ADR:

COMMON
Flushing, Serum bicarbonate level abnormal, Loss of appetite, Weight decreased, Infectious disease, Confusion, Dizziness, Impaired cognition, Impaired psychomotor performance, Memory impairment, Paresthesia, Reduced concentration span, Somnolenc, Feeling nervous, Mood disorder, Fatigue, Fever.
SERIOIUS
Erythema multiforme, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Hyperammonemia, Hypohidrosis, Increased body temperature, Metabolic acidosis , Liver failure, Drug-induced encephalopathy, Angle-closure glaucoma, Glaucoma, Myopia, Visual field defect, Suicidal thoughts, Nephrolithiasis, Withdrawal symptom.

NOTE: 室溫儲存

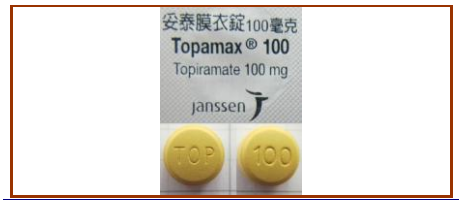
·《Contraindications》Recent alcohol use within 6 hours prior to or 6 hours after topiramate use; Metabolic acidosis with concomitant metformin use ;
·慢性、未經治療的代謝性酸血症可能會增加腎結石或腎鈣質沉積症的危險性。
·如果服用過量，應停用並給予一般的支持性療法直到臨床毒性降低或消除。
·上市後資料，不良事件增列：腎鈣質沉積症。

·衛生署未曾核准含topiramate成分作為輔助控制體重之用途
·本藥併用vitamin K-拮抗劑抗凝血藥物時，凝血"酉每"原時間/國際標準化比值(PT/INR)有減少的情形。併用時，須嚴密監控病人的國際標準化比值(INR)。
·仿單內容變更，摘述如下：(版本CCDS 17 September 2018_v1901)
具生育能力的婦女-對孕婦投予本藥可能會造成胎兒傷害。使用AEDs (包括topiramate)會導致早發性分娩及早產的風險升高。只有在潛在效益超越胎兒可能面臨之風險的情況下，才可於懷孕期間使用本藥。

藥名相似:

外觀相似:

外觀描述: 黃色圓扁錠，有TOP及100字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022508

14.06D Miscellaneous

22869 C / Caution

LAMICTAL* TABLETS 50MG 樂命達錠50毫克

Lamotrigine 50mg tab

Dosage: 1常備品 22869

Adult
·Partial seizure:
1.Monotherapy: PO, initial 25 mg qd for 2 weeks followed by 50 mg qd for 2 weeks; MD 100-500 mg/day div.1-2 doses
2.Adjunctive therapy:
·Without concomitant valproate: PO, initial 50 mg qd for 2 weeks followed by 100 mg/day div. 2 doses for 2 weeks then increased by 100 mg/week, MD 300-500 mg/day div. 2 doses
·With concomitant valproate :PO, initial 25 mg qod for 2 weeks followed by 25 mg/day for 2 weeks then increased by 25-50 mg/1-2 weeks, MD 100-200 mg/day div.1-2 doses

Pediatric (2-12yrs)
·Partial seizure:
1.Without concomitant valproate: PO, initial 0.6 mg/kg/day div. 2 doses for 2 weeks followed by 1.2 mg/kg/day for 2 weeks; MD 5-15 mg/kg/day div. 2 doses
2.With concomitant valproate: PO, initial 0.15 mg/kg/day qd for 2 weeks followed by 0.3 mg/kg/day qd for 2 weeks, MD 1-5 mg/kg/day div.1-2 doses Max.200 mg/day

Dosing adjustments in hepatic impairment:

Moderate, severe liver impairment without ascites: the initial, escalation and MD should be reduced by 25%
Severe hepatic impairment with ascites, the initial, escalation, and MD maintenance doses should be reduced by approximately 50%

Dosing adjustments in renal impairment:

Use reduced MD doses in patients with significant renal impairment

P: Tab: 50mg (22869)

ADR:

COMMON
ataxia, poor coordination, blurred vision, diplopia, dizziness, drowsiness, headache, nausea, vomiting, skin rash
SERIOUS
amnesia, anemia, eosinophilia, leukopenia, thrombocytopenia, angioedema, seizures, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, hepatic failure, hepatic necrosis

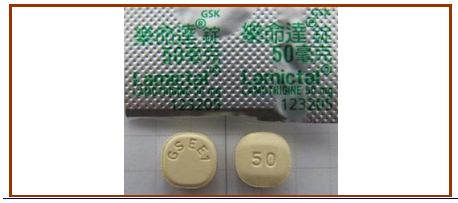
NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to lamotrigine or any component of the product；
·起始劑量過高、增加劑量過快均可能增加嚴重皮疹不良反應發生率。

藥名相似:

外觀相似:

外觀描述: 淺黃色四方圓角扁錠，一面有"50"，另一面有"GSEE1"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2020509

14.06D Miscellaneous

22872 C / Caution

SABRIL* FILM-COATED TABLETS 500MG 赦癲易膜衣錠５００公絲

Vigabatrin 500mg tab

Dosage: 1常備品 22872

Adult
·Complex partial epileptic seizure, Refractory; Adjunct : Initial 500 mg bid. The total daily dose may be titrated in 500-mg increments at weekly intervals to a max 1500 mg bid (3g/day)

Pediatric
·Safety and efficacy of vigabatrin tablets in pediatric patients less than 16 years of age with refractory complex partial seizures have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 50-80 mL/min- decreased by 25%
Clcr 30-50 mL/min- reduced by 50%
Clcr 10-30 mL/min- decreased by 75%

P: Tab: 500mg(22872)

ADR:

Drowsiness, fatigue, acute psychosis, headache, depression

NOTE: 室溫儲存

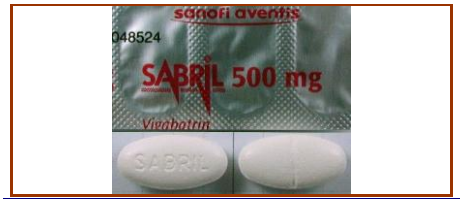
·《Contraindications》Specific contraindications have not been determined；
· Permanent vision loss (reduced visual acuity, visual field restriction), sudden or progressive has

occurred; frequent monitoring necessary

藥名相似:

外觀相似:

外觀描述: 白色長橢圓形錠，有SABRIL字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021847

14.06D Miscellaneous

22874 **D / Caution**

DEPAKINE* CHRONO 500MG FILM COATED TABLETS 帝拔癲持續性藥效膜衣錠５００公絲

Valproate sodium 333mg, valproic acid 145mg FC Tab

Dosage: 1常備品 22874

Adult
·Seizure: PO, 10-15 mg/kg/day increase by 5-10 mg/kg/day at weekly intervals, Max. 60 mg/kg/day
·Mania: PO, initial 750 mg/day in div.doses, Max. 60 mg/kg daily
·Migraine prophylaxis: PO, initial 500mg qd for 7 days, MD 500-1000mg/day

Pediatric
·Seizure disorders:
>10yrs: 10-15 mg/kg daily, increase by 5-10 mg/kg/day at weekly intervals, Max. 60 mg/kg/day

Dosing adjustments in hepatic impairment:

Reduce dose, Should not be administered to patients with hepatic disease or significant hepatic insufficiency

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: Depakine chrono(22874); Soln: 200mg/mL,40mL/bot(28542); Inj: 400mg/vial (32464)

ADR:

COMMON
abdominal pain, anorexia, dyspepsia, increased appetite, alopecia, rash, back pain, fever, asthenia, tremor, ataxia, dizziness, headache, somnolence, constipation, diarrhea, nausea, vomiting, diplopia, ambylopia, blurred vision, nystagmus, emotional lability, abnormal thinking, amnesia, flu syndrome, infection, bronchitis, weight loss, weight gain
SERIOUS
hepatic failure (children under the age of two years are at increased risk), hyperammonemic encephalopathy, including fatalities, pancreatitis (life-threatening), thrombocytopenia (>50mg/kg/day)

NOTE: 室溫儲存

·《Contraindications》Hepatic disease or significant hepatic dysfunction; Hypersensitivity to valproate sodium; Use in patients with mitochondrial disorders caused by mutations in mitochondrial DNA polymerase gamma (POLG; eg, Alpers-Huttenlocher syndrome) and in children younger than 2 years with a suspected POLG-related disorder; For prevention of migraine headaches in pregnant women and in women of childbearing potential who are not using effective contraception; Urea cycle disorders ;
·Swallow whole; do not crush or chew
·If total dose is > 250mg/day, give in div.doses
·Consider use of valproic acid or its salt form, sodium divalproex, in women of childbearing potential only after the risks have been thoroughly discussed with the patient and the potential benefits outweigh the risk of injury to the fetus. Increased risk of impaired cognitive development

藥名相似:

外觀相似:

外觀描述: 白色長橢圓形錠

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022008

14.06D Miscellaneous

22875 **ɔt be ruled out / Infant risk can**

NEURONTIN* CAPSULES 400MG 鎮頑癲膠囊400毫克

Gabapentin 400mg cap

Dosage: 1常備品 22875

Adult
· Seizure disorder: PO, 900-3600 mg/day div. 3 doses
· Postherpetic neuralgia: PO, initial 300 mg qd , 300 mg bid on the second day, and 300 mg tid on the third day, Max.1.8 g/day div. 3 doses

Pediatric
· Seizure disorder:
3-12 yrs: PO, initial 10-15 mg/kg/day, up to 50 mg/kg/day
3-4 yrs: PO, 40 mg/kg/day in 3 divided doses
>5-12 yrs: PO, 25-35 mg/kg/day in 3 divided doses
>12 yrs: PO, same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr >60 mL/min: PO, 300 mg-1.2g tid
Clcr 30-59 mL/min: PO, 200-700 mg bid
Clcr 15-29 mL/min: PO, 200-700 mg qd
Clcr =15 mL/min: PO,100-300 mg qd
Clcr <15 mL/min: Dosage should be reduced propotionally

P: Cap: 400mg(22875);Soln: 240mL(28548)

ADR:

COMMON
peripheral edema, nausea, vomiting, viral disease, ataxia, dizziness, nystagmus, somnolence, hostile behavior, fatigue, fever
SERIOUS
Stevens-Johnson syndrome, drug-induced coma, seizure, suicidal thoughts

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to gabapentin or any component of the product ;
·Avoid abrupt withdrawal, may precipitate seizures

藥名相似:

外觀相似:

外觀描述: 土黃色膠囊，有Neurontin 400mg"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022822

14.06D Miscellaneous

22876 **demonstrated / Infant risk can**

TOPAMAX* SPRINKLE CAPSULES 25MG 妥泰分散型膠囊 2 5 毫克

Topiramate 25mg Sprinkle cap

Dosage: 1常備品 22876

Adult
·Seizures-adjunct therapy: PO, initial 25-50 mg daily, titrating the daily dosage 25-50 mg weekly.Target dose of 200-400 mg/day in 2 div.dose, Max.1600 mg/day

Pediatric
·Seizures-adjunct therapy(2-16yrs): PO, initial 25 mg(based on a range of 1-3 mg/kg daily) hs for one week, the dosage should be increased at 1-2 week intervals by increments of 1-3 mg/kg/day to target dose of 5-9 mg/kg/day in 2 div.dose

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Clcr <70 mL/min: daily dosage decreased by 50%

P: Cap: 25mg(22876); Tab: 100mg(22864)

ADR:

COMMON
Flushing, Serum bicarbonate level abnormal, Loss of appetite, Weight decreased, Infectious disease, Confusion, Dizziness, Impaired cognition, Impaired psychomotor performance, Memory impairment, Paresthesia, Reduced concentration span, Somnolenc, Feeling nervous, Mood disorder, Fatigue, Fever.
SERIOIUS
Erythema multiforme, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Hyperammonemia, Hypohidrosis, Increased body temperature, Metabolic acidosis , Liver failure, Drug-induced encephalopathy, Angle-closure glaucoma, Glaucoma, Myopia, Visual field defect, Suicidal thoughts, Nephrolithiasis, Withdrawal symptom.

NOTE: 室溫儲存

·《Contraindications》Recent alcohol use within 6 hours prior to or 6 hours after topiramate use; Metabolic acidosis with concomitant metformin use ;
·慢性、未經治療的代謝性酸血症可能會增加腎結石或腎鈣質沉積症的危險性。
·如果服用過量，應停用並給予一般的支持性療法直到臨床毒性降低或消除。
·上市後資料，不良事件增列：腎鈣質沉積症。
·衛生署未曾核准含topiramate成分作為輔助控制體重之用途
·本藥併用vitamin K-拮抗劑抗凝血藥物時，凝血"酉每"原時間/國際標準化比值(PT/INR)有減少的情形。併用時，須嚴密監控病人的國際標準化比值(INR)。
·仿單內容變更，摘述如下：(版本CCDS 17 September 2018_v1901)
具生育能力的婦女-對孕婦投予本藥可能會造成胎兒傷害。使用AEDs (包括topiramate)會導致早發性分娩及早產的風險升高。只有在潛在效益超越胎兒可能面臨之風險的情況下，才可於懷孕期間使用本藥。

藥名相似:

外觀相似:

外觀描述: 白色/透明膠囊，有25mg及TOP字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023381

14.06D Miscellaneous

22877 **C / Caution**

TRILEPTAL* FILM COATED TABLETS 300MG 除癲達膜衣錠300毫克

Oxcarbazepine 300mg FC tab

Dosage: 1常備品 22877

Adult
·Partial seizure(monotherapy): PO, initial 300 mg bid, then increase the dosage by 300 mg/day every third day; MD 1200-2400 mg/day
·Partial seizure(adjunct): PO, initial 300 mg bid, may increase dosage by up to 600 mg/day at weekly intervals to 1200 mg/day

Pediatric
·Partial seizure(monotherapy, 4-16yrs): PO, initial 8-10 mg/kg/day in 2 divided doses, doses may be titrated by 5 mg/kg/day every third day; MD 600-900 mg/day for 20kg, 900-1200 mg/day for 25-30kg, 900-1500 mg/day for 35-40kg, 1200-1500 mg/day for 45kg, 1200-1800 mg/day for 50-55kg, 1200-2100 mg/day for 60-65kg, 1500-2100 mg/day for 70kg
·Partial seizure(adjunct, 4-16yrs): PO, initial 8-10 mg/kg/day in 2 divided doses, Max. 600 mg/day; MD 900 mg/day for 20-29kg, 1200 mg/day for 29.1-39kg, 1800 mg/day for greater than 39kg
·Partial seizure(adjunct, 2-3yrs): PO, initial 8-10 mg/kg/day in 2 divided doses, Max. 600 mg/day; patients under 20kg, consider initial 16-20 mg/kg/day in 2 divided doses; Max. 60 mg/kg/day in 2 divided doses

Dosing adjustments in hepatic impairment:

Mild to moderate impairment: No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr<30mL/min: Initial dose should be halved and increase slowly to achieve the desired clinical response

P: Tab: 300 mg(22877); Soln: 60 mg/mL(28546)

ADR:

COMMON
Abdominal pain, nausea, vomiting, abnormal gait, ataxia, dizziness, headache, nystagmus, somnolence, tremor, vertigo, abnormal vision, diplopia, mood swings, rhinitis, upper respiratory infection, fatigue
SERIOUS
Stevens-Johnson syndrome, toxic epidermal necrolysis, hyponatremia, multiorgan immune hypersensitivity reaction, angioedema

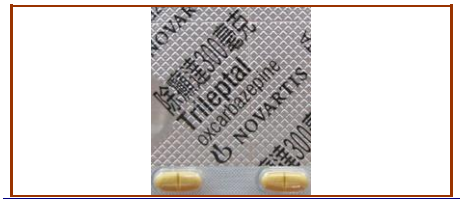
NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to oxcarbazepine, any component of the product, or eslicarbazepine acetate；
·25% to 35% of those hypersensitive to carbamazepine also have hypersensitivity reaction to oxcarbazepine.

藥名相似:

外觀相似:

外觀描述: 土黃色長橢圓錠,有CG及TE字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023524

14.06D Miscellaneous

22878 **C / Caution**

KEPPRA* FILM-COATED TABLETS 500MG 優閒 膜衣錠 5 0 0毫克

Levetiracetam F.C. 500mg tab

Dosage: 1常備品 22878

Adult
·Partial seizure, myoclonic seizure, primary generalized tonic-clonic seizures: PO, initial 500 mg bid; may increase dosage by 1g/day in 2 divided doses every 2 weeks; Max. 3 g/day

Pediatric
·Partial seizure (4-15 yrs), primary generalized tonic-clonic seizures (6-16 yrs): PO, initial 10 mg/kg bid, may increase dosage by 20 mg/kg/day in 2 divided doses every 2 weeks; Max. 60 mg/kg/day; ≧16 yrs: Same as adult
·Myoclonic seizure(≧12yrs): Same as adult

Dosing adjustments in hepatic impairment:

Mild to moderate hepatic impairment: No dosage adjustment needed
Severe hepatic impairment: Use with caution

Dosing adjustments in renal impairment:

Clcr >80mL/min: 500-1500 q12h
Clcr 50-80mL/min: 500-1000mg q12h
Clcr 30-50mL/min: 250-750mg q12h
Clcr <30mL/min: 250-500mg q12h
ESRD receiving dialysis: 500-1000mg q24h, a supplemental dose of 250-500mg following dialysis

P: Tab: 500 mg(22878); Soln: 100mg/mL 300mL/Bot(28550)

ADR:

COMMON
Loss of appetite (3-13%), vomiting (15%), infectious disease (13%), asthenia (14.7-8.9%), dizziness (5-9%), headache (14%), Somnolence (8-45%), abnormal behavior, depression (3-5%), feeling nervous (4-10%), hostile behavior (2-12%), mood disorder, mood swings (2-6%), cough (2-11%), nasopharyngitis (7-14%), pharyngitis (6-10%), rhinitis (4-13%), fatigue (10%), pain (7-6%)
SERIOUS
Pancytopenia, liver failure, suicidal intent (0.5%)

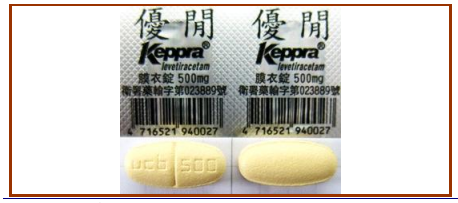
NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to levetiracetam；

藥名相似:

外觀相似:

外觀描述: 米黃色長橢圓形錠,有ucb500字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023889

14.06D Miscellaneous

22893 **ɔt be ruled out / Infant risk can**

VIMPAT* 100MG FILM-COATED TABLETS 維帕特 100毫克膜衣錠

Lacosamide 100mg FC tab

Dosage: 1常備品 22893

·Partial seizure
(1)Monotherapy: initial, PO, 100 mg bid; increase weekly by 50 mg bid up to 150 - 200 mg bid. Alternative dosing: LD, PO 200 mg, followed approximately 12 hours later by PO 100 mg bid for 1 week; may increase at weekly intervals by 50 mg bid, up to 150 - 200 mg PO bid. MD, in patients already taking an antiepileptic drug, PO 150 - 200 mg bid for at least 3 days before initiating withdrawal of the previous antiepileptic drug
(2)Adjunct: initial, PO, 50 mg bid; increase weekly by 100 mg/day given in 2 divided doses up to 200 - 400 mg/day. Alternative dosing: LD PO 200 mg, followed approximately 12 hours later by PO 100 mg bid for 1 week; may be increase at weekly intervals of 50 mg bid up to the MAX. 200 mg bid

·≧ 4 yrs
(1)Monotherapy: PO, initial 2mg/kg/day, increase weekly by 2mg/kg/day, maximum dose as follows:
BW < 40kg: up to 12 mg/kg/day; Max. 400mg/day
BW 40-50kg: up to 10mg/kg/day; Max. 400mg/day
≧ 50Kg: Same as adult
(2)Adjunct: PO, initial 2mg/kg/day, increase weekly

by 2mg/kg/day, maximum dose as follows:
BW < 20Kg: up to 12mg/kg/day
BW 20-30kg: up to 10mg/kg/day
BW 30-50kg: up to 8mg/Kg/day
≧ 50Kg: Same as adult
· < 4 yrs: Safety and efficacy not established.

Dosing adjustments in hepatic impairment:

Mild to moderate: titrate dose cautiously; MAX. 300 mg/day
Severe: use not recommended

Dosing adjustments in renal impairment:

Mild to moderate: no adjustment necessary, but titrate dose cautiously
Severe (CrCl 30 mL/min or less) or ESRD: MAX. 300 mg/day

P: Tab: 100mg (22893)

ADR:

COMMON
Nausea, Dizziness, Headache, Diplopia
SERIOUS
Atrial fibrillation and flutter, First degree atrioventricular block, Asymptomatic, Prolonged PR interval, Drug reaction with eosinophilia and systemic symptoms, Suicidal behavior, Suicidal thoughts

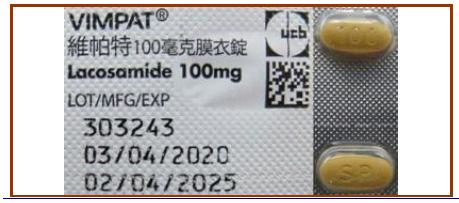
NOTE: 室溫儲存

·《Contraindications》Specific contraindications have not been determined；
·Abrupt discontinuation of therapy may precipitate withdrawal seizure; discontinue gradually over a minimum of 1 week

藥名相似:

外觀相似:

外觀描述: 暗黃色橢圓形膜衣錠，一面有"SP"字樣，另一面有"100"字樣



14.06D Miscellaneous

22894 **C / Infant risk can**

INOVELON* Film-coated Tablets 200 mg 克雷葛膜衣錠 200毫克

急用 Rufinamide 200mg FC tab

Dosage: 2急用藥 22894

·Lennox-Gastaut syndrome - Seizure; Adjunct: PO, with meal
Initial 200 mg bid, increase by 400mg/day at 2 days intervals,
Max.1800 mg/day(30-50kg)；2400 mg/day(50.1-70kg)；3200 mg/day(>70kg)

(≧4yrs)
·Lennox-Gastaut syndrome - Seizure; Adjunct: PO, with meal
<30kg: Initial 100 mg bid, increase by 200mg/day at 2 days intervals, Max.1000 mg/day(not receiving valproate) or 600 mg/day.(receiving valproate)
>30kg: Same as adult

Dosing adjustments in hepatic impairment:

severe hepatic impairment (Child-Pugh 10 to 15): Use not recommended
mild to moderate hepatic impairment (Child-Pugh 5 to 9): Use caution

Dosing adjustments in renal impairment:

CrCl <30 mL/min: No dosage adjustment necessary；Hemodialysis: Consider dosage adjustment may be reduced by 30%

P: Tab: 200mg (22894)

ADR:

COMMON
shortened QT interval, nausea, vomiting, dizziness, headache, somnolence, blurred vision, diplopia, fatigue
SERIOUS
decreased blood leukocyte number, stevens-Johnson syndrome, status epilepticus, suicidal behavio

NOTE: 儲存30℃以下

·《Contraindications》Familial Short QT syndrome; may increase risk of sudden death and ventricular arrhythmias by shortening the QT interval；
·familial Short QT syndrome

藥名相似: EXELON*

外觀相似:

外觀描述: 粉紅色橢圓形微凸錠劑，兩面有刻痕，一面印有"?262"，另一面空白。

14.06D Miscellaneous

22895 **C / Caution**

Zonegran* Film-coated Tablets 100 mg 佐能安膜衣錠 100毫克

Zonisamide 100mg FC tab

Dosage: 1常備品 22895

Adult
·Partial seizure; adjunct: PO, 100 mg/day, may increase dosage by 100 mg/day every 2 weeks to the usual effective dosage of 100-600 mg/day in 1-2 divided doses. (no additional benefit has been demonstrated with dosages above 400 mg/day).

Pediatric
·Safety and efficacy have not been established in patients less than 16 years old.
·Partial seizure; adjunct (>16yrs):Same as adult

Dosing adjustments in hepatic impairment:

May require slower titration and more frequent

monitoring.

Dosing adjustments in renal impairment:

May require slower titration and more frequent monitoring

P: Tab: 100mg (22895)

ADR:

COMMON
Pruritus, loss of appetite, ataxia, dizziness, somnolence, unable to concentrate, amblyopia, agitation, depression, disturbance in speech.
SERIOUS
Stevens-Johnson syndrome, toxic epidermal necrolysis, agranulocytosis, status epilepticus, schizophreniform disorder.

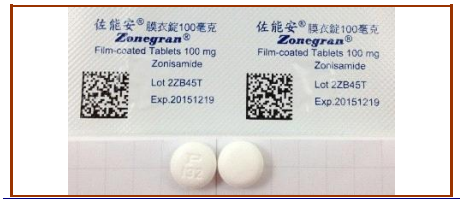
NOTE: 室溫避光

·《Contraindications》Hypersensitivity to zonisamide or sulfonamides；

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有"P"及"132"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1057199

14.06D Miscellaneous

22896 **ɔt be ruled out / Infant risk can**

Lyrica* hard Capsule 75mg 利瑞卡膠囊 75 毫克

Pregabalin 75mg cap

Dosage: 1常備品 22896

Adult
·Diabetic peripheral neuropathy - neuropathic pain: PO, initial 50 mg tid; may be increased to Max. 300 mg/day within 1 week.
·Fibromyalgia: PO, initial, 75 mg bid; may increase to 150 mg bid within 1 week, Max. 450 mg/day. No evidence of additional benefit with doses above 450 mg/day.
·Neuropathic pain - spinal cord injury: PO, initial, 75 mg bid; may increase to 150 mg bid within 1 week; may further increase to 300 mg bid after 2-3 weeks of treatment.
·Partial seizure; adjunct: PO, initial, no greater than 75 mg bid or 50 mg tid, and increased to Max. 600 mg/day in divided doses.
·Postherpetic neuralgia: PO, initial, 75 mg bid or 50 mg tid; may be increased to 300 mg/day within 1 week. Maintenance, 150 to 300 mg/day. Patients who do not experience sufficient pain relief following 2-4 weeks of treatment with 300 mg/day and are tolerating pregabalin, may increase to 600mg/day.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

CrCl 30-60 mL/min, 75-300 mg/day in 2-3 divided doses.
CrCl 15-30 mL/min, 25-150 mg/day qd or in 2 divided doses.
CrCl <15 mL/min, 25-75 mg qd.
Hemodialysis: adjust dose based on CrCl
1 supplemental (suppl.) dose of 25 or 50 mg for p' ts on 25mg qd regimen.
1 suppl. Dose of 50 or 75 mg for p' ts on 25-50 mg qd regimen.
1 suppl. Dose of 75 or 100 mg for p' ts on 50-75 mg qd regimen.
1 suppl. Dose of 100 or 150 mg for p' ts on 75 mg qd regimen.
Suppl. Dose to be taken immediately following 4-hour dialysis session.

P: Cap: 75mg (22896)

ADR:

COMMON
Peripheral edema, Increased appetite, Weight gain, Constipation, Nausea, Xerostomia, Asthenia, Ataxia, Dizziness, Headache, Incoordination, Somnolence, Tremor, Diplopia, Disturbance in thinking, Euphoria, Nasopharyngitis, Fatigue.
SERIOUS
Jaundice, Hypersensitivity reaction, Increased creatine kinase level, Blurred vision, Suicidal thoughts, Angioedema.

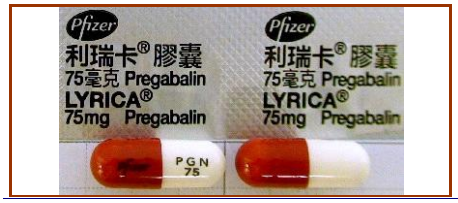
NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to pregabalin or any other component of the product ;
· Discontinuation of therapy: taper the dose gradually over a minimum of 1 week.
·突然或快速停用之後，病人可能出現失眠、噁心、頭痛、焦慮、多汗及腹瀉等症狀。

藥名相似:

外觀相似:

外觀描述: 白/棕紅色膠囊，白色端有"PGN及75"，棕紅色端有"pfizer"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024995

14.06D Miscellaneous

22897 **C / Caution**

Fycompa Film-coated Tablets 2mg 癲控達膜衣錠2毫克

Perampanel 2mg FC tab

Dosage: 1常備品 22897

· Partial seizure; Adjunct: PO initial, 2-4 mg hs; maintenance, 8-12 mg hs
· Tonic-clonic seizure; Adjunct: PO initial, 2-4 mg hs; maintenance, 8-12mg hs

· Partial seizure; Adjunct (12 years or older): PO initial, 2-4 mg hs; maintenance, 8-12 mg hs
· Tonic-clonic seizure; Adjunct (12 years or older): PO initial, 2-4 mg hs; maintenance, 8-12mg hs

Dosing adjustments in hepatic impairment:

Mild impairment, initiate at 2 mg at bedtime, may increase dose by 2 mg/d q2w to a MAX recommended dose of 6 mg/d
Moderate impairment, initiate at 2 mg at bedtime, may increase by 2 mg/d q2w to a MAX recommended dose of 4 mg/d
Severe impairment, use not recommended

Dosing adjustments in renal impairment:

Mild impairment, no adjustment required
Moderate impairment, close monitoring and slower dose titration
Severe impairment, use not recommended
Not recommended for use in patients requiring hemodialysis

P: Tab: 2mg(22897)

ADR:

COMMON
Abnormal gait, ataxia, dizziness, headache, loss of equilibrium, somnolence, irritability, mood disorder, fatigue
SERIOUS
Drug hypersensitivity syndrome, aggressive behavior, homicidal thoughts, suicidal thoughts

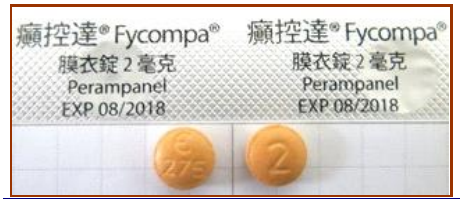
NOTE: 室溫儲存

·《Contraindications》Specific contraindications have not been determined ;
·Avoid abrupt withdrawal, may precipitate seizures

藥名相似:

外觀相似:

外觀描述: 深橘色圓扁錠,一面有"275"字樣,另一面有" 2"字樣



14.06D Miscellaneous

27534 **demonstrated / Infant risk can**

TEGRETOL CR* 200MG FILM-COATED TABLETS (DIVISIBLE) 癲通長效膜衣錠 2 0 0 毫克

Carbamazepine C.R. 200mg

Dosage: 2急用藥 27534

Adult
·Anticonvulsant: PO, initial 200 mg bid, increase by up to 200 mg/day at weekly intervals, Max. 1200 mg/day; MD 800-1200 mg/day in div.doses
·Antineuralgia: PO, 100 mg bid; increase by up to 100 mg q12h, MD 200-1200 mg/day in div.doses
·Bipolar adjuvant: PO, 200-1600 mg/day in div.doses

Pediatric
·Anticonvulsant:
<6yrs: PO, 10-20 mg/kg/day in 2-3 divided doses, Max. 35 mg/kg/day
6-12yrs: PO, initial 100 mg bid, increase by up to 100 mg/day (div. 3-4 doses) at weekly intervals, MD 400-800 mg/day, Max. 1 g/day

Dosing adjustments in hepatic impairment:

Dosage adjustment required, should not be used in cases of aggravated liver dysfunction or active liver disease

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 200mg(27534,急用藥); Susp: 20mg/mL, 100mL/Bot(28543)

ADR:

COMMON
blurred or double vision, or nystagmus, clumsiness or unsteadines, confusion, dizziness, drowsiness, lightheadedness, hypertension, hypotension, nausea, vomiting, pruritic and erythematous rashes, urticaria, photosensitivity reactions
SERIOUS
acute renal failure, renal toxicity, hyponatremia, dilutional, or water intoxication (SIADH), aplastic anemia, agranulocytosis, pancytopenia, bone marrow depression, thrombocytopenia, leukopenia, leukocytosis, eosinophilia, acute intermittent porphyria, arrhythmias, atrioventricular (AV) heart block, congestive heart failure, syncope, hepatitis, hypocalcemia, toxic epidermal necrolysis, Stevens-Johnson syndrome, aggravation of disseminated lupus erythematosus

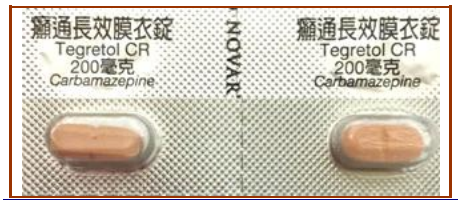
NOTE: 室溫儲存

·《Contraindications》Bone marrow depression, history; Concomitant use of an MAOI, or use within 14 days of discontinuing an MAOI; Concomitant use of boceprevir, nefazodone, delavirdine or other nonnucleoside reverse transcriptase inhibitors that are substrates of CYP3A4 , including etravirine or rilpivirine, or nefazodone; Hypersensitivity to carbamazepine or to tricyclic compounds (eg, amitriptyline, desipramine, imipramine, protriptyline, nortriptyline) ;
·"Tegretol CR " should be swallowed whole not chewed, but it can be administered half of a tablet at a time
·The onset of various dermatologic reactions occurs at 2 weeks to 5 months after starting therapy.

藥名相似:

外觀相似:

外觀描述: 淺黃橙色長橢圓錠，有H C及C G字樣



14.06D Miscellaneous

28542 **D / Infant risk can**

DEPAKINE* ORAL SOLUTION 帝拔癲口服液

Valproate sodium 200mg/mL, 40mL/B

Dosage: 1常備品 28542

Adult
·Seizure disorders: PO, initial 10-15 mg/kg daily, increase by 5-10 mg/kg/day at weekly intervals,

Max. 60 mg/kg/day
·Mania: PO, initial 750 mg/day in div.doses, Max. 60 mg/kg daily
·Migraine prophylaxis: PO, initial 500mg qd for 7 days, MD 500-1000mg/day

Pediatric
·Seizure disorders:
>10yrs: initial 10-15 mg/kg daily, increase by 5-10 mg/kg/day at weekly intervals, Max. 60 mg/kg/day

Dosing adjustments in hepatic impairment:

Reduce dose, Should not be administered to patients with hepatic disease or significant hepatic insufficiency

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: Depakine chrono(22874); Soln: 200mg/mL,40mL/bot(28542); Inj: 400mg/vial (32464)

ADR:

COMMON
abdominal pain, anorexia, dyspepsia, increased appetite, alopecia, rash, back pain, fever, asthenia, tremor, ataxia, dizziness, headache, somnolence, constipation, diarrhea, nausea, vomiting, diplopia, ambylopia, blurred vision, nystagmus, emotional lability, abnormal thinking, amnesia, flu syndrome, infection, bronchitis, weight loss, weight gain
SERIOUS
hepatic failure (children under the age of two years are at increased risk), hyperammonemic encephalopathy, including fatalities, pancreatitis (life-threatening), thrombocytopenia (>50mg/kg/day)

NOTE: 室溫儲存

·《Contraindications》Hepatic disease or significant hepatic dysfunction; Hypersensitivity to valproate sodium; Use in patients with mitochondrial disorders caused by mutations in mitochondrial DNA polymerase gamma (POLG; eg, Alpers-Huttenlocher syndrome) and in children younger than 2 years with a suspected POLG-related disorder; For prevention of migraine headaches in pregnant women and in women of childbearing potential who are not using effective contraception; Urea cycle disorders；
·本品賦形劑不含阿斯巴甜。
■隨藥附1支量筒僅有"mg"刻度，沒有"mL"刻度。(刻度於粉紅色內管，自上至下之刻度由小到大)
■建議以"mg"為處方給藥單位，以利病人量取服用。
■此藥1mL=200mg,最小包裝:8000mg/40mL/瓶。
1. If total dose is > 250mg/day, give in div.doses
2.Consider use of valproic acid or its salt form, sodium divalproex, in women of childbearing potential only after the risks have been thoroughly discussed with the patient and the potential benefits outweigh the risk of injury to the fetus. increased risk of impaired cognitive development

藥名相似:

外觀相似:

外觀描述: 白色紙盒,褐色玻璃瓶,白底黑字標籤,隨附1支粉紅色僅有劑量mg刻度的量筒

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2014902

14.06D Miscellaneous

28546 **C / Caution**

TRILEPTAL* 6% ORAL SUSPENSION 除癲達口服懸浮液 6 %

Oxcarbazepine Susp 60mg/mL,

Dosage: 1常備品 28546

Adult
·Partial seizure(monotherapy): PO, initial 300 mg bid, then increase the dosage by 300 mg/day every third day; MD 1200-2400 mg/day
·Partial seizure(adjunct): PO, initial 300 mg bid, may increase dosage by up to 600 mg/day at weekly intervals to 1200 mg/day

Pediatric
·Partial seizure(monotherapy, 4-16yrs): PO, initial 8-10 mg/kg/day in 2 divided doses, doses may be titrated by 5 mg/kg/day every third day; MD 600-900 mg/day for 20kg, 900-1200 mg/day for 25-30kg, 900-1500 mg/day for 35-40kg, 1200-1500 mg/day for 45kg, 1200-1800 mg/day for 50-55kg, 1200-2100 mg/day for 60-65kg, 1500-2100 mg/day for 70kg
·Partial seizure(adjunct, 4-16yrs): PO, initial 8-10 mg/kg/day in 2 divided doses, Max. 600 mg/day; MD 900 mg/day for 20-29kg, 1200 mg/day for 29.1-39kg, 1800 mg/day for greater than 39kg
·Partial seizure(adjunct, 2-3yrs): PO, initial 8-10 mg/kg/day in 2 divided doses, Max. 600 mg/day; patients under 20kg, consider initial 16-20 mg/kg/day in 2 divided doses; Max. 60 mg/kg/day in 2 divided doses

Dosing adjustments in hepatic impairment:

Mild to moderate impairment: No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr<30mL/min: Initial dose should be halved and increase slowly to achieve the desired clinical response

P: Tab: 300mg(22877); Susp: 60mg/mL, 100mL/Bot(28546)

ADR:

COMMON
Abdominal pain, nausea, vomiting, abnormal gait, ataxia, dizziness, headache, nystagmus, somnolence, tremor, vertigo, abnormal vision, diplopia, mood swings, rhinitis, upper respiratory infection, fatigue
SERIOUS
Stevens-Johnson syndrome, toxic epidermal necrolysis, hyponatremia, multiorgan immune hypersensitivity reaction, angioedema

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to

oxcarbazepine, any component of the product, or eslicarbazepine acetate；
· 25% to 35% of those hypersensitive to carbamazepine also have hypersensitivity reaction to oxcarbazepine.

藥名相似:

外觀相似:

外觀描述: 100mL懸浮液,褐色玻璃瓶裝

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023538

14.06D Miscellaneous

28548 **C / Caution**

Rematlin* Oral Solution "Center" "晟德" 釋癲停內服液劑

Gabapentin 50MG/ML

Dosage: 1常備品 28548

Adult
· Seizure disorder: PO, 900-3600 mg/day div. 3 doses
· Postherpetic neuralgia: PO, initial 300 mg qd , 300 mg bid on the second day, and 300 mg tid on the third day, Max.1.8 g/day div. 3 doses

Pediatric
· Seizure disorder:
3-12 yrs: PO, initial 10-15 mg/kg/day, up to 50 mg/kg/day
3-4 yrs: PO, 40 mg/kg/day in 3 divided doses
>5-12 yrs: PO, 25-35 mg/kg/day in 3 divided doses
>12 yrs: PO, same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr >60 mL/min: PO, 300 mg-1.2g tid
Clcr 30-59 mL/min: PO, 200-700 mg bid
Clcr 15-29 mL/min: PO, 200-700 mg qd
Clcr =15 mL/min: PO,100-300 mg qd
Clcr <15 mL/min: Dosage should be reduced propotionally

P: Cap: 400mg(22875); Soln: 240mL(28548)

ADR:

COMMON
peripheral edema, nausea, vomiting, viral disease, ataxia, dizziness, nystagmus, somnolence, hostile behavior, fatigue, fever
SERIOUS
Stevens-Johnson syndrome, drug-induced coma, seizure, suicidal thoughts

NOTE: 室溫儲存

· 《Contraindications》Hypersensitivity to gabapentin or any component of the product；
Avoid abrupt withdrawal, may precipitate seizures
· 本品賦形劑不含阿斯巴甜

藥名相似:

外觀相似:

外觀描述: 240ML白色塑膠瓶,白色瓶蓋

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049713

14.06D Miscellaneous

28550 **C / Caution**

Keppra* Oral Solution 100mg/ml 優開 內服液劑 100毫克/毫升

Levetiracetam oral soln 100mg/mL, 300mL/bot

Dosage: 1常備品 28550

Adult
·Partial seizure, myoclonic seizure, primary generalized tonic-clonic seizures: PO, initial 500 mg bid; may increase dosage by 1g/day in 2 divided doses every 2 weeks; Max. 3 g/day

Pediatric
·Partial seizure (4-15 yrs), primary generalized tonic-clonic seizures (6-16 yrs): PO, initial 10 mg/kg bid, may increase dosage by 20 mg/kg/day in 2 divided doses every 2 weeks; Max. 60 mg/kg/day; ≧16 yrs: Same as adult
·Myoclonic seizure(≧12yrs): Same as adult

Dosing adjustments in hepatic impairment:

Mild to moderate hepatic impairment: No dosage adjustment needed
Severe hepatic impairment: Use with caution

Dosing adjustments in renal impairment:

Clcr >80mL/min: 500-1500 q12h
Clcr 50-80mL/min: 500-1000mg q12h
Clcr 30-50mL/min: 250-750mg q12h
Clcr <30mL/min: 250-500mg q12h
ESRD receiving dialysis: 500-1000mg q24h, a supplemental dose of 250-500mg following dialysis is recommended

P: Soln: 100mg/mL 300mL/Bot(28850), Tab: 500 mg(22878)

ADR:

COMMON
Loss of appetite, vomiting,infectious disease, asthenia,dizziness,headache,somnolence, abnormal behavior, depression, feeling nervous, hostile behavior, mood disorder, mood swings, cough, nasopharyngitis, pharyngitis, rhinitis, fatigue, pain
SERIOUS
Pancytopenia, liver failure, suicidal intent

NOTE: 室溫儲存

· 《Contraindications》Hypersensitivity to levetiracetam
Safety and efficacy not established in children less than 4 years of age
· 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 300mL清澈藥液，棕色玻璃瓶裝，外有白色紙盒印有橘色Keppra字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024651

14.06D Miscellaneous

32462 D / Infant risk is

MAGNESIUM SULFATE INJECTION* "TBC" 硫酸鎂注射液

■Magnesium sulfate inj 10% 20mL amp

Dosage: 1常備品 32462

Adult
·Anticonvulsant : IV, 4 g at a rate not to exceed 1.5 mL/min; IV infusion, 4-5 g in 250 mL D5W or NS, not to exceed 3 mL/min
·Hypomagnesemia: IV infusion, 5 g in 1000mL D5W or NS over 3 hrs
·Eclampsia, preeclampsia: IV, initial 4 g then switch to continuous infusion 1-3 g/hr; alternatively; IV infusion 4 g in 250 mL D5W or NS
·Torsades de pointes (with pulses):IV, LD 1-2 g in 50-100 mL D5W over 5-60 min, followed by IV infusion 0.5-1 g/hr
·Torsades de pointes (pulseless): IV, 1-2 g in 10 mL D5W over 5-20 min

Pediatric
·Hypomagnesemia:
neonate:IV infusion , 0.2-0.4 mEq/kg/dose q8-12h for 2-3 doses
Children:IV infusion , 0.2-0.4 mEq/kg/dose q4-6h for 3-4 doses

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr < 25 mL/min : should be monitored by serum magnesium levels

P: Inj:10%, 20mL Amp(32462)

ADR:

hypermagnesaemia(loss of deep tendon reflexes and respiratory depression); nausea, vomiting, flushing of the skin, thirst, hypotension

NOTE: 室溫儲存

·《Contraindications》Mothers with toxemia of pregnancy during the 2 hours preceding delivery；

藥名相似:

外觀相似:

外觀描述: 20mL透明溶液，透明塑膠小瓶，紅色標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1004771

14.06D Miscellaneous

32464 D / Caution

DEPAKINE* LYOPHILIZED INJECTION 400MG/VIAL 帝拔癲凍晶注射劑４００公絲 / 小瓶

Valproate sodium Inj 400mg vial

Dosage: 1常備品 32464

Adult
·Absence seizure, Simple and complex: IV, 15 mg/kg/day, increase by 5-10 mg/kg/day at weekly intervals (Max. 60 mg/kg/day)
·Complex partial epileptic seizure:IV, 10-15 mg/kg/day, increase by 5-10 mg/kg/day at weekly intervals (Max. 60 mg/kg/day)

Pediatric(>10yrs)
Same as adult

Dosing adjustments in hepatic impairment:

Reduce dose, Should not be administered to patients with hepatic disease or significant hepatic insufficiency

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 400mg/vial (32464); Tab: Depakine chrono (22874); Soln: 200mg/mL, 40mL/bot (28542)

ADR:

COMMON
Alopecia, rash, increased appetite, weight gain, weight loss, abdominal pain, constipation, diarrhea, dyspepsia, loss of appetite, nausea, vomiting, back pain, amnesia, asthenia, ataxia, dizziness, headache, nystagmus, somnolence, tremor, amblyopia, blurred vision, diplopia, disturbance in thinking, mood swings, bronchitis, fever, infectious disease, influenza
SERIOUS
hepatic failure (children under the age of two years are at increased risk), hyperammonemic encephalopathy, including fatalities, pancreatitis (life-threatening), thrombocytopenia (>50mg/kg/day)

NOTE: 儲存25℃以下

·《Contraindications》Hepatic disease or significant hepatic dysfunction; Hypersensitivity to valproate sodium; Use in patients with mitochondrial disorders caused by mutations in mitochondrial DNA polymerase gamma (POLG; eg, Alpers-Huttenlocher syndrome) and in children younger than 2 years with a suspected POLG-related disorder; For prevention of migraine headaches in pregnant women and in women of childbearing potential who are not using effective contraception; Urea cycle disorders；
·Following dilution to final concentration, administer over 60min at a rate of ≤20 mg/min. Alternatively,

single dose up to 15mg/kg have been administered as a rapid infusion over 5-10 min.
·If the total daily dose exceeds 250 mg, it should be given in divided doses.
·Use for periods of more than 14 days has not been studied; switch to oral valproate products as soon as it is clinically feasible.
·Consider use of valproic acid or its salt form, sodium divalproex, in women of childbearing potential only after the risks have been thoroughly discussed with the patient and the potential benefits outweigh the risk of injury to the fetus. Increased risk of impaired cognitive development

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『紫』蓋透明玻璃小瓶，蓋上有FLIP及OFF字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022395

14.06D Miscellaneous

32466 C / Caution

Keppra* Concentrate for Solution for Infusion 100mg/ml 優閒濃縮輸注液100毫克/毫升

Levetiracetam inj 500mg/5mL vial

Dosage: 1常備品 32466

Adult
·Monotherapy (>16 yr): IV Inf., recommended start with 250 mg bid, should be increased to an initial dose of 500mg bid after 2 wks. The dose can be further increased by 250 mg bid every 2 wks; Max. 1500 mg bid.
·Add-on therapy (> 12 yr) BW≧ 50 Kg: IV Inf., initial 500 mg bid, can be increased up to 1500mg bid. Dose changes can be made in 500 mg bid increments or decrements every 2 to 4 wks.

Pediatric
·Add-on therapy (> 4yr) when BW< 50 Kg: IV, initial 10 mg/kg bid, can be increased up to 30 mg/kg bid. Dose changes should not exceed increments or decrements of 10 mg/kg bid every 2 wks.
·BW≧ 50 Kg : same as in adults.

Dosing adjustments in hepatic impairment:

Mild to moderate hepatic impairment: No dosage adjustment needed
Severe hepatic impairment: a 50% reduction of the daily maintenance dose is recommended when the Clcr is < 70 mL/min.

Dosing adjustments in renal impairment:

Clcr >80mL/min: 500-1500 mg twice daily
Clcr 50-79mL/min: 500-1000 mg twice daily
Clcr 30-49mL/min: 250-750 mg twice daily
Clcr <30mL/min: 250-500 mg twice daily
ESRD undergoing dialysis: 500-1000 mg once daily, a supplemental dose of 250-500 mg following dialysis is recommended

P: Inj: 500mg/5mL(32466); Tab: 500 mg(22878); Soln: 100mg/mL 300mL/Bot(28550)

ADR:

COMMON
Loss of appetite, vomiting, infectious disease, neck pain, asthenia, dizziness, headache, somnolence, abnormal behavior, depression, feeling nervous, hostile behavior, irritability, mood disorder, mood swings, cough, nasopharyngitis, pharyngitis, rhinitis, fatigue, pain.
SERIOUS
Stevens-Johnson syndrome, toxic epidermal necrolysis, pancytopenia, thrombocytopenia, liver failure, suicidal intent, suicide

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to levetiracetam ;
1.Safety and efficacy not established in children less than 4 years of age.
2.There is no experience with administration of IV levetiracetam for longer period than 4 days.

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液，『橘』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025316

14.06D Miscellaneous

37734 ɔt be ruled out / Infant risk can

VIMPAT* 10MG/ML SOLUTION FOR INFUSION 維帕特 10毫克/毫升輸液溶液

Lacosamide inj 200mg/20mL vial

Dosage: 1常備品 37734

·Partial seizure
(1)Monotherapy: initial, 100 mg IV twice daily; increase weekly by 50 mg twice daily up to 150 to 200 mg twice daily. Alternative dosing: 200 mg IV once, followed 12 hours later by 100 mg twice daily for 1 week.
(2)Adjunct: initial, 50 mg IV twice daily; increase weekly by 100 mg/day given in 2 divided doses up to 200 to 400 mg/day. Alternative dosing: 200 mg IV once, followed 12 hours later by 100 mg twice daily for 1 week.

·≧ 4 yrs
(1)Monotherapy: IV, initial 2mg/kg/day, increase weekly by 2mg/kg/day, maximum dose as follows:
BW < 40kg: up to 12 mg/kg/day; Max. 400mg/day
BW 40-50kg: up to 10mg/kg/day; Max. 400mg/day
≧ 50Kg: Same as adult
(2)Adjunct: IV, initial 2mg/kg/day, increase weekly by 2mg/kg/day, maximum dose as follows:
BW < 20Kg: up to 12mg/kg/day
BW 20-30kg: up to 10mg/kg/day
BW 30-50kg: up to 8mg/Kg/day

≧50Kg: Same as adult
· < 4 yrs: Safety and efficacy not established.

Dosing adjustments in hepatic impairment:

Mild to moderate: titrate dose cautiously and reduce MAX dose by 25%
Severe: use not recommended

Dosing adjustments in renal impairment:

Mild to moderate: no adjustment necessary, but titrate dose cautiously
Severe (CrCl 30 mL/min or less) or ESRD: Reduce MAX dose by 25%

P: Tab : 100mg(22893), Inj: 200mg/20mL(37734)

ADR:

COMMON
Nausea, Dizziness, Headache, Diplopia
SERIOUS
Atrial fibrillation and flutter, First degree atrioventricular block, Asymptomatic, Prolonged PR interval, Drug reaction with eosinophilia and systemic symptoms, Suicidal behavior, Suicidal thoughts

NOTE: 室溫貯存

·《Contraindications》Specific contraindications have not been determined；
Abrupt discontinuation of therapy may precipitate withdrawal seizure; discontinue gradually over a minimum of 1 week

藥名相似:

外觀相似:

外觀描述: 20mL透明藥液，『灰』色蓋玻璃小瓶

14.08B1 Dopamine Precursor

22900 **C / Caution**

STALEVO* FILM-COATED TABLETS 100/25/200MG 始立膜衣錠100/25/200毫克

Levodopa 100mg, carbidopa 25mg, entacapone 200mg Tab

Dosage: 1常備品 22900

Adult
· Parkinson's disease, Idiopathic: PO, individualize and adjust according to desired therapeutic response; Max. 8 tab/day
· Patients treated with carbidopa/levodopa AND entacapone: currently taking 200 mg entacapone with each dose of standard carbidopa/levodopa can be directly switched to corresponding strength of carbidopa/entacapone/levodopa containing same amounts of carbidopa and levodopa.
· Patients NOT currently treated with entacapone: if current levodopa dose is more than 600 mg/day, levodopa dose reduction likely required with addition of entacapone; patients should first be titrated individually with carbidopa/levodopa product and entacapone product, then transferred to corresponding dose of carbidopa/entacapone/levodopa fixed dose combination product once stabilized
· Patients NOT currently treated with entacapone: if current levodopa dose is 600 mg/day or less and no dyskinesias, may transfer to corresponding dose of carbidopa/entacapone/levodopa fixed dose combination product

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution in patients with severe renal impairment

P: Tab: Stalevo(22900), Sinemet(22903), entacapon(22906); Cap: Madopar(22901)

ADR:

COMMON
Abdominal pain, diarrhea, nausea, confusion, dizziness, somnolence, hallucinations, discolored urine, fatigue
SERIOUS
Heart disease, orthostatic hypotension, diarrhea, dyskinesia, psychotic disorder

NOTE: 室溫儲存

LEVODOPA
·《Contraindications》Concurrent use with nonselective MAOIs (eg, phenelzine, tranylcypromine) or with recent use (within 2 weeks) of a nonselective MAOI；
CARBIDOPA
·《Contraindications》Narrow-angle glaucoma; Hypersensitivity to any component of the drug; Concomitant administration of nonselective MAO-A inhibitors or use within 2 weeks of discontinuation of MAO-A inhibitor therapy；
ENTACAPONE
·《Contraindications》Hypersensitivity to entacapone or any component of the product；

1.One tablet contains one treatment dose. The tablets should always be swallowed whole.
2.Contraindications: nonselective MAOI concurrently or less than 2 weeks prior, narrow-angle glaucoma, history of melanoma or suspicious undiagnosed skin lesions

藥名相似:

外觀相似:

外觀描述: 磚紅色，長橢圓扁錠，有LCE及100字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024171

14.08B1 Dopamine Precursor

22903 C / Unsafe

SINEMET 25/250 TABLETS 心寧美２５／２５０錠

Carbidopa 25mg& Levodopa 250mg tab

Dosage: 1常備品 22903

Adult
·Parkinsonian syndrome: PO, 1 tab tid-qid and dosage increased by 1/2 or 1 tab every 1 or 2 days until Max. 8 tab/day (2 g of levodopa and 200 mg of carbidopa)

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: Madopar(22901); Tab: Sinemet(22903), Stalevo(22900)

ADR:

COMMON
anorexia, nausea, vomiting
SERIOUS
cardiac abnormalities, orthostatic hypotension, dyskinesias, psychotic symptoms

NOTE: 室溫儲存

LEVODOPA
·《Contraindications》Concurrent use with nonselective MAOIs (eg, phenelzine, tranylcypromine) or with recent use (within 2 weeks) of a nonselective MAOI ;
CARBIDOPA
·《Contraindications》Narrow-angle glaucoma; Hypersensitivity to any component of the drug; Concomitant administration of nonselective MAO-A inhibitors or use within 2 weeks of discontinuation of MAO-A inhibitor therapy ;
·仿單內容變更，摘述如下：(1030711來文，文號：乙1030007498)
1.增列SINEMET*錠劑成分及外觀說明的相關資訊。
2.用量用法：(A)加註本藥配方變更後因缺乏本產品剝半或磨粉後產品吸收與安定性資料，故無法建議剝半或磨粉使用。(B)常用的起始劑量-刪除SINEMET* 25/250 tab起始劑量的相關資訊。?維持劑量-劑量的調整方式刪除增加「半顆」的敘述。
3.注意事項：加註(A)黑色素瘤。(B)定期監測病人發生衝動控制障礙的情況。
4.藥物相互作用：增列鐵製劑(本藥的生體可用率會下降)。
5.上市後使用副作用：加註已有報告說明會發生病態性(強迫性)賭博，性衝動增加，性慾亢進，強迫性花費/購物及狂飲/強迫性進食的情形。

藥名相似:

外觀相似:

外觀描述: 淺藍色橢圓錠，一面中央有刻痕且一側有『654』字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2020162

14.08B1 Dopamine Precursor

22911 C / Unsafe

MADOPAR* 250 TABLETS "ROCHE" "羅氏" 美道普錠 200/50毫克

Levodopa(L-Dopa) 200mg, benserazide 50mg tab

Dosage: 1常備品 22911

Adult
·Parkinson's disease: PO, 30min before or 1h after meals, initial 0.5 to 1 tab bid, gradually be increased by 1/4 to 0.5 tab every 3-7 days, Max. 4 tabs/day

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Use in decompensated hepatic disease is contraindicated

Dosing adjustments in renal impairment:

Use in decompensated renal disease is contraindicated

P: Tab: Madopar(22911), Stalevo(22900), Sinemet(22903); Cap: Madopar(22901)

ADR:

Nausea, vomiting, anorexia, orthostatic hypotension, dyskinesias, involuntary movements, agitation, anxiety, sleep disturbance, depression

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to any component of the formulation; use with or within 14 days of MAO inhibitors; patients with clinical laboratory evidence of uncompensated cardiovascular, endocrine, renal, hepatic, hematologic, or pulmonary disease; patients with decompensated endocrine, renal, hepatic, cardiac disorders, psychiatric disorders, narrow-angle glaucoma, or closed-angle glaucoma; patients <25 years of age; pregnancy or use in women of childbearing potential without adequate contraception ;

藥名相似:

外觀相似:

外觀描述: 粉紅色圓扁錠， 雙面皆有十字刻痕，一面刻有"RO"、"C"、"HE"及六邊形圖案

14.08B3 Dopamine Agonist

22907 C / Caution

REQUIP* FILM-COATED TABLETS 1MG 力必平膜衣錠 1毫克

Ropinirole 1mg FC tab

Dosage: 1常備品 22907

Adult
·Parkinson's disease: PO, initial 0.25 mg tid;

ascending dose schedule:
week 1, 0.25 mg tid; week 2, 0.5 mg tid; week 3, 0.75 mg tid; week 4, 1 mg tid; after week 4, may increase daily dosage by 1.5 mg/day on weekly basis up to 9 mg/day, then by up to 3 mg/day weekly to total dose of 24 mg/day

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 1mg(22907)

ADR:

COMMON
dizziness, headache, somnolence, nausea, vomiting
SERIOUS
dyskinesia, hallucinations (dose related), sleep attacks, postural hypotension, syncope

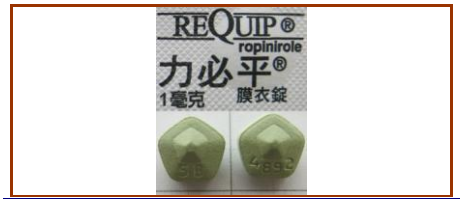
NOTE: 室溫避光

·《Contraindications》Hypersensitivity to rOPINIRole or any component of the product ;
1.Ropinirole should be gradually discontinued over a 7 day period

藥名相似:

外觀相似:

外觀描述: 綠色五角形錠，有SB及4892字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022883

14.08B3 Dopamine Agonist

22908 C / Caution

Mirapex 1.5mg prolonged-release tablets 樂伯克持續性藥效錠1.5毫克

Pramipexole dihydrochloride monohydrate 1.5mg PR tab

Dosage: 1常備品 22908

Adult
·Parkinson's disease: PO, initial, 0.375 mg qd, slow titration every 5-7 days, first to 0.75 mg/day and then in 0.75-mg increments; Max. 4.5 mg/day; evaluate response at a minimal interval of 5 days or longer after each dose increment; taper dose over 1 week when discontinuing therapy.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

·Parkinson's Disease
Clcr 30-50mL/min: Initial 0.375mg qod ; do not increase dose until after 1 week, at 0.375-mg increments up to a maximum of 2.25 mg/day.
Clcr <30mL/min or on hemodialysis: do not use.

P: Tab: 0.25mg(22899), 1.5mg(22908)

ADR:

COMMON
Orthostatic hypotension, constipation, nausea, amnesia, asthenia, confusion, dizziness, dream disorder, dyskinesia, extrapyramidal movements, headache, insomnia, somnolence, hallucinations.
SERIOUS
Heart failure, malignant melanoma, sleep attack

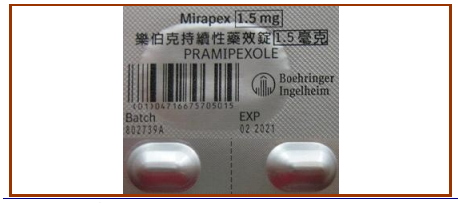
NOTE: 室溫避光

·《Contraindications》Specific contraindications have not been determined ;
·Abrupt withdrawal may result in emergent hyperpyrexia and confusion (symptom complex resembling neuroleptic malignant syndrome)
·Treatment discontinuation
PD: It should be tapered off over several days.

藥名相似:

外觀相似:

外觀描述: 白色長橢圓形扁錠，一面有"P3"字樣，另一面有商標圖案



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025260

14.08B3 Dopamine Agonist

22909 C / Unsafe

Requip* PD 4mg Prolonged Release Tablet 力必平持續性藥效膜衣錠4毫克

Ropinirole 4mg prolonged release tab

Dosage: 1常備品 22909

Adult
·Parkinson's disease: PO, initial 2mg qd for 1-2 weeks; titrate at a weekly or longer interval to therapeutic response at 2mg/day increments; Max. 24mg/day

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Clcr 30-50mL/min: No dosage adjustment needed
Clcr <30mL/min: Not recommended

P: Tab: 1mg(22907), P.R. Tab: 4mg(22909)

ADR:

COMMON
Abdominal pain, constipation, nausea, vomiting, dizziness, dyskinesia (dose related), headache, fatigue
SERIOUS
Orthostatic hypotension, sinus node dysfunction, syncope, sleep attack, somnolence, hallucinations

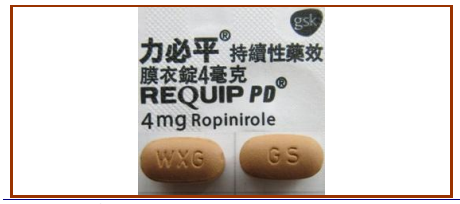
NOTE: 室溫避光

·《Contraindications》Hypersensitivity to rOPINIRole or any component of the product ;
·Swallow whole. Do not chew, crush or divide it.
·Ropinirole should be gradually discontinued over a 7 day period.
·The dose of ropinirole prolonged-release tablets should be based on the total daily dose of immediate release formulation that the patient was receiving.

藥名相似:

外觀相似:

外觀描述: 淺褐色長橢圓錠，有GS及WXG字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025119

14.08B3 Dopamine Agonist

22913 **C / Caution**

MIRAPEX* 0.375mg prolonged-release tablets 樂伯克持續性藥效錠0.375毫克

Pramipexole dihydrochloride monohydrate 0.375mg PR tab

Dosage: 1常備品 22913

Adult
·Parkinson's disease: PO, initial, 0.375 mg qd, slow titration every 5-7 days, first to 0.75 mg/day and then in 0.75-mg increments; Max. 4.5 mg/day; evaluate response at a minimal interval of 5 days or longer after each dose increment; taper dose over 1 week when discontinuing therapy.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

·Parkinson's Disease
Clcr 30-50mL/min: Initial 0.375mg qod ; do not increase dose until after 1 week, at 0.375-mg increments up to a maximum of 2.25 mg/day.
Clcr <30mL/min or on hemodialysis: do not use.

P: Tab: 0.25mg(22899), 0.375mg(22913), 1.5mg(22908)

ADR:

COMMON
Orthostatic hypotension, constipation, nausea, amnesia, asthenia, confusion, dizziness, dream disorder, dyskinesia, extrapyramidal movements, headache, insomnia, somnolence, hallucinations.
SERIOUS
Heart failure, malignant melanoma, sleep attack

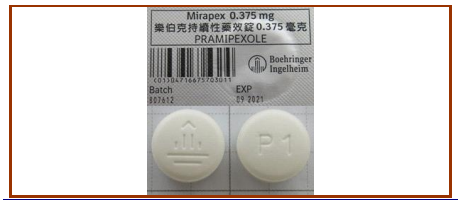
NOTE: 室溫避光

·《Contraindications》Specific contraindications have not been determined ;
·Abrupt withdrawal may result in emergent hyperpyrexia and confusion (symptom complex resembling neuroleptic malignant syndrome)
·Treatment discontinuation
PD: It should be tapered off over several days.

藥名相似:

外觀相似:

外觀描述: 白色圓形錠，一面有"P1"字樣，另一面有商標圖案



14.08B3 Dopamine Agonist

27205 **B / Unsafe**

DOSTINEX* TABLETS 0.5MG 過乳降錠0.5毫克

Cabergoline 0.5mg tab

Dosage: 1常備品 27205

·Hyperprolactinemia: PO, initial 0.25 mg twice weekly, increase by 0.25 mg twice weekly at 4 wk intervals; Max.1 mg twice weekly, with meal.
·Parkinson's disease: PO, initial 0.5-1 mg daily in morning, increase by 0.5 mg in weekly intervals or longer; Max.10 mg daily, with meal.
·Lactation suppression, puerperal: PO, 1 mg as a single dose given within 24-27 hours of delivery, with meal.
·Suppression of established lactation: PO, 0.25 mg bid for 2 days, with meal.

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Dose reduction in severe hepatic failure (Child-Pugh scores of 10 or higher)

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 0.5mg(27205)

ADR:

COMMON
dizziness, fatigue, headache, constipation, nausea, somnolence, depression
SERIOUS
orthostatic hypotension, pleural effusion, pulmonary fibrosis, abdominal pain, vertigo

NOTE: 儲存25℃以下

·《Contraindications》Cardiac valvular disorder, active or history of; indicated by valvulopathy of any valve, thickening of valve leaflet, valve restriction, or mixed valve restriction stenosis; Hypersensitivity to ergot derivatives; Hypertension, uncontrolled; Pulmonary, pericardial, or retroperitoneal fibrotic disorders, history of ;

藥名相似:

外觀相似:

外觀描述: 白色長橢圓錠,有PU及700字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022658

14.08B3 Dopamine Agonist

29148 **c / Unsafe**

Neupro Transdermal Patch 6mg/24h 紐普洛穿皮貼片劑 6 毫克/ 24 小時

Rotigotine 6mg/24hr transdermal patch

Dosage: 1常備品 29148

Adult
·Parkinson's disease(Early-stage): 1 pk transdermally. MAX, 6 mg/24 hours

Pediatric
·Safety and effectiveness have not been established

Dosing adjustments in hepatic impairment:

mild to moderate hepatic dysfunction:no dosage adjustment is necessary

Dosing adjustments in renal impairment:

No dosage adjustment is necessary

P: TTS: 6 mg/24hr(29148)

ADR:

COMMON
Orthostatic hypotension, peripheral edema, application site reaction, diaphoresis, loss of appetite, nausea, vomiting, xerostomia, dizziness, dyskinesia, headache, sleep disorder, somnolence
SERIOUS
Atrioventricular block, syncope, compulsive behavior, hallucinations, impulse control disorder

NOTE: 室溫儲存30℃以下

·《Contraindications》Hypersensitivity to rotigotine or any component of the product；
1.Apply the patch to clean, dry skin that has very little or no hair. Do not put the patch over burns, cuts, irritated, or oily skin.
2.Remove this patch before you have a medical procedure that involves electricity, such as MRI or cardioversion, because the patch contains aluminum.
3.建議在固定期間或視覺異常時作眼科檢查。
4.可能會增強L-dopa的多巴胺受體作用，因而引起運動困難及(或)使運動困難惡化。

藥名相似:

外觀相似:

外觀描述: 貼片，白底黑字鋁箔紙袋包裝，有綠色區塊

14.08B3 Dopamine Agonist

29155 **c / Unsafe**

NEUPRO* transdermal patch 8mg/24h 紐普洛穿皮貼片劑 8 毫克/ 24 小時

急用Rotigotine 8mg/24hr transdermal patch

Dosage: 2急用藥 29155

Adult
·Parkinson's disease(Advanced-stage): 1 pk transdermally. MAX, 8 mg/24 hours.

Pediatric
·Safety and effectiveness have not been established

Dosing adjustments in hepatic impairment:

mild to moderate hepatic dysfunction:no dosage adjustment is necessary

Dosing adjustments in renal impairment:

No dosage adjustment is necessary

P: TTS: 6 mg/24hr(29148), 8 mg/24hr(29155)

ADR:

COMMON
Orthostatic hypotension, peripheral edema, application site reaction, diaphoresis, loss of appetite, nausea, vomiting, xerostomia, dizziness, dyskinesia, headache, sleep disorder, somnolence
SERIOUS
Atrioventricular block, syncope, compulsive behavior, hallucinations, impulse control disorder

NOTE: 室溫儲存30℃以下

·《Contraindications》Hypersensitivity to rotigotine or any component of the product；
1.Apply the patch to clean, dry skin that has very little or no hair. Do not put the patch over burns, cuts, irritated, or oily skin.
2.Remove this patch before you have a medical procedure that involves electricity, such as MRI or cardioversion, because the patch contains aluminum.
3.建議在固定期間或視覺異常時作眼科檢查。
4.可能會增強L-dopa的多巴胺受體作用，因而引起運動困難及(或)使運動困難惡化。

藥名相似:

外觀相似:

外觀描述: 貼片，白底黑字鋁箔紙袋包裝，有藍色區塊

14.08C MAO-B Inhibitor

22910 **C / Caution**

PARKRYL TABLETS "M.S."(SELEGILINE) 巴可癒錠（希利治林）

Selegiline HCl 5mg tab

Dosage: 1常備品 22910

Adult
·Parkinson's disease: PO, 5 mg bid, at breakfast and lunch to minimize possible insomnia, Max. 10 mg/day

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

No dosage adjustment is necessary for patients with mild to moderate hepatic impairment

Dosing adjustments in renal impairment:

No dosage adjustment is necessary for patients with mild to moderate renal impairment

P: Tab: 5mg(22910)

ADR:

COMMON
abdominal pain, nausea, dizziness, lightheadedness/fainting, confusion, hallucinations

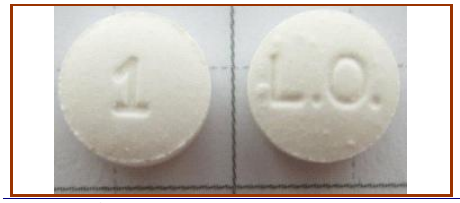
NOTE: 室溫儲存

Increased risk of nonselective MAO inhibition occurs with doses > 10mg/day

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有"1"字樣，另一面有"L. O."字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1036215

14.08C MAO-B Inhibitor

22912 **C / Unsafe**

RAKINSON* TABLETS "CENTER" "晟德"律莎錠

Rasagiline mesylate 1mg tab

Dosage: 1常備品 22912

Adult
· Parkinson's disease: (monotherapy or adjunct therapy; not taking levodopa): PO, initial 1mg qd, do not exceed 1 mg/day.
· Parkinson's disease: (concomitant levodopa, with or without other Parkinson agents): PO, initial, 0.5 mg qd; may increase to 1 mg qd based on clinical response; do not exceed 1 mg/day.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Mild (Child-Pugh score 5 or 6): 0.5 mg qd
Moderate (Child-Pugh score 7 to 9)
Severe (Child-Pugh score 10 to 15): do not use

Dosing adjustments in renal impairment:

No dosage adjustment is needed with mild or moderate impairment, not studied in severe impairment

P: P Tab: 1mg(22912)

ADR:

COMMON
Orthostatic hypotension, peripheral edema, rash, weight decreasing, constipation, indigestion, nausea, vomiting, xerostomia, arthralgia, ataxia, dizziness, dyskinesia, headache, depression, falling injury, influenza-like illness.
SERIOUS
Hypertension, compulsive behavior, serotonin syndrome.

NOTE: 室溫保存

藥名相似:

外觀相似:

外觀描述: 白色圓錠，一面有"R"字樣，另一面中央有刻痕)

14.08D COMT Inhibitor

22906 **C / Caution**

COMTAN* FILM-COATED TABLET 200MG 諾康停膜衣錠 200毫克

Entacapone 200mg FC tab

Dosage: 1常備品 22906

Adult
·Parkinson's disease, adjunct: PO, 200 mg with each levodopa/carbidopa dose, up to a Max. 8 times/day(1600 mg/day)

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Use with caution.

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 200mg(22906), Stalevo(22900)

ADR:

COMMON
dizziness, fatigue, abdominal pain, constipation, diarrhea, nausea, vomiting, urine discoloration
SERIOUS
dyskinesia, hallucinations, hyperkinesia

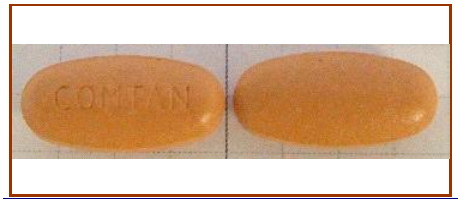
NOTE: 室溫儲存

1. Patients is receiving 800 mg or more of levodopa daily before initiating entacapone therapy required a reduction in levodopa dosage; the average reduction in daily levodopa dosage was about 25%
2.Always administer entacapone in combination with levodopa/carbidopa. Entacapone has no antiparkinsonian effect of its own

藥名相似:

外觀相似: Salazopyrin* Sulfasalazine (21202)

外觀描述: 橙黃色長橢圓錠，有COMTAN字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023248

14.10B Nonvolatile Anesthetics

32543 B / Caution

FRESOFOL* 1% MCT/LCT 飛可復1%注射液

■Propofol inj 200mg/20mL amp

Dosage: 1常備品 32543

Adult
·Anesthesia: Induction, IV, 1.5-2.5 mg/kg (approximately 20-40 mg every 10 sec until onset of induction). MD, IV infusion, 50-200 mcg/kg/min
·Sedation:ICU, IV infusion, 5 mcg/kg/min for 5 min, increments of 5-10 mcg/kg/min over 5-10 min, MD 5-50 mcg/kg/min

Pediatric
·Anesthesia: Induction (3-16 yr), IV over 20-30 sec, 2.5-3.5 mg/kg. MD (2 mons-16 yr), IV infusion, 125-300 mcg/kg/min

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Inj: 200mg/20mL emulsion(32543)

ADR:

COMMON
injection site pain, involuntary muscle movement, nausea, vomiting
SERIOUS
anaphylaxis, apnea, respiratory acidosis bradycardia, hypertension, hypotension

NOTE: 儲存25℃以下

■輕中度鎮靜止痛
·《Contraindications》Allergies to eggs, egg products, soybeans, or soy products ; Hypersensitivity to propofol or any of its components ;
Fresenius Propoven 2% emulsion: Known hypersensitivity to propofol or any of its excipients (eg, soybean oil, medium-chain triglycerides, purified egg phosphatides, glycerol, oleic acid, sodium hydroxide); water for injections Fresenius Propoven 2% emulsion should not be used in patients who are hypersensitive to peanut or soy ;

藥名相似:

外觀相似:

外觀描述: 20mL乳白色注射液,透明安瓿頸部有"紅"點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022868

14.12A1 TCAs,Tricyclics

22933 C / Unsafe

COLIAN* CAPSULES 25MG "JOHNSON" "強生" 可立安膠囊 25 毫克

Doxepin HCl 25mg cap

Dosage: 1常備品 22933

Adult
·Mild depression : 25-50 mg/day in 1-3 div. doses
·Severe depression : 75-150 mg/day may be increased to 300 mg daily
·Chronic idiopathic urticaria (unlabeled use): 10-30 mg/day

Pediatric
·Safety and effectiveness not established in pediatric patients

Dosing adjustments in hepatic impairment:

Dosage adjustment needed

Dosing adjustments in renal impairment:

No data available

P: Cap:25mg(22933) (27558)(急用藥), Cream: 5% 15g/tube(29329)

ADR:

COMMON
Weight gain, bloating symptom, constipation, xerostomia, dizziness, somnolence, blurred vision, urinary retention
SERIOUS
Hypertension, hypotension, tachyarrhythmia, agranulocytosis, leukopenia, pancytopenia, purpuric disorder, thrombocytopenia, worsening depression, suicidal thoughts, suicide

NOTE: 室溫儲存25℃以下

·《Contraindications》Coadministration with or within 2 weeks of an MAOI ; Glaucoma ; Glaucoma, untreated narrow angle ; Hypersensitivity to doxepin, any component of the product , or other dibenzoxepines ; Urinary retention, tendency towards or severe ;

藥名相似:

外觀相似:

外觀描述: 藍色膠囊

14.12A1 TCAs,Tricyclics

22934 c /

FRONIL* S.C. TABLETS "JOHNSON" 福樂你糖衣錠

Imipramine HCl 25mg tab

Dosage: 1常備品 22934

Adult
·Depression: PO, initial 25 mg tid-qid, Max. 300 mg/day (hospitalized patients), 200 mg/day (outpatients)

Pediatric
·Depression : unlabeled use; not recommended for <12yrs
PO, initial 1.5 mg/kg/day then increased by 1 mg/kg every 3-4 days up to 5 mg/kg/day div.1-4 doses

·Enuresis : not recommended for <6yrs
PO, initial 25 mg qhs then increased by 25 mg/day at 1 wk intervals until desired effect achieved. Max. 2.5 mg/kg/day or 50 mg/day(6-12 yrs); Max. 75 mg/day(≧12yrs)

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 25mg(22934)

ADR:

COMMON
blurred vision, drowsiness, dizziness, weakness, fatigue, headache, dry mouth, constipation, bloating, urinary retention, weight gain
SERIOUS
agranulocytosis, arrhythmias, AV conduction changes, heart block, palpitations, jaundice, hepatic dysfunction, myocardial infarction, stroke, orthostatic hypotension, syncope, hypertension, psychotic reactions, seizures

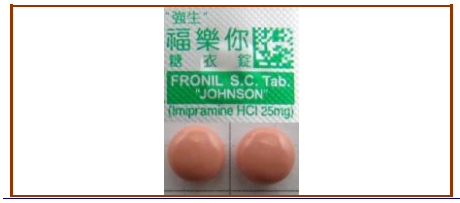
NOTE: 室溫儲存

·《Contraindications》Coadministration with a MAOI or use within 14 days of discontinuing a MAOI ; Hypersensitivity to imipramine hydrochloride or other dibenzazepines ; Myocardial infarction, during the acute recovery period ;

藥名相似:

外觀相似: Lowen* 0.5mg tab(23015), Ritalin* 10mg tab

外觀描述: 粉橘色圓扁糖衣錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12001752

14.12A1 TCAs,Tricyclics

22936 **UK /**

DEANXIT FILM COATED TABLETS "隆柏" 得安緒膜衣錠

Flupentixol 2HCl[C] 0.5mg & Melitracen HCl 10mg tab

Dosage: 1常備品 22936

Adult
·Antidepression, antianxiolytic : 2 tab/day div.in morning and noon. In severe cases the morning dose may be increased to 2 tab. MD 1 tab qd

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: Deanxit*(22936), Fluanxol* 3mg(22967); Inj: Fluanxol* Depot 20mg/1mL Amp (32562)

ADR:

Extrapyramidal symptoms, tachycardia, orthostatic hypotension, tremor, sedation, sleep disorders

NOTE: 室溫儲存

Melitracen
·《Contraindications》Acute alcohol; sedative; analgetic or psychopharmaceutical intoxication; acute delirium ; narrow angle glaucoma ; prostate adenoma, hematopoietic dysfunction ; combination with monoamine oxidase inhibitors ;

藥名相似:

外觀相似:

外觀描述: 桃紅色圓形膜衣錠

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2011315

14.12A3 Serotonin Modulators

22926 **ɔt be ruled out / Infant risk can**

Brintellix Film-Coated Tablets 10mg 敏特思膜衣錠10毫克

Vortioxetine 10mg FC tab

Dosage: 1常備品 22926

ADULT
·Major depressive disorder: PO, initial, 10mg QD; maintenance, increase to 20mg QD as tolerated, may decrease to 5mg QD if intolerant

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

·Mild to moderate: No dosage adjustment needed
·Severe: Use not recommended

Dosing adjustments in renal impairment:

·Mild to ESRD: No dosage adjustment needed

P: P Tab: 10mg(22926)

ADR:

COMMON
Constipation, nausea, vomiting
SERIOUS
Hyponatremia, abnormal hemorrhage, hypersensitivity reaction, serotonin syndrome

NOTE: 室溫儲存

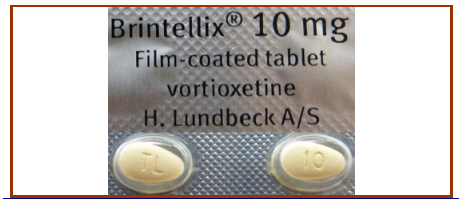
·《Contraindications》Concomitant use with an MAOI (use within 14 days of discontinuing an MAOI used to treat psychiatric disorders or MAOI use within 21 days after vortioxetine discontinuation), including linezolid or IV methylene blue; increased risk of serotonin syndrome ; Hypersensitivity to vortioxetine or any component of the product ;
·May abruptly discontinue if needed; although transient adverse events have occurred with abrupt discontinuation of 15 or 20 mg/day; to avoid the transient adverse events associated with abrupt discontinuation, as experienced by patients receiving 15 to 20 mg/day in clinical studies, taper dose to 10 mg/day for 1 week prior to full discontinuation
·Vortioxetine should not be used concomitantly with MAOIs intended to treat psychiatric disorders

or with linezolid or IV methylene blue. Do not initiate vortioxetine within 14 days of MAOI discontinuation. Do not initiate an MAOI within 21 days of discontinuing vortioxetine. Do not initiate vortioxetine in patients being treated with linezolid or IV methylene blue; may resume vortioxetine 24 hours after the last linezolid or IV methylene blue dose

藥名相似: Brilinta*(25241)

外觀相似:

外觀描述: 黃色杏仁形錠，一面有"TL"字樣，另一面有"10"字樣



14.12A3 Serotonin Modulators

22931 C /

MESYREL TABLETS 50MG "LOTUS" "美時" 美舒鬱錠50毫克

Trazodone HCl 50mg tab

Dosage: 1常備品 22931

Adult
·Depression: PO, initial 50 mg tid, may be increased by 50 mg/day every 3 to 4 days up to 400 mg/day for outpatient. Dosage up to 600 mg daily may be required in hospitalized or severely depressed patients.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 50mg(22931)

ADR:

COMMON
Anorexia, constipation, dry mouth, nausea, vomiting, diarrhea, blurred vision, sweating, weight changes, dizziness, drowsiness, lethargy, headache, insomnia, memory impairment
SERIOUS
Arrhythmias, hyper or hypotension, hemolytic anemia, leukocytosis, methemoglobinemia, priapism, seizures

NOTE: 室溫儲存

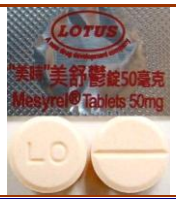
·《Contraindications》Coadministration with an MAOI, including linezolid or IV methylene blue, or use within 14 days of discontinuing an MAOI; increased risk of serotonin syndrome ; Concomitant use with saquinavir/ritonavir ; Hypersensitivity to trazodone hydrochloride ;

·Taken with meals since it decrease the incidence of dizziness or lightheadedness.

藥名相似:

外觀相似:

外觀描述: 淺膚色圓扁錠，一面中央有刻痕，另一面有"LO"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1033664

14.12A4 SSRIs, Selective Serotonin Reuptake Inhibitors

22927 C / Unsafe

Leeyo F.C. Tablets 10 mg 離憂膜衣錠 10 毫克

Escitalopram oxalate 10mg

Dosage: 1常備品 22927

Adult
·Major depressive disorder, generalized anxiety disorder: PO, initial 10 mg/day in the morning or evening; may increase to 20 mg/day after at least 1 week
·Panic disorder: PO, initial 5 mg/day for the first week before increasing the dose to 10 mg/day; Max. 20 mg/day
·Social anxiety disorder: PO, initial 10 mg once daily, the dose may subsequently be decreased to 5 mg or increased to maximum of 20 mg daily

Pediatric
·Major depressive disorder(≧12 yrs), PO initial, 10 mg/day as a single dose in the morning or evening.
·Major depressive disorder(≧12 yrs), PO maintenance, 10 mg/day, may increase to 20 mg/day only after a minimum of 3 weeks.

Dosing adjustments in hepatic impairment:

10mg/day

Dosing adjustments in renal impairment:

Mild to moderate: no dose adjustment recommended
Severe (CrCl<20mL/min): use with caution

P: Tab: 10mg(22927)

ADR:

COMMON
Palpitations, diaphoresis, weight increased, constipation, diarrhea, indigestion, nausea, xerostomia, anemia, contusion, epistaxis, hematoma, agitation, dizziness, feeling nervous, headache, insomnia, lightheadedness, somnolence, tremor, disorder of ejaculation, impotence, fatigue
SERIOUS
Heart failure, myocardial infarction, prolonged QT interval, Torsades de pointes, diabetes mellitus, syndrome of inappropriate antidiuretic hormone secretion, pancreatitis, rectal hemorrhage, grand mal seizure, neuroleptic malignant syndrome, depression, worsening (rare), suicidal thoughts (rare), suicide (rare), serotonin syndrome

NOTE: 室溫儲存

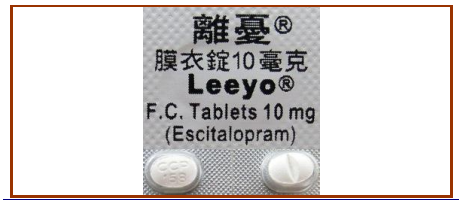
·《Contraindications》Increased risk of serotonin

syndrome with concomitant use with an MAOI, including linezolid or IV methylene blue, or use of escitalopram within 14 days of discontinuing an MAOI used to treat psychiatric disorders, or use of an MAOI used to treat psychiatric disorders within 14 days of discontinuing escitalopram ; Concomitant use of pimozide ; Hypersensitivity to citalopram, escitalopram, or any other component of the product ;

藥名相似:

外觀相似:

外觀描述: 白色長橢圓扁錠，一面有"CCP 158"字樣，一面中間有刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049629

14.12A4 SSRIs, Selective Serotonin Reuptake Inhibitors

22928 C /

FLURONIN* CAPSULES 20MG "YUNG SHIN" 伏憂寧膠囊２０公絲〝永信〞

Fluoxetine HCl 20mg cap

Dosage: 1常備品 22928

Adult
·Depression: PO, initial 20mg as a single morning dose up to 80mg/day (geriatric up to 60mg daily)
·Bulimia nervosa: PO, initial 20 mg/day, up to 60 mg/day
·Obsessive-compulsive disorder: PO, initial 20 mg/day, MD 20-80 mg/day
·Premenstrual dysphoric disorder: PO, initial 20 mg/day, up to 80 mg/day
·Panic disorder: PO, initial 10 mg/day for 1 week then increase to 20 mg/day, up to 60 mg/day

Pediatric
·Depression(> 8 yrs): PO, 10-20 mg once daily
·Obsessive-compulsive disorde(> 7 yrs): Initial, PO 10 mg once daily; may increase to 20 mg once daily after 2 weeks; recommended dose range, 20-60 mg daily

Dosing adjustments in hepatic impairment:

Dosage adjustment needed.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Cap: 20mg(22928)

ADR:

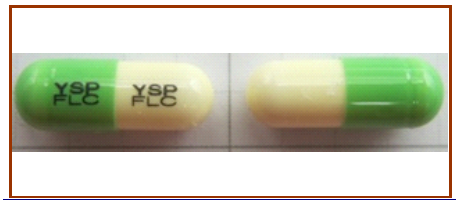
NOTE: 室溫儲存

·《Contraindications》Concomitant use with an MAOI , including linezolid or IV methylene blue, or within 14 days of discontinuing an MAOI; at least 5 weeks should elapse after fluoxetine hydrochloride discontinuation before MAOI initiation due to risk of serotonin syndrome ;
Concomitant use of pimozide or thioridazine; increases risk of QT prolongation ;
1.Doses over 20mg/day should be taken in 2 div.doses, in the morning and at noon
2.Contraindications: Fluoxetine should not be started for at least 2 weeks after stopping MAOI, thioridazine or MAOI should not be started for at least 5 weeks after stopping fluoxetine

藥名相似:

外觀相似:

外觀描述: 淺綠色/淡黃色膠囊，有"YSP"及"FLC"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043523

14.12A4 SSRIs, Selective Serotonin Reuptake Inhibitors

22930 C /

ZAPLINE* FC tab 50mg 憂必晴膜衣錠

Sertraline 50mg tab

Dosage: 1常備品 22930

Adult
·Depression, obsessive-compulsive disorder: PO, initial 50 mg qd, may be increased at intervals of at least 1 wk to Max. 200 mg/day
·Panic disorder, posttraumatic stress disorder, social phobia: PO, initial 25 mg qd for 1 wk, then increase to 50 mg qd; may then be increased at intervals of at least 1 wk to Max. 200 mg/day

Pediatric
·Obsessive-compulsive disorder(6-12yrs): PO, initial 25 mg qd, may be increased at intervals of at least 1 wk to Max. 200 mg/day
·Obsessive-compulsive disorder(13-17yrs): Same as adult

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 50mg(22930); Soln: 20mg/mL, 60mL/Bot(28547)

ADR:

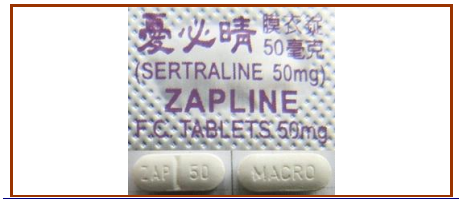
NOTE: 室溫儲存

·《Contraindications》Concomitant use of disulfiram with oral concentrate ; Concomitant use of MAOIs, including linezolid or IV methylene blue, within 14 days of sertraline discontinuation or use of sertraline within 14 days of discontinuing an MAOI; increased risk of serotonin syndrome ; Concomitant use of pimozide ; Hypersensitivity to sertraline or any other component of the product ;
1.Administer once daily, either in the morning or evening
2.Allow at least 14 days between discontinuing MAOIs and initiation of sertraline or between stopping sertraline and initiation of MAOIs

藥名相似:

外觀相似:

外觀描述: 白色長橢圓錠,一面有MACRO,另一面中央有刻痕及ZAP 50字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1047638

14.12A4 SSRIs, Selective Serotonin Reuptake Inhibitors

22944 C / Caution

LUVOX* 50, film-coated tablets "亞培" 無鬱寧膜衣錠 50 毫克

急用Fluvoxamine maleate 50mg tab

Dosage: 2急用藥 22944

Adult
·Depression: PO, initial 50-100mg hs; Max. 300mg/day
·Obsessive-Compulsive Disorder: PO, initial 50mg hs, may increase by 50mg increments every 4-7 days, Max. 300mg/day. Daily dosages exceeding 150mg should be given in 2 or 3 divided doses

Pediatric
·Obsessive-Compulsive Disorder (8-17yr): PO, initial 25mg hs, may increase by 25mg increments every 4-7 days, Max. 200mg/day (8~11yr), 300mg/day (11~17yr). Daily doses exceeding 50mg should be given in 2 or 3 divided doses

Dosing adjustments in hepatic impairment:

Reduced initial dose and slow titration may be required.

Dosing adjustments in renal impairment:

NDA

P:

ADR:

COMMON
Sweating, diarrhea, indigestion, loss of appetite, nausea, xerostomia, asthenia, dizziness, insomnia, somnolence, tremor, anxiety, feeling nervous, abnormal ejaculation, orgasm incapacity
SERIOUS
Stevens-Johnson syndrome, toxic epidermal necrolysis, hyponatremia, agranulocytosis, abnormal bleeding, anaphylaxis, seizure, suicide, suicidal thoughts, worsen depression, neuroleptic malignant syndrome, serotonin syndrome

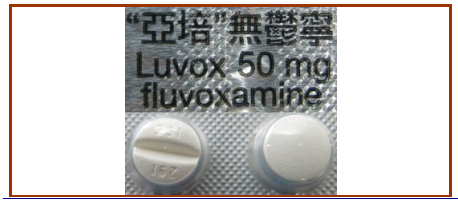
NOTE: 室溫儲存

·《Contraindications》Concomitant use with alosetron, pimozide, thioridazine, tizanidine , or ramelteon ; Concomitant use of MAOIs, including linezolid or IV methylene blue, within 14 days of fluvoxamine discontinuation or use of fluvoxamine within 14 days of discontinuing an MAOI; increased risk of serotonin syndrome ;
1.May be administered with or without food
2. Allow at least 14 days between discontinuing MAOIs and initiation of fluvoxamine or between stopping fluvoxamine and initiation of MAOIs

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面中央有刻痕及"291"字樣



14.12A4 SSRIs, Selective Serotonin Reuptake Inhibitors

28549 c / Unsafe

Talopram* Oral Solution "CENTER" "晟德"易復樂內服液劑

Escitalopram oxalate 1mg/mL

Dosage: 1常備品 28549

Adult
·Major depressive disorder, generalized anxiety disorder: PO, initial 10 mg/day as a single dose in the morning or evening; may increase to 20 mg/day after a minimum of 1 week.
·Panic disorder: PO, initial 5 mg/day for the first week before increasing the dose to 10 mg/day; Max. 20 mg/day.
·Social anxiety disorder: PO, initial 10 mg once daily, the dose may subsequently be decreased to 5 mg or increased to maximum of 20 mg daily.
·Obsessive-compulsive disorder: PO, initial 10 mg once daily, the dose may be increased to maximum of 20 mg daily.

Pediatric
·Should not be used in the treatment of children and adolescents under the age of 18 years.

Dosing adjustments in hepatic impairment:

10mg/day

Dosing adjustments in renal impairment:

Mild to moderate: no dose adjustment recommended
Severe (CrCl<20mL/min): use with caution

P: Soln: 1mg/mL,150mL/bot(28549); Tab: 10mg(22927)

ADR:

COMMON
Diaphoresis, abdominal pain, constipation, diarrhea, indigestion, nausea, vomiting xerostomia, dizziness, headache, insomnia, somnolence, disorder of ejaculation, erectile dysfunction, orgasm incapacity, reduced libido, fatigue
SERIOUS
Depression, worsening, suicidal thoughts, suicide, serotonin syndrome

NOTE: 室溫儲存

·《Contraindications》Increased risk of serotonin syndrome with concomitant use with an MAOI, including linezolid or IV methylene blue, or use of escitalopram within 14 days of discontinuing an MAOI used to treat psychiatric disorders, or use of

an MAOI used to treat psychiatric disorders within 14 days of discontinuing escitalopram; Concomitant use of pimozide; Hypersensitivity to citalopram, escitalopram, or any other component of the product ;

· 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 白色上蓋，150mL白色塑膠瓶

14.12A5 SNRIs, Serotonin Norepinephrine Reuptake Inhibitors

23007 **C / Infant risk can**

Easyfor SR Capsules 75mg 悅康持續藥效膠囊 75 毫克

Venlafaxine 75mg cap

Dosage: 1常備品 23007

Adult

·Depression: PO, initial 75 mg qd with meal; dose may be increased by up to 75 mg/day increments at intervals of not less than 4 days up to 225-375 mg/day (in divided doses).

·Generalized anxiety disorder, social anxiety disorder: PO, initial 75 mg/day; may increase dosage by up to 75 mg/day increments at intervals of not less than 4 days up to Max. 225 mg/day

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Moderate hepatic impairment: reduce total daily dosage by 50%

Dosing adjustments in renal impairment:

Clcr 10-70 mL/min: decreased dose by 25-50%

P: Cap: 75mg(23007)

ADR:

COMMON

·Cardiovascular: Hypertension (3% to 13%)

·Dermatologic: Sweating symptom (6.7% to 25%)

·Endocrine metabolic: Weight loss (3% to 47%)

·Gastrointestinal: Constipation (8% to 15%), Loss of appetite (8% to 22%), Nausea (21% to 58%), Xerostomia (12% to 22%)

·Neurologic: Asthenia (8% to 19%), Dizziness (11% to 23.9%), Dream disorder (3% to 7%), Headache (25% to 38%), Insomnia (14% to 24%), Somnolence (14% to 26%), Tremor (1.1% to 10.2%)

·Ophthalmic: Blurred vision (4% to 6%)

·Psychiatric: Feeling nervous (4% to 21.3%)

·Reproductive: Abnormal ejaculation (2.2% to 19%), Erectile dysfunction (2.1% to 6%), Orgasm disorder (2% to 5%)

SERIOUS

·Endocrine metabolic: Hyponatremia

·Gastrointestinal: Gastrointestinal hemorrhage (rare)

·Hematologic: Hemorrhage, Abnormal

·Hepatic: Hepatitis

·Neurologic: Seizure (0.3%)

·Psychiatric: Depression, Exacerbation (rare), Hypomania, Mania, Suicidal thoughts, Suicide

·Other: Neuroleptic malignant syndrome, Serotonin syndrome

NOTE: 室溫儲存

·《Contraindications》Concomitant use of MAOIs, including linezolid or IV methylene blue, within 7 days of venlafaxine discontinuation or use of venlafaxine within 14 days of discontinuing an MAOI; increased risk of serotonin syndrome ; Hypersensitivity to venlafaxine hydrochloride , desvenlafaxine , or to any excipients in the formulation ;

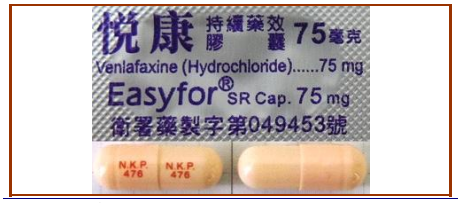
1.Should be swallowed whole; do not crushed or chewed

2.Contraindications: recent or concomitant use of MAOI

藥名相似:

外觀相似:

外觀描述: 淡粉紅色膠囊，有"N.K.P"及"476"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049453

14.12A5 SNRIs, Serotonin Norepinephrine Reuptake Inhibitors

23024 **C / Unsafe**

CYMBALTA* 30MG 千憂解 30毫克

Duloxetine 30mg cap

Dosage: 1常備品 23024

Adult

·Major depressive disorder: PO, initial 40-60mg/day (60mg qd or 30mg bid); MD 60mg qd; Max. 120mg/day

(There is no evidence that doses>60mg/day provide additional therapeutic benefit)

·Diabetic peripheral neuropathy pain: PO, 60mg qd; Max. 60mg/day

·Generalized anxiety disorder: PO, initial, 60 mg qd, may start at 30 mg qd for 1 week and then titrate up to 60 mg qd; may increase by increments of 30 mg qd; MD 60-120 mg qd. Max. 120 mg/day

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Not recommended

Dosing adjustments in renal impairment:

Clcr>30mL/min: Initiated at a lower dose and then increased gradually

Clcr<30mL/min: Not recommended

P: Cap: 30mg(23024)

ADR:

COMMON

Diaphoresis, constipation, decrease in appetite, diarrhea, nausea, xerostomia, dizziness, headache, insomnia, somnolence, fatigue
SERIOUS
Abnormal bleeding, hepatotoxicity, worsening of depression, suicidal thoughts, serotonin syndrome, withdrawal sign or symptom

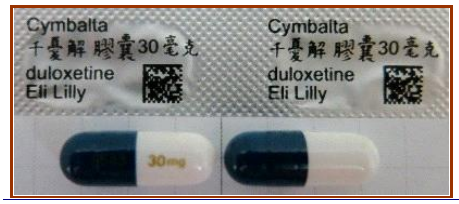
NOTE: 室溫儲存

·《Contraindications》Concomitant use with an MAOI, including linezolid or IV methylene blue, or within 14 days of discontinuing an MAOI; at least 5 days should elapse after discontinuation of duloxetine before MAOI initiation due to risk of serotonin syndrome；
·Swallow whole. It should not be chewed or crushed. Do not open the capsule and sprinkle the contents on food or in liquids.
·Because withdrawal effects may occur, abrupt discontinuance of duloxetine should be avoided.

藥名相似:

外觀相似:

外觀描述: 白色/藍色膠囊，有30mg及9543字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024240

14.12A6 MAO-A I, Monoamine Oxidase -A Inhibitors

22940 UK / No report(毫

BIORIX F.C. TABLETS 150MG "CBC" 保鬱舒膜衣錠１５０公絲

急用Moclobemide 150mg FC tab

Dosage: 2急用藥 22940

Adult
·Depression: PO, initial 300 mg/day div. 2-3 doses, up to 600 mg/ day as needed

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Reduced dose by one-half or one-third (or the dosage interval prolonged)

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 150mg(22940)

ADR:

Dizziness, dry mouth, headache, tremor, insomnia, constipation, nausea, blurred vision, hypotension, tachycardia

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to moclobemide or any component of the formulation; acute confusional states; concurrent use of bupropion, conventional monoamine oxidase inhibitors, dextromethorphan, meperidine, selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, selegiline, thioridazine, tramadol, tricyclic/tetracyclic antidepressants；

藥名相似:

外觀相似:

外觀描述: 鵝黃色橢圓錠，二面之標記分別為 CBC及112 | 112[反向字]

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043892

14.12A7 NaSSA, Noradrenergic and specific serotonergic antidepressant

22948 C / Infant risk can

Mirtapine* Orally Disintegrating tablets 30mg 美妥平口溶錠 30 毫克

Mirtazapine 30mg OD tab

Dosage: 1常備品 22948

Adult
·Depression: PO, initial 15 mg hs, titrate up to 15-45 mg/day with dose increases made no more frequently than every 1-2 wks, Max 45mg/day

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P: Tab: 30mg(22948)

ADR:

COMMON
Increased appetite, Serum triglycerides raised, 7% or greater Weight gain, Constipation, Xerostomia, ALT/SGPT level raised, Asthenia, Dizziness, Somnolence, Disturbance in thinking.
SERIOUS
Agranulocytosis, Neutropenia, Cirrhosis of liver, Status epilepticus, Tonic-clonic seizure, Depression, exacerbation, Suicidal thoughts, Suicide, Neuroleptic malignant syndrome, Serotonin syndrome.

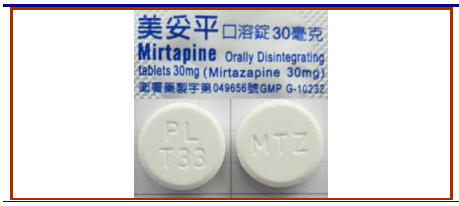
NOTE: 室溫儲存25°C以下

·《Contraindications》Concomitant use of MAOIs, including linezolid or IV methylene blue, or use within 14 days of initiating or discontinuing an MAOI; Hypersensitivity to mirtazapine or any component of the product；
·Open blister pack with dry hands and place the tablet on tongue, tablet will disintegrate rapidly on the tongue and can be swallowed with saliva; use tablet immediately after removal from package
·含阿斯巴甜，苯酮尿症者不宜使用。

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有MTZ，一面有PL及T33字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049656

14.12A8 Dopamine Reuptake Blocker

22954 **C / Caution**

Wellbutrin XL 150 mg Tablet "Canada" 威克倦持續性藥效錠150毫克

Bupropion HCL 150 mg XL tab

Dosage: 1常備品 22954

Adult
·Major depressive disorder: PO, initial 150 mg in the morning for 3 days, then increase to 300 mg qd for several weeks.(MAX daily dose is 450 mg given as a single dose)

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Mild to moderate hepatic cirrhosis: reduced frequency or dose
Severe hepatic cirrhosis: Max. 150 mg qod

Dosing adjustments in renal impairment:

Dosage adjustment needed, reduce frequency and/or dose should be considered

P: Tab: 150mg(22954)

ADR:

COMMON
Hypertension, tachyarrhythmia, pruritus, rash, urticaria, constipation, nausea, arthralgia, myalgia, confusion, dizziness, headache, insomnia, tremor, tinnitus, agitation, anxiety, hostile behavior, disorder of menstruation, pharyngitis, xerostomia
SERIOUS
Cardiac dysrhythmia, wide QRS complex, Stevens-Johnson syndrome, anaphylaxis, seizure, depression exacerbation, mania, psychotic disorder, suicidal thoughts

NOTE: 室溫儲存

·《Contraindications》Abrupt discontinuation of alcohol, benzodiazepines, barbiturates, or antiepileptic drugs; increased risk of seizures ; Concomitant use of an MAOI indicated to treat psychiatric disorders, as well as linezolid and IV methylene blue, or use within 14 days of discontinuing an MAOI; Concomitant use of other buPROPion products; incidence of seizure is dose-dependent ; Hypersensitivity to buPROPion or any component of the product ; Prior or current diagnosis of bulimia or anorexia; higher incidence of seizures ; Seizure disorders ;
1. Do not crush or chew
2. Contraindications: seizure disorders, patients undergoing abrupt discontinuation of alcohol or sedatives (including benzodiazepines), prior or current diagnosis of bulimia or anorexia, concomitant MAO inhibitor

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，有GS 5FV字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025106

14.12A9 Melatonergic Receptor Agonist

22957 **b1 / Infant risk can**

Valdoxan* film-coated tablets 25mg 煩多閃膜衣錠25毫克

Agomelatine 25mg tab

Dosage: 1常備品 22957

Adult
·Depression: PO, 25 mg hs. After 2 weeks, the dose may be increased to 50 mg at bedtime if necessary.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

1.Contra-indicated in patients with hepatic impairment.
2.Agomelatine should be stopped if jaundice occurs.

Dosing adjustments in renal impairment:

No data available

P: P Tab: 25mg(22957)

ADR:

COMMON
Hyperhidrosis, Abdominal pain, Constipation, Diarrhea, Nausea, Vomiting, Backache, Dizziness, Headache, Insomnia, Migraine, Somnolence, Anxiety, Fatigue.
SERIOUS
Hepatitis, Jaundice, Liver failure, Hallucinations.

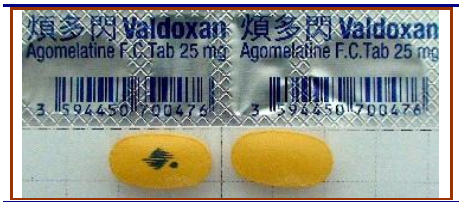
NOTE: 室溫儲存30℃以下

·《Contraindications》Concomitant use of potent CYP1A2 inhibitors ; Hepatic impairment (ie, cirrhosis or active liver disease) or transaminase levels greater than 3 times ULN ; Hypersensitivity to agomelatine or any component of the product ;
1. Liver function should be tested before starting agomelatine, and after about 6, 12, and 24 weeks of treatment.
2. Used with caution in patients with bipolar disorder because of the risk of precipitating mania.
3. Drugs that inhibit or induce the CYP1A2 have the potential to interact with agomelatine.

藥名相似:

外觀相似:

外觀描述: 土黃色橢圓形扁錠，其中一面印有藍色商標圖案



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025451

14.12A9 Melatonergic Receptor Agonist

22958 C / Caution

Rozerem Tablets 8 mg 柔速瑞膜衣錠 8 毫克

Ramelteon 8mg tab

Dosage: 1常備品 22958

Adult
·Insomnia: PO, 4-8 mg taken within 30 min of bedtime; Max. 8 mg/day.

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Moderate hepatic impairment: use with caution
Severe hepatic impairment (Child-Pugh Class C): not recommended

Dosing adjustments in renal impairment:

No dose adjustment is necessary

P: Tab: 8mg(22958)

ADR:

COMMON
Nausea, dizziness, fatigue, insomnia exacerbated, somnolence
SERIOUS
Depression worsening, hallucinations, mania, angioedema

NOTE: 室溫儲存

·《Contraindications》Angioedema with prior exposure ; Concomitant use with fluvoxamine ;
Do not take this medicine with or right after a high-fat meal.

藥名相似:

外觀相似:

外觀描述: 淡橘黃色圓形膜衣錠，兩面有TAK,RAM-8字樣

14.12B1 Typical Agents: Phenothiazines

22961 c / Unsafe

Winsumin* F.C. Tablets 25mg "JOHNSON" "強生"穩舒眠膜衣錠25毫克

Chlorpromazine HCl 25mg tab

Dosage: 1常備品 22961

Adult
·Antipsychotic : PO, initial 25 mg bid-tid, may increase dosage after 1-2 days by 20-50 mg at semiweekly intervals. MD usually 400 mg/day, some patients may require 1-2 g/day.
·Antiemetic : PO, 10-25 mg q4-6h
·Intractable hiccups : PO, 25-50 mg 3-4 times/day
·Premedication : PO, 25-50 mg given 2-3 hrs before surgery

Pediatric
·Apprehension, Presurgical, PO 0.25 mg/pound of body weight; 2-3 hr before operation.
·Nausea and vomiting, PO 0.25 mg/pound of body weight.
·Problem behavior (severe), (outpatients, 6 months-12 yr), PO 0.25 mg/pound of body weight every 4-6 hr as needed.

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 25mg(22961)

ADR:

Hypotension, akathisia, tardive dyskinesia, arrhythmias, constipation, hematologic effects, agranulocytosis (especially between 4-10 weeks), autonomic effects, pseudo-parkinsonism

NOTE: 室溫儲存

·《Contraindications》comatose state ; concomitant use with large doses of CNS depressants (eg, barbiturates, alcohol, narcotics) ;
hypersensitivity to phenothiazines ;

藥名相似:

外觀相似:

外觀描述: 淡藍色圓扁形膜衣錠 、一面中間有一刻痕

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12005616

14.12B1 Typical Agents: Phenothiazines

22969 c / Caution

PROCHLORPERAZINE MALEATE* TABLETS "JOHNSON" "強生"蘋果酸丙氯陪拉辛錠

Prochlorperazine maleate 8mg tab(base=Prochlorperazine 5mg)

Dosage: 1常備品 22969

Adult
·Psychotic disorders: PO, 5-10 mg tid-qid, Max. 150 mg/day
·Nausea and vomiting: PO, 5-10 mg tid-qid, Max. 40 mg/day

Pediatric (>2yrs or >9kg)
·Antiemetic: PO,
0.4 mg/kg/day in 3-4divided doses, or
9-13kg: 2.5 mg qd-bid, Max. 7.5 mg/day
14-17kg: 2.5 mg bid-tid, Max. 10 mg/day
18-39kg: 2.5 mg tid or 5 mg bid, Max 15 mg/day
·Psychotic disorders
2-12yrs : PO, 2.5 mg bid-tid, Max. 20 mg/day(2-5yrs) or 25 mg/day(6-12yrs)

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab:5mg(22969); Inj: 5mg/1mL Amp (32566)

ADR:

EPS, drowsiness, postural hypotension, NMS, cholestatic jaundice, leukopenia, CNS depression, severe hypotension

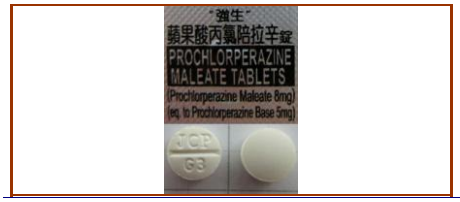
NOTE: 儲存15~30℃

·《Contraindications》Children with conditions where dosage has not been established ; Children under 20 pounds or 2 years of age ; Comatose states ; Hypersensitivity to phenothiazines ; Pediatric surgery ; Present use of large doses of CNS depressants such as barbiturates, alcohol, or narcotics ;

藥名相似:

外觀相似: Vit B6 Pyridoxine (26804), Eltroxin* Thyroxine

外觀描述: 白色圓扁錠，一面中間有刻痕及"JCP G3"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12005040

14.12B1 Typical Agents: Phenothiazines

32566 **c / Caution**

NOVAMIN* INJECTION 5MG/ML (PROCHLORPERAZINE) 諾安命注射液 5 毫克/毫升

Prochlorperazine mesylate 5mg/1mL amp

Dosage: 1常備品 32566

Adult
·Nausea and vomiting: IM, 5-10 mg q3-4h as needed, Max.40 mg/day
·Surgical nausea and vomiting: IM, 5-10 mg 1-2 hr before induction or to control symptoms during or after surgery; may repeat once if necessary
·Psychotic disorders: IM, 10-20 mg q4-6h as needed

Pediatric
·Nausea and vomiting, psychoses: IM, 0.13 mg/kg/dose

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 5mg(22969); Inj: 5mg/1mL Amp (32566)

ADR:

EPS, drowsiness, postural hypotension, NMS, cholestatic jaundice, leukopenia, CNS depression, severe hypotension

NOTE: 室溫25℃以下避光儲存

·《Contraindications》Children with conditions where dosage has not been established ; Children under 20 pounds or 2 years of age ; Comatose states ; Hypersensitivity to phenothiazines ; Pediatric surgery ; Present use of large doses of CNS depressants such as barbiturates, alcohol, or narcotics ;

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液『棕』色安瓿頸部有白點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1027716

14.12B2 Typical Agents: Butyrophenone

22966 **C / Unsafe**

HOPAN* TABLETS 0.5MG (HALOPERIDOL) "KOJAR" 和寧錠 0．5 公絲（哈泊度）

Haloperidol 0.5mg tab

Dosage: 1常備品 22966

·Psychotic disorders: PO, initial 0.5-2 mg bid-tid, higher doses may be required; most studies used doses of 4 to 20 mg/day.

Pediatric (3-12 yrs or 15-40 kg)
·Psychotic disorders: PO, 0.05-0.15 mg/kg/day in 2-3 div. doses
·Tourette's syndrome, non-psychotic behavioral problems: PO, 0.05-0.075 mg/kg/day in 2-3 div. doses

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 0.5mg(22966), 5mg(22975); Inj: 5mg/1mL Amp(32565), 50mg/1mL Amp(32569)

ADR:

Sedation, dystonic reactions, extrapyramidal reactions, hypotension, arrhythmias, insomnia, anxiety, withdrawal emergent neurological signs, tardive dyskinesia, tachycardia

NOTE: 室溫儲存

·《Contraindications》Comatose state from any cause ; Hypersensitivity to haloperidol ; Parkinson disease ; Severe toxic central nervous system depression ;
·MAX of 100 mg/day or greater has been used in severely resistant patients, but safety of prolonged use of such large doses has not been shown in limited clinical usage.

藥名相似:

外觀相似:

外觀描述: 藍色正方型扁錠，有"KOJAR"及"KJ"、"019"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1037352

14.12B2 Typical Agents: Butyrophenone

22975 C / Unsafe

BININ-U* TABLETS 5MG (HALOPERIDOL) "瑞士"易寧優錠 5 毫克（哈泊度）

Haloperidol 5mg tab

Dosage: 1常備品 22975

·Psychotic disorders: PO, initial 0.5-2 mg bid-tid, higher doses may be required; most studies used doses of 4 to 20 mg/day.

Pediatric (3-12 yrs or 15-40 kg)
·Psychotic disorders: PO, 0.05-0.15 mg/kg/day in 2-3 div. doses
·Tourette's syndrome, non-psychotic behavioral problems: PO, 0.05-0.075 mg/kg/day in 2-3 div. doses

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 0.5 mg(22966), 5mg(22975); Inj: 5mg/1mL Amp(32565), 50mg/1mL Amp(32569)

ADR:

COMMON
·Cardiovascular: Hypotension
·Gastrointestinal: Constipation, Xerostomia
·Neurologic: Akathisia, Extrapyramidal disease (Frequent), Somnolence
·Ophthalmic: Blurred vision
·Endocrine/Metabolic Effects: Gynecomastia, Hyperglycemia, Hyperprolactinemia(female: menstrual abnormalities; male: erectile or ejaculatory dysfunction)
SERIOUS
·Cardiovascular: Prolonged QT interval, Sudden cardiac death, Torsades de pointes
·Gastrointestinal: Paralytic ileus
·Hematologic: Agranulocytosis
·Neurologic: Dystonia, Neuroleptic malignant syndrome, Seizure, Tardive dyskinesia
·Reproductive: Priapism

NOTE: 室溫儲存

·《Contraindications》Comatose state from any cause ; Hypersensitivity to haloperidol ; Parkinson disease ; Severe toxic central nervous system depression ;
·MAX of 100 mg/day or greater has been used in severely resistant patients, but safety of prolonged use of such large doses has not been shown in limited clinical usage.

藥名相似:

外觀相似:

外觀描述: 淺綠色圓扁錠，一面中間有十字刻痕

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1032584

14.12B2 Typical Agents: Butyrophenone

32565 C / Unsafe

BININ-U* INJECTION (HALOPERIDOL) 易寧優注射液（哈羅哌利杜）

■Haloperidol inj 5mg/1mL amp

Dosage: 1常備品 32565

Adult
·Schizophrenia: IM, 2-5 mg, may repeat every 4 to 8 hours depending on patient response; increase to every 1 hour if needed, Max. 20 mg/day
·Antipsychomotor excitement: IM, 2-5 mg, may repeat every 4 to 8 hours depending on patient response; increase to every 1 hour if needed, Max. 20 mg/day
·Antiemetic: IM, 2.5-5 mg

Pediatric
·Safety and efficacy have not been established in patients less than 3 years old.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 0.5mg(22966), 5mg(22975); Soln: 2mg/mL, 15mL/bot(28552); Inj: 5mg/1mL Amp(32565), 50mg/1mL Amp(32569)

ADR:

Sedation, dystonic reactions, extrapyramidal reactions, hypotension, arrhythmias, insomnia, anxiety, withdrawal emergent neurological signs, tardive dyskinesia, tachycardia

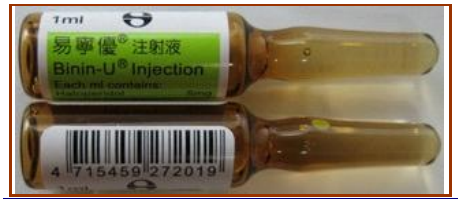
NOTE: 室溫儲存

·《Contraindications》Comatose state from any cause ; Hypersensitivity to haloperidol ; Parkinson disease ; Severe toxic central nervous system depression ; Dementia with Lewy bodies ;

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液『棕』色安瓿頸部有『黃』點，白/綠底黑色字標籤



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1022272

14.12B2 Typical Agents: Butyrophenone

32569 C / Unsafe

BINISON* INJ. 50MG/ML (HALOPERIDOL)"SWISS" "瑞士"易寧神注射液50毫克/毫升(哈伯度)

■Haloperidol decanoate inj 50mg/1mL amp

Dosage: 1常備品 32569

Adult
·Chronic schizophrenia: Deep IM, 10-15 times the previous daily oral dose monthly or every 4 weeks; initial doses greater than 100 mg should be administered in 2 separate IM injections 3 to 7 days apart

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 0.5 mg(22966), 5mg(22975); Inj: 5mg/1mL Amp(32565), 50mg/1mL Amp(32569)

ADR:

Sedation, dystonic reactions, extrapyramidal reactions, hypotension, arrhythmias, insomnia, anxiety, withdrawal emergent neurological signs, tardive dyskinesia, tachycardia

NOTE: 室溫儲存

·《Contraindications》Comatose state from any cause ; Hypersensitivity to haloperidol ; Parkinson disease ; Severe toxic central nervous system depression ; Dementia with Lewy bodies ;
·Haloperidol decanoate injection should not be administered IV

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液『棕』色安瓿頸部有『黃』點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1035430

14.12B3 Typical Agents: Benzamide

22970 UK / Caution

SULPIN F.C. TABLETS 200MG (SULPIRIDE) "S.T." "信東" 舒復寧膜衣錠２００毫克（斯比樂）

Sulpiride 200mg FC tab

Dosage: 1常備品 22970

Adult
·Schizophrenia: PO, 300-600mg/day in divided doses, Max. 1.2g/day
·Depression: PO, 150-300mg/day in divided dose, Max. 600mg/day
·Peptic ulcer disease; Adjunct: 50mg tid

Pediatric
·Schizophrenia, mainly positive symptoms(≧14yrs): PO, initial 200-400 mg bid, increased up to Max. 1.2 g bid.
·Schizophrenia, mainly negative symptoms(≧14yrs): PO, initial 200-400 mg bid, increased up to total of 800 mg daily.
·Schizophrenia. With mixed positive and negative symptoms, with neither predominating, (≧14yrs): PO, 400-600 mg bid.
·Tourette's syndrome, (2-12 yrs): PO, 50-400 mg bid.
·Tourette's syndrome, (12-18 yrs): PO, 100-400 mg bid.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 30 - 60 mL/min: 70% of normal dose
Clcr 10 - 30 mL/min: 50% of normal dose
Clcr <10 mL/min: 34% of normal dose

P: Tab: 200mg(22970)

ADR:

Extrapyramidal reactions, sedation, tardive dyskinesia, neuroleptic malignant syndrome, cholestatic jaundice

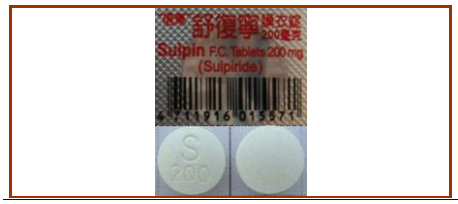
NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to sulpiride ; Pheochromocytoma ; Parkinson's disease ;

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，有S及200字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1028078

14.12B4 Typical Agents: Thioxanthene

22967 c / Caution

FLUANXOL 3MG film coated tablets "隆柏" 福祿安錠 3 毫克

Flupentixol dihydrochloride 3mg tab

Dosage: 1常備品 22967

Adult
·Schizophrenia: 3-15 mg/day in 2-3 div. doses, Max. 40 mg/day

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: Deanxit*(22936), Fluanxol* 3mg(22967); Inj: Fluanxol* Depot 20mg/1mL Amp (32562)

ADR:

Extrapyramidal symptoms, tardive dyskinesias, weight gain, neuroleptic malignant syndrome

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to

flupentixol, thioxanthenes, or any component of the formulation; acute intoxication (ethanol, barbiturate, or opioid); CNS depression due to any cause; coma; severely-agitated psychotic patients, psychoneurotic patients, or geriatric patients with confusion and/or agitation; suspected or established subcortical brain damage; cerebrovascular or renal insufficiency; severe cardiovascular disease/circulatory collapse; liver damage; concomitant use with large doses of hypnotics ;

藥名相似:

外觀相似:

外觀描述: 土黃色圓扁膜衣錠，一面有"F I"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2004858

14.12B4 Typical Agents: Thioxanthene

32562 **c / Caution**

FLUANXOL* DEPOT 1ML "隆柏" 福祿安持續性注射液

cis-Flupentixol decanoate 20mg/1mL amp

Dosage: 1常備品 32562

Adult
·Schizophrenia: IM, initial 20 mg, followed by 20-40 mg every 2-4 wks

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: Deanxit*(22936), Fluanxol* 3mg(22967); Inj: Fluanxol* Depot 20mg/1mL Amp (32562)

ADR:

Extrapyramidal symptoms, tardive dyskinesias, weight gain, neuroleptic malignant syndrome

NOTE: 30℃以下避光儲存

·《Contraindications》Hypersensitivity to flupentixol, thioxanthenes, or any component of the formulation; acute intoxication (ethanol, barbiturate, or opioid); CNS depression due to any cause; coma; severely-agitated psychotic patients, psychoneurotic patients, or geriatric patients with confusion and/or agitation; suspected or established subcortical brain damage; cerebrovascular or renal insufficiency; severe cardiovascular disease/circulatory collapse; liver damage; concomitant use with large doses of hypnotics ;

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液透明安瓿『黃』色標籤 ，頸部有紅點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2005037

14.12B5 Atypical Agents: Benzisoxazole

22979 **C / Unsafe**

Risperdal* Film Coated Tablet 3mg 理思必妥膜衣錠 3 毫克

Risperidone 3mg tab

Dosage: 1常備品 22979

Adult
·Schizophrenia: PO, initial 1 mg bid, then 2 mg bid on the 2nd day, 3 mg bid on the 3rd day, as tolerated, to a target dose of 3 mg bid.

Pediatric
·Schizophrenia(Safety and efficacy have not been established in patients less than 13 years old):
(≥13 yrs) : PO, initial, 0.5 mg qd AM or evening; adjust dosage at intervals not less than 24 hrs and in increments of 0.5-1 mg/day up to 3 mg/day.
·Bipolar mania(Safety and efficacy have not been established in patients less than 10 years old):
(≥10 yrs) : PO, initial, 0.5 mg qd in AM or evening; adjust dosage at intervals not less than 24 hrs and in increments of 0.5-1 mg/day up to 2.5 mg/day.
·Autistic disorder(Safety and efficacy have not been established in patients less than 5 years old or <15 kg):
- Irritability(≥5 yrs; <20 kg) : PO, initial, 0.25 mg qd or half the total daily dose given twice daily; may increase after a minimum of 4 days to 0.5 mg/day; maintenance, 0.5 mg qd or half the total daily dose given twice daily; maintain the dose for a minimum of 14 days and may increase doses at 2-week intervals or longer, in increments of 0.25 mg/day.
- Irritability(≥ 5 yrs; ≥20 kg) : PO, initial, 0.5 mg qd or half the total daily dose given twice daily; may increase after a minimum of 4 days to 1 mg/day; maintenance, 1 mg qd or half the total daily dose given twice daily; maintain the dose for a minimum of 14 days; may increase doses at 2-week intervals or longer, in increments of 0.5 mg/day.

Dosing adjustments in hepatic impairment:

Starting dose of 0.5mg bid, increased at increments of 0.5 mg bid; increases beyond a dosage above 1.5 mg bid should be made at intervals of at least 1 week.

Dosing adjustments in renal impairment:

Starting dose of 0.5mg bid, increased at increments of 0.5 mg bid; increases beyond a dosage above 1.5 mg bid should be made at intervals of at least 1 week.

P: Tab: 3mg(22979); Soln: 1mg/ml, 30ml/B(28553); Inj: 25mg Vial(32567), 37.5mg Vial(32572)

ADR:

COMMON
·Dermatologic: Rash (oral, adults, 1% to 4%; pediatrics, up to 11% ; IM, less than 4%)

·Endocrine metabolic: Hyperprolactinemia (Oral, adults, less than 1%; pediatrics, 49% to 87% ; IM, less than 4%), Weight increased (oral, adult, 8.7% to 20.9%; pediatric, 14% to 32.6% ; IM, adult, 8% to 10%)
·Gastrointestinal: Constipation (oral, 8% to 21% ; IM, 5% to 7%), Diarrhea (oral, 1% to 8% ; IM, less than 4%), Excessive salivation (oral, 1% to 10% ; IM, 1% to 4%), Increased appetite (oral, adult, more than 5%; pediatric, 4% to 47% ; IM, 4%), Indigestion (oral, 2% to 10% ; IM, 6%), Nausea (oral, 4% to 16% ; IM, 3% to 4%), Upper abdominal pain (oral, adult, more than 5%; pediatric, 13% to 16%), Vomiting (oral, 10% to 25% ; IM, less than 4%), Xerostomia (oral, 4% to 15% ; IM, up to 7%)
·Neurologic: Akathisia (oral, up to 10% ; IM, 4% to 11%), Dizziness (oral, 4% to 16% ; IM, 3% to 11%), Dystonia (oral, adult, 3% to 5%; pediatric, 2% to 6% ; IM, adult, less than 4%), Parkinsonism (oral, 6% to 28% ; IM, 8% to 15%), Sedated (5% to 63%), Tremor (oral, 2% to 12% ; IM, 3% to 24%)
·Ophthalmic: Blurred vision (oral, 1% to 7% ; IM, 2% to 3%)
·Psychiatric: Anxiety (oral, up to 16% IM, less than 4%)
·Respiratory: Cough (oral, adults, 2%; pediatrics, 24% ; IM, 2% to 4%), Nasal congestion (oral, adult, 4% to 6%; pediatric, 13%), Nasopharyngitis (oral, adult, 3% to 4%; pediatric, 21%), Pain in throat (oral, adult, more than 5%; pediatric, 3% to 10%), Upper respiratory infection (oral, 2% to 8% ; IM, 2% and 6%)
·Other: Fatigue (oral, adult, 1% to 3%; pediatric, 18% to 42% ; IM, 3% to 9%), Pain, General (IM, 1% to 4%)
SERIOUS
·Cardiovascular: Prolonged QT interval, Sudden cardiac death, Syncope (oral, up to 1% ; IM, up to 2%)
·Endocrine metabolic: Diabetic ketoacidosis, Hypothermia
·Gastrointestinal: Pancreatitis
·Hematologic: Agranulocytosis, Leukopenia, Neutropenia, Thrombocytopenia, Thrombotic thrombocytopenic purpura
·Neurologic: Cerebrovascular accident, Seizure (0.3%), Tardive dyskinesia (oral, less than 5% ; IM, less than 4%)
·Reproductive: Priapism
·Respiratory: Pulmonary embolism
·Other: Neuroleptic malignant syndrome

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to risperiDONE , paliperidone (an active metabolite of risperiDONE), or any component of the product ；同時接受精神興奮劑(如：methylphenidate)和本藥時應謹慎，可能發生遲發性運動困難/錐體外徑症狀。

藥名相似:

外觀相似:

外觀描述: 黃色長橢圓扁錠，有Ris 3字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022769

14.12B5 Atypical Agents: Benzisoxazole

27541 ɔt be ruled out / Infant risk can

INVEGA* Extended Release Tablets 6mg 思維佳持續性藥效錠6毫克

急用Paliperidone 6mg ER tab

Dosage: 2急用藥 27541

Adult
·Schizophrenia: PO, initial 6mg qd in the morning; may increase by 3mg/day increments at intervals of more than 5 days; Max. 12mg/day
·Schizoaffective disorder: PO, initial 6mg qd in the morning; may increase by 3mg/day increments at intervals of more than 4 days; Max. 12mg/day

Pediatric
·Schizophrenia: (age 12 to 17 years; weight 51 kg or greater)：PO, initial 3 mg/day; may increase by 3 mg/day increments at intervals of more than 5 days; Max.12 mg/day
·Schizophrenia: (age 12 to 17 years; weight less than 51 kg)：PO, initial 3 mg/day; may increase by 3 mg/day increments at intervals of more than 5 days; Max. 6 mg/day

Dosing adjustments in hepatic impairment:

Child-Pugh Class A and B, no dose adjustment required.

Dosing adjustments in renal impairment:

Clcr 50-80mL/min: Initial 3mg qd; Max. 6mg/day
Clcr 10-50mL/min: Initial 1.5mg qd; Max. 3mg/day
Clcr <10mL/min: Use is not recommended

P: Tab: 3mg(27545), 6mg(27541, 急用藥), 9mg(27549, 急用藥); Inj: 234mg/1.5mL syringe(37794, 急用藥), 156mg/1mL syringe(37979, 急用藥)

ADR:

COMMON
Tachycardia, Hyperprolactinemia, Weight gain, Constipation, Indigestion, Akathisia, Dyskinesia, Dystonia, Extrapyramidal disease , Parkinsonism, Somnolence, Tremor, Anxiety, Nasopharyngitis.
SERIOUS
Prolonged QT interval, Agranulocytosis, Leukopenia, Dysphagia, Tardive dyskinesia, Priapism.

NOTE: 室溫儲存

·《Contraindications》Known hypersensitivity to paliperidone, risperidone, or to any product component ；
· Swallow whole. Do not chewed, divided or crushed.
·此藥未被核准用於治療失智症相關精神病人。仿單警語：在老年失智病人身上會增加致命機率。
·授乳婦女使用本藥，應監視嬰兒是否發生嗜睡、生長遲緩、顫動及錐體外症狀(顫抖及肌肉運動異常)，如有徵兆應立即就醫。

·此藥可能會因促使血清泌乳激素濃度升高而導致育齡女性生育力降低，此影響是可逆的。
·告知有直立性低血壓的風險，特別是在剛開始治療、重新開始治療、或是提高劑量的時候。
·告知可能減弱判斷、思考或行動的能力，應告誡避免操作危險機械，包括汽車，直到治療不會對他們造成不良影響為止。
·藥物成分容納在不可為身體吸收外殼內，設計為控制速率釋出藥物。藥錠的外殼與不可溶的核心組成會一併排出體外。

藥名相似:

外觀相似:

外觀描述: 黃色圓柱錠,有PAL 6字樣

14.12B5 Atypical Agents: Benzisoxazole

27545 **ɔt be ruled out / Infant risk can**

INVEGA* Extended Release Tablets 3mg 思維佳持續性藥效錠 3 毫克

Paliperidone 3mg ER tab

Dosage: 1常備品 27545

Adult
·Schizophrenia: PO, initial 6mg qd in the morning; may increase by 3mg/day increments at intervals of more than 5 days; Max. 12mg/day
·Schizoaffective disorder: PO, initial 6mg qd in the morning; may increase by 3mg/day increments at intervals of more than 4 days; Max. 12mg/day

Pediatric
·Schizophrenia: (age 12 to 17 years; weight 51 kg or greater)：PO, initial 3 mg/day; may increase by 3 mg/day increments at intervals of more than 5 days; Max.12 mg/day
·Schizophrenia: (age 12 to 17 years; weight less than 51 kg)：PO, initial 3 mg/day; may increase by 3 mg/day increments at intervals of more than 5 days; Max. 6 mg/day

Dosing adjustments in hepatic impairment:

Child-Pugh Class A and B, no dose adjustment required.

Dosing adjustments in renal impairment:

Clcr 50-80mL/min: Initial 3mg qd; Max. 6mg/day
Clcr 10-50mL/min: Initial 1.5mg qd; Max. 3mg/day
Clcr <10mL/min: Use is not recommended

P: Tab: 3mg(27545), 6mg(27541, 急用藥), 9mg(27549, 急用藥); Inj: 234mg/1.5mL syringe(37794, 急用藥), 156mg/1mL syringe(37979, 急用藥)

ADR:

COMMON
Tachycardia, Hyperprolactinemia, Weight gain, Constipation, Indigestion, Akathisia, Dyskinesia, Dystonia, Extrapyramidal disease , Parkinsonism, Somnolence, Tremor, Anxiety, Nasopharyngitis.
SERIOUS
Prolonged QT interval, Agranulocytosis, Leukopenia, Dysphagia, Tardive dyskinesia, Priapism.

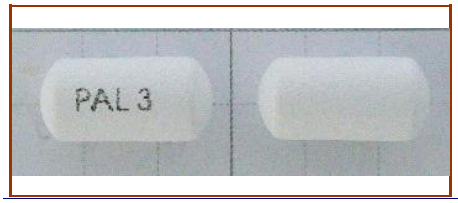
NOTE: 室溫儲存

·《Contraindications》Known hypersensitivity to paliperidone, risperidone, or to any product component；
· Swallow whole. Do not chewed, divided or crushed.
·此藥未被核准用於治療失智症相關精神病人。仿單警語：在老年失智病人身上會增加致命機率。
·授乳婦女使用本藥，應監視嬰兒是否發生嗜睡、生長遲緩、顫動及錐體外症狀(顫抖及肌肉運動異常)，如有徵兆應立即就醫。
·此藥可能會因促使血清泌乳激素濃度升高而導致育齡女性生育力降低，此影響是可逆的。
·告知有直立性低血壓的風險，特別是在剛開始治療、重新開始治療、或是提高劑量的時候。
·告知可能減弱判斷、思考或行動的能力，應告誡避免操作危險機械，包括汽車，直到治療不會對他們造成不良影響為止。
·藥物成分容納在不可為身體吸收外殼內，設計為控制速率釋出藥物。藥錠的外殼與不可溶的核心組成會一併排出體外。

藥名相似:

外觀相似:

外觀描述: 白色圓柱錠,有PAL 3字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024732

14.12B5 Atypical Agents: Benzisoxazole

27549 **ɔt be ruled out / Infant risk can**

Invega* Extended Release Tablets 9mg 思維佳持續性藥效錠9毫克

Paliperidone 9mg ER tab

Dosage: 1常備品 27549

Adult
·Schizophrenia: PO, initial 6mg qd am; may increase by 3mg/day increments at intervals of more than 5 days; Max. 12mg/day
·Schizoaffective disorder: PO, initial 6mg qd am; may increase by 3mg/day increments at intervals of more than 4 days; Max. 12mg/day

Pediatric
·Schizophrenia: (age 12 to 17 years; weight 51 kg or greater)：PO, initial 3 mg/day; may increase by 3 mg/day increments at intervals of more than 5 days; Max.12 mg/day
·Schizophrenia: (age 12 to 17 years; weight less than 51 kg)：PO, initial 3 mg/day; may increase by 3 mg/day increments at intervals of more than 5 days; Max. 6 mg/day

Dosing adjustments in hepatic impairment:

Child-Pugh Class A and B, no dose adjustment required.

Dosing adjustments in renal impairment:

Clcr 50-80mL/min: Initial 3mg qd; Max. 6mg/day

Clcr 10-50mL/min: Initial 1.5mg qd; Max. 3mg/day
Clcr <10mL/min: Use is not recommended

P: Tab: 3mg(27545), 6mg(27541, 急用藥), 9mg(27549, 急用藥); Inj: 234mg/1.5mL syringe(37794, 急用藥), 156mg/1mL syringe(37979, 急用藥)

ADR:

COMMON
Tachycardia, Hyperprolactinemia, Weight gain, Constipation, Indigestion, Akathisia, Dyskinesia, Dystonia, Extrapyramidal disease , Parkinsonism, Somnolence, Tremor, Anxiety, Nasopharyngitis.
SERIOUS
Prolonged QT interval, Agranulocytosis, Leukopenia, Dysphagia, Tardive dyskinesia, Priapism.

NOTE: 室溫儲存

·《Contraindications》Known hypersensitivity to paliperidone, risperidone, or to any product component；
· Swallow whole. Do not chewed, divided or crushed.
·此藥未被核准用於治療失智症相關精神病人。仿單警語：在老年失智病人身上會增加致命機率。
·授乳婦女使用本藥，應監視嬰兒是否發生嗜睡、生長遲緩、顫動及錐體外症狀(顫抖及肌肉運動異常)，如有徵兆應立即就醫。
·此藥可能會因促使血清泌乳激素濃度升高而導致育齡女性生育力降低，此影響是可逆的。
·告知有直立性低血壓的風險，特別是在剛開始治療、重新開始治療、或是提高劑量的時候。
·告知可能減弱判斷、思考或行動的能力，應告誡避免操作危險機械，包括汽車，直到治療不會對他們造成不良影響為止。
·藥物成分容納在不可為身體吸收外殼內，設計為控制速率釋出藥物。藥錠的外殼與不可溶的核心組成會一併排出體外。

藥名相似:

外觀相似:

外觀描述: 粉紅色圓柱錠，有PAL 9字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025158

14.12B5 Atypical Agents: Benzisoxazole

28553 **C / Unsafe**

Seridol* Oral Solution 1mg/ml "Center" "晟德" 賽力多內服液劑1毫克/毫升

Risperidone soln 30mg/30mL

Dosage: 1常備品 28553

Adult
·Schizophrenia: PO, initial 1 mg bid, then 2 mg bid on the 2nd day, 3 mg bid on the 3rd day, as tolerated, to a target dose of 3 mg bid.

Pediatric
·Schizophrenia
·Safety and efficacy have not been established in patients less than 13 years old.
·Schizophrenia (≧13 yrs) : PO, initial, 0.5 mg qd AM or evening; adjust dosage at intervals not less than 24 hrs and in increments of 0.5-1 mg/day up to 3 mg/day.
·Bipolar mania
·Safety and efficacy have not been established in patients less than 10 years old.
·Bipolar I disorder(≧10 yrs) : PO, initial, 0.5 mg qd in AM or evening; adjust dosage at intervals not less than 24 hrs and in increments of 0.5-1 mg/day up to 2.5 mg/day.
·Autistic disorder
·Safety and efficacy have not been established in patients less than 5 years old or <15 kg.
·Autistic disorder - Irritability(≧5 yrs; <20 kg) : PO, initial, 0.25 mg qd or half the total daily dose given twice daily; may increase after a minimum of 4 days to 0.5 mg/day; maintenance, 0.5 mg qd or half the total daily dose given twice daily; maintain the dose for a minimum of 14 days and may increase doses at 2-week intervals or longer, in increments of 0.25 mg/day.
·Autistic disorder - Irritability(≧ 5 yrs; ≧20 kg) : PO, initial, 0.5 mg qd or half the total daily dose given twice daily; may increase after a minimum of 4 days to 1 mg/day; maintenance, 1 mg qd or half the total daily dose given twice daily; maintain the dose for a minimum of 14 days; may increase doses at 2-week intervals or longer, in increments of 0.5 mg/day.

Dosing adjustments in hepatic impairment:

Starting dose of 0.5mg bid, increased at increments of 0.5 mg bid; increases beyond a dosage above 1.5 mg bid should be made at intervals of at least 1 week

Dosing adjustments in renal impairment:

Starting dose of 0.5mg bid, increased at increments of 0.5 mg bid; increases beyond a dosage above 1.5 mg bid should be made at intervals of at least 1 week

P: Tab: 3mg(22979); Soln: 1mg/ml, 30ml/B(28553); Inj: 25mg Vial(32567), 37.5mg Vial(32572)

ADR:

Somnolence, dizziness, hyperkinesia, nausea, extrapyramidal effects, constipation, anxiety, headache, rhinitis, rash, dyspepsia, tachycardia

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to risperidone, paliperidone (an active metabolite of risperidone), or any component of the product；Oral solution can be mixed with water, coffee, orange juice but is not compatible with cola, grapefruit juice, or tea.
· 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 外紙盒，內為30mL白色塑膠瓶及量藥器乙支

14.12B5 Atypical Agents: Benzisoxazole

32567 **C / Unsafe**

RISPERDAL CONSTAR 25MG SUSPENSION FOR I.M. INJECTION 維思通(R)肌肉注射用懸液劑25毫克

Risperidone inj 25mg vial

Dosage: 1常備品 32567

Adult
·Schizophrenia: IM, initial 25 mg every 2 wks; MD increase to 37.5 mg or 50 mg at intervals of at least 4 wks. Max. 50 mg every 2 wks.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

·Use titrated oral dose prior to initiating long-acting IM injection
·Initial, PO, 0.5 mg bid for 1 wk, then may be increased to 1 mg bid or 2 mg qd in the 2nd wk; if 2 mg is well tolerated, IM, 25 mg every 2 wks.

Dosing adjustments in renal impairment:

·Use titrated oral dose prior to initiating long-acting IM injection
·Initial, PO, 0.5 mg bid for 1 wk, then may be increased to 1 mg bid or 2 mg qd in the 2nd wk; if 2 mg is well tolerated, IM, 25 mg every 2 wks.

P: Tab: 3mg(22979); Soln: 1mg/mL, 30mL/B(28553); Inj: 25mg Vial(32567), 37.5mg Vial(32572)

ADR:

COMMON
Rash, Hyperprolactinemia, Weight increased, Constipation, Diarrhea, Excessive salivation, Increased appetite, Indigestion, Nausea, Upper abdominal pain, Vomiting, Xerostomia, Akathisia, Dizziness, Dystonia, Parkinsonism, Sedated, Tremor, Blurred vision, Anxiety, Cough, Nasal congestion, Nasopharyngitis, Pain in throat, Upper respiratory infection, Fatigue, General Pain.
SERIOUS
Prolonged QT interval, Sudden cardiac death, Syncope, Diabetic ketoacidosis, Hypothermia, Pancreatitis, Agranulocytosis, Leukopenia, Neutropenia, Thrombocytopenia, Thrombotic thrombocytopenic purpura, Cerebrovascular accident, Seizure, Tardive dyskinesia, Priapism, Pulmonary embolism, Neuroleptic malignant syndrome.

NOTE: 冰箱冷藏，不可冷凍

·《Contraindications》Hypersensitivity to risperiDONE , paliperidone (an active metabolite of risperiDONE), or any component of the product ;
·Do not administer intravenously. Administer by deep intramuscular gluteal injection, alternating between the two buttocks.
·當病人同時接受精神興奮劑（如methylphenidate ）和 risperidone 應謹慎，因調整其中一種或兩種藥物時可能出現"錐體外徑症狀(EPS)。應考慮逐步停用一種或兩種治療。

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『粉紅』蓋透明玻璃小瓶，蓋上有FLIP及OFF字樣，附一支預先充填好2mL賦形劑溶液的針筒 ，2支HypointTM20G 2"TW針，1支肌肉注射用的Needle-Pro針

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023857

14.12B5 Atypical Agents: Benzisoxazole

32573 **ɔt be ruled out / Infant risk can**

Invega Trinza Prolonged-Release Suspension for Injection 善妥達持續性藥效肌肉注射懸浮劑

Paliperidone palmitate 819mg/2.625mL (= Paliperidone 525mg) syringe

Dosage: 1常備品 32573

Adult (Doses based on paliperidone palmitate)
·Schizophrenia: IM, initial after 4 doses of monthly injections with Invega Sustenna (last 2 doses of same strength)
give Invega Trinza 273 mg IM if previous monthly dose was 78 mg IM; 410 mg IM if previous monthly dose was 117 mg IM; 546 mg IM if previous monthly dose was 156 mg IM; 819 mg IM if previous monthly dose was 234 mg IM].

·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild to moderate: No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 50-80mL/min: 156mg on day 1, followed by 117mg 1 week later; MD 78mg every month; may switch to Invega Trinza 3-month extended-release injection after stabilized on 1-month formulation formulation.
Clcr <50mL/min: Use is not recommended

P: Tab: 3mg(27545), 6mg(27541, 急用藥), 9mg(27549); Inj: 819mg/2.625mL syringe(32573), 234mg/1.5mL syringe(37794), 156mg/1mL syringe(37979)

ADR:

COMMON
Injection site reaction, Hyperprolactinemia, Weight gain, Akathisia, Dizziness, Extrapyramidal disease, Headache, Parkinsonism, Somnolence, Agitation.
SERIOUS
Orthostatic hypotension, Prolonged QT interval, Syncope, Agranulocytosis, Leukopenia, Neutropenia, Anaphylaxis(Rare), Seizure, Tardive dyskinesia, Tonic-clonic seizure, Priapism, At risk for imbalanced body temperature, Neuroleptic malignant syndrome.

NOTE: 室溫儲存

·《Contraindications》Known hypersensitivity to paliperidone, risperidone, or to any product component；
·此藥未被核准用於治療失智症相關精神病人。
·切勿與任何其他產品或溶劑混合使用。
·授乳婦女使用本藥，應監視嬰兒是否發生嗜睡、生長遲緩、顫動及錐體外症狀(顫抖及肌肉運動異常)，如有徵兆應立即就醫。
·此藥可能會因促使血清泌乳激素濃度升高而導致育齡女性生育力降低，此影響是可逆的。

藥名相似:

外觀相似:

外觀描述: 2.625 mL乳白色注射液針筒 ，含2支安全針頭

14.12B5 Atypical Agents: Benzisoxazole

32574 ɔt be ruled out / Infant risk can

Invega Trinza Prolonged-Release Suspension for Injection 善妥達持續性藥效肌肉注射懸浮劑

Paliperidone palmitate inj 546mg/1.75mL(= Paliperidone 350mg) syringe

Dosage: 1常備品 32574

Adult (Doses based on paliperidone palmitate)
·Schizophrenia: IM, initial after 4 doses of monthly injections with Invega Sustenna (last 2 doses of same strength)
give Invega Trinza 273 mg IM if previous monthly dose was 78 mg IM; 410 mg IM if previous monthly dose was 117 mg IM; 546 mg IM if previous monthly dose was 156 mg IM; 819 mg IM if previous monthly dose was 234 mg IM].

·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild to moderate: No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 50-80mL/min: 156mg on day 1, followed by 117mg 1 week later; MD 78mg every month; may switch to Invega Trinza 3-month extended-release injection after stabilized on 1-month formulation formulation.
Clcr <50mL/min: Use is not recommended

P: Tab: 3mg(27545), 6mg(27541, 急用藥), 9mg(27549); Inj: 819mg/2.625mL syringe(32573), 546mg/1.75mL syringe(32574), 234mg/1.5mL syringe(37794), 156mg/1mL syringe(37979)

ADR:

COMMON
Injection site reaction, Hyperprolactinemia, Weight gain, Akathisia, Dizziness, Extrapyramidal disease, Headache, Parkinsonism, Somnolence, Agitation.
SERIOUS
Orthostatic hypotension, Prolonged QT interval, Syncope, Agranulocytosis, Leukopenia, Neutropenia, Anaphylaxis(Rare), Seizure, Tardive dyskinesia, Tonic-clonic seizure, Priapism, At risk for imbalanced body temperature, Neuroleptic malignant syndrome.

NOTE: 室溫儲存

·《Contraindications》Known hypersensitivity to paliperidone, risperidone, or to any product component；
·此藥未被核准用於治療失智症相關精神病人。
·切勿與任何其他產品或溶劑混合使用。
·授乳婦女使用本藥，應監視嬰兒是否發生嗜睡、生長遲緩、顫動及錐體外症狀(顫抖及肌肉運動異常)，如有徵兆應立即就醫。
·此藥可能會因促使血清泌乳激素濃度升高而導致育齡女性生育力降低，此影響是可逆的。

藥名相似:

外觀相似:

外觀描述: 1.75 mL乳白色注射液針筒 ，含2支安全針頭

14.12B5 Atypical Agents: Benzisoxazole

37794 C / Caution

INVEGA SUSTENNA* PROLONGED RELEASE SUSPENSION FOR INTRAMUSCULAR INJECTION 100MG/ML 善思達持續性藥效肌肉注射懸浮劑１００毫克／毫升

Paliperidone palmitate 234mg/1.5mL (= Paliperidone 150mg) syringe

Dosage: 1常備品 37794

Adult (Doses based on paliperidone palmitate)
·Schizophrenia: IM, initial 234mg on day 1, followed by 156mg 1 week later administered in the deltoid muscle.The second dose may be administered 2 days before or after the weekly timepoint. MD 117mg every month administered in either the deltoid or gluteal muscle, may be given 7 days before or after the monthly timepoint

·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild to moderate: No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 50-80mL/min: Initial 156mg on day 1, followed by 117mg 1 week later; MD 78mg every month
Clcr <50mL/min: Use is not recommended

P: Tab: 3mg(27545), 6mg(27541, 急用藥), 9mg(27549); Inj: 819mg/2.625mL syringe(32573), 546mg/1.75mL syringe(32574, 急用藥), 234mg/1.5mL syringe(37794), 156mg/1mL syringe(37979)

ADR:

COMMON
Injection site reaction, Hyperprolactinemia, Weight gain, Akathisia, Dizziness, Extrapyramidal disease,

Headache, Parkinsonism, Somnolence, Agitation.
SERIOUS
Orthostatic hypotension, Prolonged QT interval, Syncope, Agranulocytosis, Leukopenia, Neutropenia, Anaphylaxis(Rare), Seizure, Tardive dyskinesia, Tonic-clonic seizure, Priapism, At risk for imbalanced body temperature, Neuroleptic malignant syndrome.

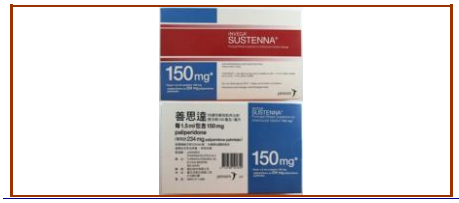
NOTE: 室溫儲存

·《Contraindications》Known hypersensitivity to paliperidone, risperidone, or to any product component ;
· Dose expressed as paliperidone palmitate 39, 78, 117, 156, and 234mg equate to 25, 50, 75, 100, and 150mg of paliperidone base (pharmacologically active fraction).
· Conversion from oral paliperidone to IM paliperidone palmitate should be initiated using the recommended regimen:
oral dose 12mg/day, then then IM dose 234mg/mon; oral dose 6mg/day, then IM 117mg/mon; oral dose 3mg/day, then IM 39-78mg/mon.
· When switching patients from previous long-acting injectable antipsychotics, initiate INVEGA SUSTENNA* therapy in place of the next scheduled injection. It should be continued at monthly intervals. The one-week initiation dosing regimen is not required.
·投予時僅可使用包裝中所提供的針頭。
·尚未核准用於治療失智症相關精神疾病的人。
·切勿與任何其他產品或溶劑混合使用。
·授乳婦女使用本藥，應監視嬰兒是否發生嗜睡、生長遲緩、顫動及錐體外症狀(顫抖及肌肉運動異常)，如有徵兆應立即就醫。
·此藥可能會因促使血清泌乳激素濃度升高而導致育齡女性生育力降低，此影響是可逆的。

藥名相似:

外觀相似:

外觀描述: 1.5 mL乳白色注射液『灰』蓋注射針筒 ，2支安全針頭



14.12B5 Atypical Agents: Benzisoxazole

37979 ɔt be ruled out / Infant risk can

INVEGA SUSTENNA* PROLONGED RELEASE SUSPENSION FOR INTRAMUSCULAR INJECTION 100MG/ML 善思達持續性藥效肌肉注射懸浮劑１００毫克／毫升

Paliperidone palmitate 156mg/1mL (= Paliperidone 100mg) syringe

Dosage: 1常備品 37979

Adult (Doses based on paliperidone palmitate)
·Schizophrenia: IM, initial 234mg on day 1, followed by 156mg 1 week later administered in the deltoid muscle.The second dose may be administered 2 days before or after the weekly timepoint. MD 117mg every month administered in either the deltoid or gluteal muscle, may be given 7 days before or after the monthly timepoint

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild to moderate: No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 50-80mL/min: Initial 156mg on day 1, followed by 117mg 1 week later; MD 78mg every month
Clcr <50mL/min: Use is not recommended

P: Tab: 3mg(27545), 6mg(27541, 急用藥), 9mg(27549); Inj: 819mg/2.625mL syringe(32573), 546mg/1.75mL syringe(32574, 急用藥), 234mg/1.5mL syringe(37794), 156mg/1mL syringe(37979)

ADR:

COMMON
Injection site reaction, Hyperprolactinemia, Weight gain, Akathisia, Dizziness, Extrapyramidal disease, Headache, Parkinsonism, Somnolence, Agitation.
SERIOUS
Orthostatic hypotension, Prolonged QT interval, Syncope, Agranulocytosis, Leukopenia, Neutropenia, Anaphylaxis(Rare), Seizure, Tardive dyskinesia, Tonic-clonic seizure, Priapism, At risk for imbalanced body temperature, Neuroleptic malignant syndrome.

NOTE: 室溫儲存

·《Contraindications》Known hypersensitivity to paliperidone, risperidone, or to any product component ;
· Dose expressed as paliperidone palmitate 39, 78, 117, 156, and 234mg equate to 25, 50, 75, 100, and 150mg of paliperidone base (pharmacologically active fraction).
· Conversion from oral paliperidone to IM paliperidone palmitate should be initiated using the recommended regimen:
oral dose 12mg/day, then then IM dose 234mg/mon; oral dose 6mg/day, then IM 117mg/mon; oral dose 3mg/day, then IM 39-78mg/mon.
· When switching patients from previous long-acting injectable antipsychotics, initiate INVEGA SUSTENNA* therapy in place of the next scheduled injection. It should be continued at monthly intervals. The one-week initiation dosing regimen is not required.
·投予時僅可使用包裝中所提供的針頭。
·尚未核准用於治療失智症相關精神疾病的人。
·切勿與任何其他產品或溶劑混合使用。
·授乳婦女使用本藥，應監視嬰兒是否發生嗜睡、生長遲緩、顫動及錐體外症狀(顫抖及肌肉運動異常)，如有徵兆應立即就醫。
·此藥可能會因促使血清泌乳激素濃度升高而導致育齡女性生育力降低，此影響是可逆的。

藥名相似:

外觀相似:

外觀描述: 1 mL乳白色注射液『灰』蓋注射針筒 ，2支安全針頭

14.12B6 Atypical Agents: Dibenzodiazepine

22965 **B / Caution**

CLOZARIL* 100mg tab 可致律錠

Clozapine 100mg tab

Dosage: 1常備品 22965

Adult
·Schizophrenia: PO, initial 12.5 mg qd-bid, if well tolerated, dosage may be increased by 25-50 mg/day over a 2-week period until a dosage of 300-450 mg/day is achieved, Max. 900 mg/day

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 100mg(22965)

ADR:

Agranulocytosis, sedation, salivation, dizziness/vertigo, seizures, ECG changes, tachycardia, orthostatic hypotension, with or without syncope, N/V, headache/tremor

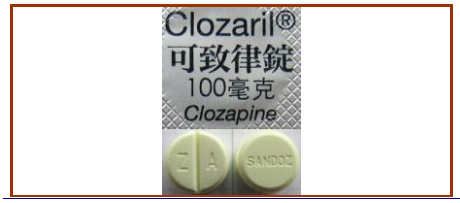
NOTE: 室溫儲存

·《Contraindications》 history of clozapine-induced agranulocytosis or severe granulocytopenia, myeloproliferative disorders, WBC count less than 3500 mm(3), severe central nervous system depression, comatose states, uncontrolled epilepsy ;

藥名相似:

外觀相似:

外觀描述: 黃色圓扁錠，一面中間有一刻痕，有Z及A字樣，另一面則有SANDOZ字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2018542

14.12B7 Atypical Agents: Dibenzothiazepine

22946 **C / Caution**

Apo-Quetiapine Tablets 100mg 安保思樂錠100毫克

Quetiapine 100mg tab

Dosage: 1常備品 22946

Adult
·Schizophrenia : Initial, 25mg bid; increase in increments of 25-50mg 2-3 times/day on the second or third day, if tolerated, to a target dose of 300-400mg in 2-3 div.doses by day 4. Make further adjustments at intervals of at least 2 days in adjustments of 25-50mg twice daily. Usual MD, 300-800mg/day.
·Bipolar disorder,
Depression: Initial 50 mg/day the first day at bedtime, increase to 100 mg/day on day 2, further increasing by 100 mg/day each day to a target of 300 mg/day by day 4. Further increase up to 600 mg/day by day 8 have been evaluated in clinical trials.
Mania: Initial, 50 mg bid on day 1, increase dose in increments of 100 mg/day to 200 mg bid on day 4; may increase to a target dose of 800 mg/day by day 6 at increments <200 mg/day. Usual dose: 400-800 mg/day.

Pediatric
·Manic bipolar I disorder(10-17yrs): PO, 50 mg/day on D1, 100 mg/day on D2, 200 mg/day on D3, 300 mg/day on D4, 400 mg/day on D5 administered 2-3 times daily. Further dosage adjustments in increments of not more than 100 mg/day up to recommended dosage of 400- 600 mg/day. Max. 600 mg/day.
·Schizophrenia(13-17 yrs): PO, 50 mg/day on D1, 100 mg/day on D2, 200 mg/day on D3, 300 mg/day on D4, 400 mg/day on D5 administered 2-3 times daily. Further dosage adjustments in increments of not more than 100 mg/day up to recommended dosage of 400-800 mg/day. Max. 800 mg/day.

Dosing adjustments in hepatic impairment:

Initial 25 mg/day, increase dose by 25-50 mg/day to effective dose.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 50mg ER(27553), 100 mg(22946), 200mg ER(22951), 25mg(27539, 急用藥)

ADR:

COMMON
hypertension, abdominal pain, constipation, dry mouth , dyspepsia , dizziness, somnolence, nasal congestion, tachycardia, postural hypotension, EPS, weight gain
SERIOUS
leukopenia, neuroleptic malignant syndrome, seizures, tardive dyskinesia, suicidal thoughts

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to quetiapine or any component of the product ; Anaphylactic reactions have been reported ;

藥名相似:

外觀相似:

外觀描述: 黃色圓扁錠，有 QUE 100 及 APO 字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025653

14.12B7 Atypical Agents: Dibenzothiazepine

22951 C / Caution

Seroquel* XR TM 200 mg Extended-Release Tablets 思樂康持續性藥效錠200 毫克

Quetiapine 200mg ER Tab

Dosage: 1常備品 22951

Adult
·Schizophrenia: initial, 300mg QD; increase in incremnets of up to 300mg/day at intervals of at least 1 day. Usual MD, 400-800mg/day.
·Bipolar disorder
Depression: initial, 50mg on day 1, then 100mg on day 2, then 200mg on day 3, then 300mg on day 4.
Mania: initial, 300mg on day 1; increase to 600mg on day 2 and adjust dose to 400-800mg QD on day 3, depending on response and tolerance.

Pediatric
·Safety and efficacy of extended-release tablets have not been established.

Dosing adjustments in hepatic impairment:

Initial, 50mg/day; increase dose by 50mg/day to effective dose, based on clinical response and tolerability.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 100mg(22946), 25mg(27539, 急用藥), 200mg ER(22951), 50mg ER(27553)

ADR:

COMMON
abdominal pain, hypertension, constipation, dry mouth , dyspepsia , dizziness, somnolence, nasal congestion , tachycardia, postural hypotension, weight gain, EPS
SERIOUS
leukopenia, neuroleptic malignant syndrome, seizures, tardive dyskinesia, succidal thoughts

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to quetiapine or any component of the product ; Anaphylactic reactions have been reported ;
·Administer without food or with a light meal (<=300 calories), preferably in the evening.
·Patients with divided doses of immediate release Seroquel* may be switched to Seroquel* XR at the equivalent total daily dose taken once daily. Individual dosage adjustments may be necessary.

藥名相似:

外觀相似:

外觀描述: 淺黃色長橢圓錠，一面有XR200字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024887

14.12B7 Atypical Agents: Dibenzothiazepine

22952 UK / Unknown(有

Etumine Tablets 40mg (Clotiapine) 意妥明錠

Clotiapine 40mg tab

Dosage: 1常備品 22952

Adult
·Psychotic disorders: Initial, PO, 120-200 mg/day div. into 2-3 doses, Max. 360mg/day. Maintenance, 20-160 mg/day div. into 2-3 doses.
·Major affective and anxiety disorders : PO, 20-120 mg/day div. into 2-3 doses.
·Withdrawal syndromes : Initial, PO, 120-160 mg/day div. into 2-3 doses, Max.240 mg/day. Long-term treatment : 100 mg/day div. into 2-3 doses, gradually decreasing to 10 mg/day.
·Sleep disorders : PO, 20-40 mg hs.

Pediatric
·Should not be used in individuals below 16 years of age.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 40mg(22952)

ADR:

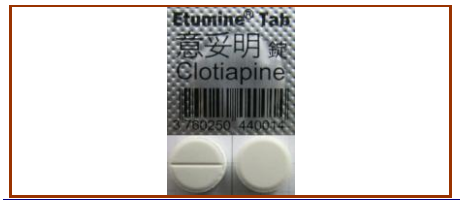
COMMON
atopic dermatitis, seborrheic dermatitis, dysphagia, elevated white cell counts, abnormal liver function, elevated CPK level, hyperthermia, anxiety, akathisia, tardive dyskinesia
SERIOUS
rhabdomyolysis, neuroleptic malignant syndrome, extrapyramidal sign, changes in mental status, diaphoresis and supraventricular tachycardia, dysphoric mood, obsessive-compulsive disorder

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面中間有一刻痕)



14.12B7 Atypical Agents: Dibenzothiazepine

27539 C / Caution

SEROQUEL* TABLETS 25MG 思樂康膜衣錠 2 5 公絲

急用Quetiapine 25mg tab

Dosage: 2急用藥 27539

Adult
·Schizophrenia: PO, initial 25mg bid; increase in increments of 25-50mg 2-3 times/day on the second and third day, if tolerated, to a target dose of 300-400mg/day in 2-3 div. doses by day 4. Make further adjustments at intervals of at least 2 days in adjustments of 25-50mg twice daily. Usual MD, 300-

800mg/day
·Bipolar disorder: PO,
Depression: Initial 50mg/day the first day, increase to 100mg/day on day 2, further increasing by 100mg/day each day to a target of 300mg/day by day 4. Further increase up to 600mg/day by day 8 have been evaluated in clinical trials.
Mania: Initial 50mg bid on day 1, increase dose in increments of 100mg/day to 200mg bid on day 4; may increase to a target dose of 800mg/day by day 6 at increments <200mg/day. Usual dose: 400-800mg/day

Pediatric
·Manic bipolar I disorder(10-17yrs): PO, 50 mg/day on D1, 100 mg/day on D2, 200 mg/day on D3, 300 mg/day on D4, 400 mg/day on D5 administered 2-3 times daily. Further dosage adjustments in increments of not more than 100 mg/day up to recommended dosage of 400- 600 mg/day. Max. 600 mg/day.
·Schizophrenia(13-17 yrs): PO, 50 mg/day on D1, 100 mg/day on D2, 200 mg/day on D3, 300 mg/day on D4, 400 mg/day on D5 administered 2-3 times daily. Further dosage adjustments in increments of not more than 100 mg/day up to recommended dosage of 400-800 mg/day. Max. 800 mg/day.

Dosing adjustments in hepatic impairment:

Initial 25mg/day, increase dose by 25-50mg/day to effective dose

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 100mg(22946), 25mg(27539, 急用藥), 200mg ER(22951), 50mg ER(27553)

ADR:

COMMON
Abdominal pain, constipation, increased appetite, indigestion, vomiting, xerostomia, increased liver enzymes, backache, asthenia, dizziness, extrapyramidal disease, headache, insomnia, lethargy, sedated, somnolence, tremor, agitation, nasal congestion, pharyngitis, fatigue, pain, orthostatic hypotension, tachycardia, postural hypotension, serum cholesterol/triglycerides raised, weight gain
SERIOUS
Sudden cardiac death, syncope, agranulocytosis, leukopenia, neutropenia, anaphylaxis, neuroleptic malignant syndrome, seizure, tardive dyskinesia, suicidal thoughts, priapism, death

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to quetiapine or any component of the product ; Anaphylactic reactions have been reported ;

藥名相似:

外觀相似:

外觀描述: 桃紅色圓形錠，有SEROQUEL 25字樣

14.12B7 Atypical Agents: Dibenzothiazepine

27553 **C / Caution**

Seroquel XR* TM 50 mg Extended-Release Tablets 思樂康持續性藥效錠 50 毫克

Quetiapine 50mg ER tab

Dosage: 1常備品 27553

Adult
·Schizophrenia: initial, 300mg QD; increase in incremnets of up to 300mg/day at intervals of at least 1 day. Usual MD, 400-800mg/day.
·Bipolar disorder
Depression: initial, 50mg on day 1, then 100mg on day 2, then 200mg on day 3, then 300mg on day 4.
Mania: initial, 300mg on day 1; increase to 600mg on day 2 and adjust dose to 400-800mg QD on day 3, depending on response and tolerance.

Pediatric
·Safety and efficacy of extended-release tablets have not been established.

Dosing adjustments in hepatic impairment:

Initial 50mg/day, increase dose by 50mg/day to effective dose

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 100mg(22946), 25mg(27539, 急用藥), 200mg ER(22951), 50mg ER(27553)

ADR:

COMMON
hypertension , orthostatic hypotension , tachycardia , serum cholesterol raised , serum triglycerides raised, weight gain , abdominal pain, constipation, Increased appetite, Indigestion, vomiting, xerostomia , Increased liver enzymes , backache , asthenia, dizziness, extrapyramidal disease,headache, Insomnia, lethargy, somnolence, tremor , Agitation , nasal congestion, pharyngitis , fatigue, pain
SERIOUS
prolonged QT interval, sudden cardiac death, syncope , diabetic ketoacidosis, pancreatitis, agranulocytosis, leukopenia, neutropenia , anaphylaxis, seizure, tardive dyskinesia , suicidal thoughts, priapism, neuroleptic malignant syndrome

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to quetiapine or any component of the product ; Anaphylactic reactions have been reported ;

藥名相似:

外觀相似:

外觀描述: 淡紅色長橢圓錠，一面有XR50字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025001

14.12B8 Atypical Agents: Dibenzothiepine

22972 UK / Caution

ZONIN* S.C. TABLETS 50MG 柔靈平糖衣錠 50 毫克

Zotepine 50mg S.C. tab

Dosage: 1常備品 22972

Adult
·Schizophrenia: 25-50 mg tid, Max. 450 mg/day.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

NDA

P: Tab: 50 mg(22972)

ADR:

Tachycardia, hypotension, depression, anxiety, agitation, neuroleptic malignant syndrome, weight gain/weight loss, urinary retention, sexual dysfunction, elevated liver enzymes, cholestasis, leukopenia, palpitations, leukocytosis, anemia, thrombocytopenia,

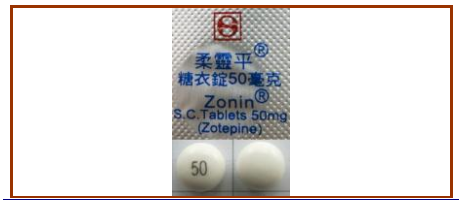
NOTE: 室溫儲存

Contraindications: acute drug intoxication, impaired hematopoiesis, children, pregnancy, breastfeeding

藥名相似:

外觀相似: Gaster* D 20mg (25028), Harnalidge* D Tab (

外觀描述: 白色圓形糖衣錠，有50字樣)



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049345

14.12B9 Atypical Agents: Thienobenzodiazepine

22953 C / Caution

ZYPREXA* ZYDIS 5MG ORODISPERSIBLE TABLETS 津普速 口溶錠 5公絲

Olanzapine micronized 5mg OD tab

Dosage: 1常備品 22953

Adult
·Schizophrenia: PO, initial 5-10mg qd, adjust by 5mg/day at intervals of not less than 7 days, Max. 20mg/day
·Bipolar I mania(monotherapy): PO, initial 10-15mg qd, increase by 5 mg/day at intervals of not less than 24hrs, Max. 20mg/day
·Bipolar I mania(in combination with lithium or valproate): PO, initial 10mg qd, Max. 20mg/day

Pediatric
·Safety and efficacy have not been established in patients less than 13 years old.
·Schizophrenia (13-17 yrs) : PO, initial 2.5-5 mg, with a target dose of 10 mg/day; dose adjustments should be made in 2.5 mg or 5 mg increments/decrements; Max. 20 mg/day.
·Bipolar I disorder, acute mixed or manic episodes(13-17 yrs) : PO, initial 2.5 or 5 mg/day, with target dose of 10 mg/day; dose adjustments recommended in increments/decrements of 2.5 or 5 mg; Max. 20 mg/day.
·Depressed bipolar I disorder, In combination with fluoxetine(10-17 yrs) : PO, initial 2.5 mg with fluoxetine PO 20 qd evening; may adjust dose for efficacy and tolerability.

Dosing adjustments in hepatic impairment:

A lower initial dose of 5 mg daily should be considered

Dosing adjustments in renal impairment:

Renal impairment: no dosage adjustment required
Dialysis: not removed by dialysis

P: OD Tab: 5mg(22953); Inj: 10mg Vial(32570); Tab: 10mg (22942)

ADR:

Common
Orthostatic hypotension, peripheral edema, hypercholesterolemia, hyperglycemia, hyperprolactinemia, increased appetite, serum triglycerides raised, weight increased, constipation, xerostomia, akathisia, asthenia, dizziness, somnolence, tremor, personality disorder
Serious
Sudden cardiac death, diabetes mellitus, diabetic coma with ketoacidosis, diabetic ketoacidosis, hyperglycemic hyperosmolar state, acute hemorrhagic pancreatitis, leukopenia, venous thromboembolism, hypersensitivity reaction, cerebrovascular disease, dystonia, seizure, status epilepticus, suicidal intent, pulmonary embolism

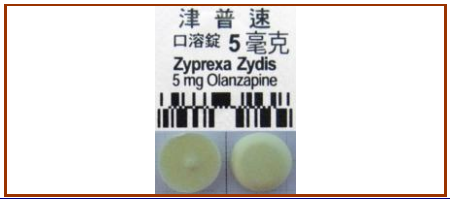
NOTE: 室溫儲存

·《Contraindications》Specific contraindications have not been determined ;
含阿斯巴甜，苯酮尿症者不宜使用。

藥名相似:

外觀相似:

外觀描述: 黃色圓形錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023913

14.12B9 Atypical Agents: Thienobenzodiazepine

32570 C / Caution

ZYPREXA* 10MG POWDER FOR SOLUTION FOR INJECTION 金普薩 凍晶注射劑10公絲

Olanzapine inj 10mg vial

Dosage: 1常備品 32570

Adult
·Agitation associated with schizophrenia or bipolar I mania: IM, initial 10 mg, a lower dose of 5 mg or 7.5 mg may be given upon clinical status; followed by 5-10 mg as required after 2 hours; Max. 20 mg/day (including olanzapine given by mouth)

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

A lower initial dose of 5 mg daily should be considered

Dosing adjustments in renal impairment:

A lower initial dose of 5 mg daily should be considered

P: Inj: 10mg Vial(32570); OD Tab: 5mg(22953); Tab: 10mg (22942)

ADR:

COMMON
Chest pain, orthostatic hypotension, peripheral edema, tachyarrhythmia, increased appetite, weight gain, constipation, dyspepsia, xerostomia, ecchymosis, arthralgia, back pain, pain in limb, abnormal gait, akathisia, asthenia, dizziness, extrapyramidal disease, parkinsonian, somnolence, tremor, agitation, personality disorder, cough, rhinitis, accidental injury, fever
SERIOUS
Water intoxication syndrome (rare), tardive dyskinesia (rare)

NOTE: 室溫儲存

·《Contraindications》Specific contraindications have not been determined ;
·Not more than 3 injections should be given in any 24-hr period and the maximum daily dose should not exceed 20mg(including olanzapine given by mouth).
·Injections may be given for up to a maximum of 3 days but transfer to oral therapy as soon as possible.

藥名相似:

外觀相似:

外觀描述: 黃色乾粉、『紫』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024083

14.12Ba Atypical Agents: Benzamide

22980 **UK / Unsafe**

SOLIAN* TABLET 200MG 首利安錠200毫克

Amisulpride 200mg tab

Dosage: 1常備品 22980

Adult
·Schizophrenia, acute exacerbations with positive symptoms: PO, 400-800mg/day in 2 divided doses, Max. 1200mg/day
·Chronic schizophrenia with predominant negative symptoms: PO, 50-300mg/day

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 30-60mL/min: One-half of normal dose
Clcr 10-30mL/min: One-third of normal dose

P: Tab: 200mg(22980)

ADR:

Sedation or somnolence(high doses), early dyskinesia, extrapyramidal syndrome, tardive dyskinesia, hyperprolactinemia, weight gain, QT prolongation (rare)

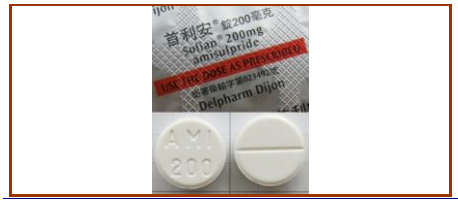
NOTE: 室溫儲存

·《Contraindications》Known hypersensitivity to amisulpride ;
·Doses up to 300 mg may be given once daily, while higher doses should be divided into two doses per day

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠,一面有AMI 200字樣,另一面中央有刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023492

14.12Bb Atypical Agents: Indole Derivatives

22981 **C / Infant risk can**

GEODON* CAPSULES 40MG 哲思膠囊4 0毫克

Ziprasidone 40mg cap

Dosage: 1常備品 22981

Adult:
·Manic bipolar I disorder: PO, initial 40mg bid; MD 40-80 mg bid with meal
·Schizophrenia: PO, initial 20mg bid, increase dose every 2 days to Max. 80 mg bid with meal

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

No dosage adjustment is recommended

Dosing adjustments in renal impairment:

1. No dosage adjustment is recommended
2. Ziprasidone is not moved by hemodialysis

P: Cap: 40mg(22981)

ADR:

COMMOM
·Dermatologic: Rash (up to 5%)
·Endocrine metabolic: Abnormal weight gain (0.4% to 10%)
·Gastrointestinal: Constipation (9%), Diarrhea (5%), Indigestion (8%), Nausea (10%), Vomiting (1% to

5%), Xerostomia (4% to 5%)
·Neurologic: Akathisia (8% to 10%), Anxiety (5%), Asthenia (5% to 6%), Behavior showing reduced motor activity (bipolar mania, less than 10%; schizophrenia, less than 5%), Dizziness (bipolar mania, 16%; schizophrenia, 8%), Extrapyramidal disease (bipolar mania, 31%; schizophrenia, 14%), Headache (18%), Increased muscle tone (bipolar mania, less than 10%; schizophrenia, less than 5%), Somnolence (bipolar mania, 31%; schizophrenia, 14%), Spasmodic movement (bipolar mania, less than 10%; schizophrenia, less than 5%), Tremor (bipolar mania, less than 10%; schizophrenia, less than 5%)
·Ophthalmic: Abnormal vision (3% to 6%)
·Respiratory: Respiratory tract infection (8%)
SERIOUS
·Cardiovascular: Prolonged QT interval (0.06%), Syncope (0.6%), Torsades de pointes (rare)
·Dermatologic: Disorder of skin, cutaneous reaction
·Endocrine metabolic: Diabetes mellitus, Hyperglycemia, Hyperprolactinemia
·Gastrointestinal: Dysphagia (0.1% to 2%)
·Hematologic: Bone marrow depression
·Immunologic: Drug reaction with eosinophilia and systemic symptoms
·Neurologic: Neuroleptic malignant syndrome (rare), Seizure (0.4%), Tardive dyskinesia (rare)
·Reproductive: Priapism (rare)

NOTE: 室溫儲存

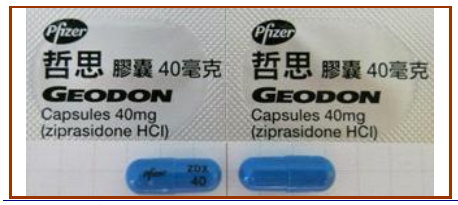
·《Contraindications》Concomitant administration with arsenic trioxide, chlorpromazine, dofetilide, dolasetron mesylate, droperidol, gatifloxacin, halofantrine, levomethadyl acetate, mefloquine, mesoridazine, moxifloxacin, pentamidine, pimozide, probucol, quinidine, sotalol, sparfloxacin, tacrolimus, thioridazine, class IA and III antiarrhythmics, and other drugs that cause QT prolongation; possible additive QT prolongation effect ; Heart failure, uncompensated ; Hypersensitivity to ziprasidone ; Myocardial infarction, acute and recent ; QT prolongation, including congenital long QT syndrome, known history of ;
·Grapefruit juice may increase ziprasidone serum conc.
·仿單內容變更，摘述如下：(版本CDS 20120725-2)
1.中文品名重量單位標示由「公絲」改為「毫克」。
2.更新藥動學特性的相關資訊。
·仿單內容變更，摘述如下：(版本20130227-2)
1.特殊警語及使用注意事項：增列靜脈血栓栓塞。
2.藥物交互作用：加註本藥併服CYP-3A4與P-gp的誘發劑，如carbamazepine、rifampin，可能造成本藥的血中濃度降低。
3.懷孕期之使用：加註只有在對母親的潛在效益超過對嬰兒的危險時，才在懷孕期間使用本藥。
4.上市後的不良反應：增列靜脈血栓栓塞。

仿單內容變更，摘述如下：(版本20180512-3)
·可能會嗜睡、姿態性低血壓和運動以及感覺不穩定，對於伴有可能加劇這些影響的疾病、狀態或藥物的病人，開始抗精神病治療時應完成跌倒風險評估，而對於長期接受抗精神病療法的病人應反覆進行跌倒風險評估。
·有生育力的婦女接受治療時，最好採取適當的避孕措施。

藥名相似:

外觀相似:

外觀描述: 藍色膠囊,有Pfizer及ZDX 40字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023471

14.12Bb Atypical Agents: Indole Derivatives

22983 ɔt be ruled out / Infant risk can

Latuda (lurasidone hydrochloride) 40 mg tablet 樂途達錠40毫克

Lurasidone 40mg tab 防跌

Dosage: 1常備品 22983

ADULT
·Bipolar disorder, depressed phase, in combination with lithium or valproate; adjunct: PO, initial, 20mg QD with food (at least 350 calories). Dose titration not required; Max. 120mg QD
·Schizophrenia: PO, initial, 40mg QD with food (at least 350 Calories). Dose titration not required; Max. 160mg QD

PEDIATRIC
·Bipolar disorder, depressed phase, monotherapy (10-17yrs): PO, initial, 20mg QD with food (at least 350 calories) and may increase after 1 week based on response although dose titration is not required; Max. 80mg/day
·Schizophrenia (13-17 yrs): PO, initial, 40mg with food (at least 350 Calories). Dose titration not required; Max. 80mg QD

Dosing adjustments in hepatic impairment:

·Moderate (Child-Pugh score 7-9): Initial, 20mg/day; Max. 80 mg/day
·Severe (Child-Pugh score 10-15): Initial, 20mg/day; Max. 40 mg/day

Dosing adjustments in renal impairment:

·Moderate to severe (CrCl < 50 mL/min): Initial, 20 mg/day; MAX, 80 mg/day

P: P Tab: 40mg(22983)

ADR:

COMMON
Dyslipidemia, increased glucose level, weight increased, diarrhea, nausea, vomiting, akathisia, extrapyramidal disease, parkinsonism, somnolence, anxiety
SERIOUS
Orthostatic hypotension, syncope, agranulocytosis, cerebrovascular accident, seizure, tardive dyskinesia, transient ischemic attack, suicidal thoughts, serum creatinine raised, neuroleptic malignant syndrome

NOTE: 室溫儲存

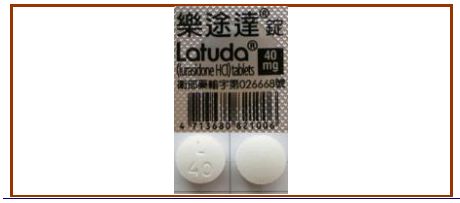
·《Contraindications》Coadministration with strong CYP3A4 inducers (eg, rifampin, avasimibe, St. John's wort, phenytoin, carbamazepine) ; Coadministration with strong CYP3A4 inhibitors (eg,

ketoconazole, clarithromycin, ritonavir, voriconazole, mibefradil) ;
Hypersensitivity to lurasidone hydrochloride or any components in the formulation; angioedema has been reported ;
·Impaired core body temperature regulation may occur; caution with strenuous exercise, heat exposure, dehydration, and concomitant medication possessing anticholinergic effects.
·Administration with food (≧350 calories) increased Cmax and AUC of lurasidone ~3 times and 2 times, respectively, compared to administration under fasting conditions.
·Lurasidone serum concentrations may be increased when taken with grapefruit or grapefruit juice.

藥名相似:

外觀相似:

外觀描述: 白色圓錠，一面有"L40"字樣



14.12Bc Atypical Agents: Quinolinone

22950 C / Caution

ABILIFY* TABLETS 10MG OTSUKA 大塚安立復錠１０毫克

Aripiprazole 10mg tab

Dosage: 1常備品 22950

Adult
·Schizophrenia: PO, initial 10-15mg qd, dosage titration should not be more frequent than every 2 wks; Max. 30mg/day
·Acute manic and mixed episodes associated with bipolar disorder: PO, 15mg qd as monotherapy or 10-15mg qd as adjunctive therapy with lithium or valproate, may increase to 30mg qd if clinically indicated
·Major depressive disorder: PO, 2-5mg qd (range 2-15mg/day), dose may be adjusted by 5mg/day at intervals of at least 1 week

Pediatric
·Schizophrenia(≧13yrs): PO, initial 2mg qd for 2 days, followed by 5mg qd for 2 days and then increase to 10mg qd; Max. 30mg/day
·Acute manic and mixed episodes associated with bipolar disorder(≧10yrs): PO, initial 2mg qd for 2 days, followed by 5mg qd for 2 days and then increase to 10mg qd as monotherapy or as adjunctive therapy with lithium or valproate; Max. 30mg/day
·Irritability associated with autistic disorder(≧6yrs): PO, 2mg qd for 7 days, then increase to 5mg qd; Max. 15mg/day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 10mg (22950), 5mg (27551)

ADR:

COMMON
Weight increased, constipation, nausea, vomiting, akathisia, dizziness, extrapyramidal disease, headache, insomnia, sedated, somnolence, tremor, blurred vision, anxiety, restlessness, fatigue
SERIOUS
Prolonged QT interval, diabetic ketoacidosis, agranulocytosis, leukopenia, neutropenia, immune hypersensitivity reaction (rare), cerebrovascular accident, seizure, tardive dyskinesia, transient ischemic attack, at risk for suicide, suicidal behavior, neuroleptic malignant syndrome (rare)

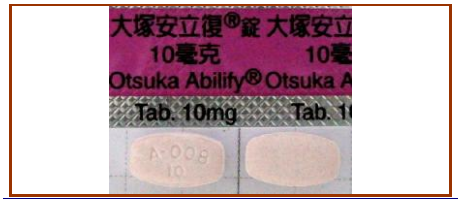
NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to aripiprazole
·Dose should be doubled if concurrent use CYP3A4 inducers; dose should be halved if concurrent use CYP3A4 or CYP2D6 inhibitors(eg, fluoxetine, paroxetine)

藥名相似:

外觀相似:

外觀描述: 粉橘色橢圓錠，有A-008及10字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024047

14.12Bc Atypical Agents: Quinolinone

27551 C / Caution

OTSUKA ABILIFY* TABLETS 5MG 大塚安立復錠5毫克

Aripiprazole 5mg tab

Dosage: 1常備品 27551

Adult
·Schizophrenia: PO, initial 10-15mg qd, dosage titration should not be more frequent than every 2 wks; Max. 30mg/day
·Acute manic and mixed episodes associated with bipolar disorder: PO, 15mg qd as monotherapy or 10-15mg qd as adjunctive therapy with lithium or valproate, may increase to 30mg qd if clinically indicated
·Major depressive disorder: PO, 2-5mg qd (range 2-15mg/day), dose may be adjusted by 5mg/day at intervals of at least 1 week

Pediatric
·Schizophrenia(≧13yrs): PO, initial 2mg qd for 2 days, followed by 5mg qd for 2 days and then increase to 10mg qd; Max. 30mg/day
·Acute manic and mixed episodes associated with bipolar disorder(≧10yrs): PO, initial 2mg qd for 2 days, followed by 5mg qd for 2 days and then increase to 10mg qd as monotherapy or as adjunctive therapy with lithium or valproate; Max. 30mg/day
·Irritability associated with autistic disorder(≧6yrs): PO, 2mg qd for 7 days, then increase to 5mg qd; Max. 15mg/day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 10mg (22950), 5mg (27551)

ADR:

COMMON
Weight increased, constipation, nausea, vomiting, akathisia, dizziness, extrapyramidal disease, headache, insomnia, sedated, somnolence, tremor, blurred vision, anxiety, restlessness, fatigue
SERIOUS
Prolonged QT interval, diabetic ketoacidosis, agranulocytosis, leukopenia, neutropenia, immune hypersensitivity reaction (rare), cerebrovascular accident, seizure, tardive dyskinesia, transient ischemic attack, at risk for suicide, suicidal behavior, neuroleptic malignant syndrome (rare)

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to aripiprazole；
·Dose should be doubled if concurrent use CYP3A4 inducers; dose should be halved if concurrent use CYP3A4 or CYP2D6 inhibitors(eg, fluoxetine, paroxetine)

藥名相似:

外觀相似:

外觀描述: 藍色橢圓錠，有A-007及5字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024046

14.12Bc Atypical Agents: Quinolinone

32576 **C / Caution**

ABILIFY MAINTENA* for extended-release injectable suspension, 300mg/Pre-filled dual chamber syringe 安立復美達持續性藥效肌肉注射用懸浮劑300毫克/預充填注射筒

Aripiprazole prolonged release suspension 300mg/1.5mL syringe

Dosage: 1常備品 32576

Adult
·Schizophrenia : Initial and MD : 400 mg IM once monthly (no sooner than 26 days after the previous injection). If there are ADRs, reduce to 300 mg once monthly.

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 10mg (22950), 5mg (27551) Inj: 300mg/1.5mL syringe(32576), 400mg/2mL syringe(32577)

ADR:

COMMON
weight increased, constipation, nausea, vomiting: akathisia, dizziness, extrapyramidal sign, headache, insomnia, sedated, somnolence, tremor , blurred vision, anxiety, restlessness, fatigue
SERIOUS
cardiorespiratory arrest, cardiorespiratory failure, myocardial infarction, prolonged QT interval, diabetic ketoacidosis, pancreatitis, agranulocytosis, leukopenia, neutropenia, rhabdomyolysis,cerebrovascular accident, seizure, tardive dyskinesia, transient ischemic attack, at risk for suicide, suicidal behavior, angioedema, increased body temperature, neuroleptic malignant syndrome.

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to aripiprazole
1.For patients who have never taken aripiprazole, tolerability with oral aripiprazole must occur prior to initiating treatment with Abilify Maintena.
2.After the first injection, treatment with 10 mg to 20 mg oral aripiprazole per day should be continued for 14 consecutive days to maintain therapeutic aripiprazole concentrations during initiation of therapy.
3.Dose adjustment for cytochrome P450 considerations
·Patients taking 400 mg of Abilify Maintena:
Strong CYP2D6 or strong CYP3A4 inhibitors : adjust to 300mg
Strong CYP2D6 and strong CYP3A4 inhibitors : adjust to 200mg
CYP3A4 inducers : Avoid use
· Patients taking 300 mg of Abilify Maintena
Strong CYP2D6 or strong CYP3A4 inhibitors : adjust to 200mg
Strong CYP2D6 and strong CYP3A4 inhibitors : adjust to 160mg
CYP3A4 inducers : Avoid use

藥名相似:

外觀相似:

外觀描述: 300 毫克懸浮注射液，預充填注射筒，注射筒上印有"300mg Abilify Maintena"字樣

14.12Bc Atypical Agents: Quinolinone

32577 **C / Infant risk can**

ABILIFY MAINTENA* for extended-release injectable suspension, 400mg/Pre-filled dual chamber syringe 安

立復美達持續性藥效肌肉注射用懸浮劑400毫克/預充填注射筒

Aripiprazole prolonged release suspension 400mg/2mL syringe

Dosage: 1常備品 32577

·Schizophrenia : Initial and MD : 400 mg IM once monthly (no sooner than 26 days after the previous injection). If there are ADRs, reduce to 300 mg once monthly.

Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 10mg (22950), 5mg (27551) Inj: 300mg/1.5mL syringe(32576), 400mg/2mL syringe(32577)

ADR:

COMMON
weight increased, constipation, nausea, vomiting: akathisia, dizziness, extrapyramidal sign, headache, insomnia, sedated, somnolence, tremor , blurred vision, anxiety, restlessness, fatigue
SERIOUS
cardiorespiratory arrest, cardiorespiratory failure, myocardial infarction, prolonged QT interval, diabetic ketoacidosis, pancreatitis, agranulocytosis, leukopenia, neutropenia, rhabdomyolysis,cerebrovascular accident, seizure, tardive dyskinesia, transient ischemic attack, at risk for suicide, suicidal behavior, angioedema, increased body temperature, neuroleptic malignant syndrome.

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to aripiprazole
1.For patients who have never taken aripiprazole, tolerability with oral aripiprazole must occur prior to initiating treatment with Abilify Maintena.
2.After the first injection, treatment with 10 mg to 20 mg oral aripiprazole per day should be continued for 14 consecutive days to maintain therapeutic aripiprazole concentrations during initiation of therapy.
3.Dose adjustment for cytochrome P450 considerations
·Patients taking 400 mg of Abilify Maintena:
Strong CYP2D6 or strong CYP3A4 inhibitors : adjust to 300mg
Strong CYP2D6 and strong CYP3A4 inhibitors : adjust to 200mg
CYP3A4 inducers : Avoid use
· Patients taking 300 mg of Abilify Maintena
Strong CYP2D6 or strong CYP3A4 inhibitors : adjust to 200mg
Strong CYP2D6 and strong CYP3A4 inhibitors : adjust to 160mg
CYP3A4 inducers : Avoid use

藥名相似:

外觀相似:

外觀描述: 400 毫克懸浮注射液，預充填注射筒，注射筒上印有"400mg Abilify Maintena"字樣

14.12C Antimanic Agents

22963 **D / Unsafe**

LIGILIN* CAPSULES 鋰膏寧膠囊

Lithium carbonate (Li2CO3) 300mg cap

Dosage: 1常備品 22963

Adult
·Mania(acute): PO, 1800 mg/day in 2-3 div.doses; desired serum lithium level between 1-1.5 mEq/L
·Mania(maintenance): PO, 900-1200 mg/day in 2-3 div.doses; desired serum lithium levels between 0.6-1.2 mEq/L

Pediatric
·Safety and efficacy have not been established in patients less than 12 years old.
·Bipolar disorder, maintenance(≧12yrs): PO, 300 mg t.i.d.-q.i.d.
·Bipolar disorder, acute mania (≧12yrs): PO, 600 mg t.i.d.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr> 50 mL/min: no dosage reduction
Clcr 10- 50 mL/min: 50 to 75% of the usual dose
Clcr< 10 mL/min: 25 to 50% of the usual dose

P: Tab: 300mg(22963)

ADR:

COMMON
albuminuria, oliguria, polyuria, glycosuria, ataxia, fine hand tremor, muscle hyperirritability, hyperactive deep tendon reflexes, blurred vision, transient scotomata,
drowsiness, muscular weakness, diarrhea, vomiting(may be signs of toxicity), dry mouth, mild nausea, polyuria, mild thirst,
EEG changes, EKG changes
SERIOUS
ataxia, giddiness, blurred vision, tinnitus (may be signs of serious toxicity), cardiac arrhythmia, hypotension, sinus node dysfunction with severe bradycardia, coma, epileptiform seizures, large output of dilute urine (may be a sign of serious toxicity), pseudotumor cerebri (increased intracranial pressure and papilledema)

NOTE: 室溫儲存

Contraindications: lactation, significant renal impairment, significant cardiovascular disease, severe debilitation, dehydration, sodium depletion

藥名相似:

外觀相似:

外觀描述: 粉紅色膠囊,有WW及7512字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1009299

14.14B Benzodiazepines

23000 **c / Caution**

BROMAZIN* TABLETS 3MG "Johnson"(BROMAZEPAM) "強生" 牟靜錠 3 毫克（布馬平）

Bromazepam 3mg tab

Dosage: 1常備品 23000

Adult
·Anxiety: PO, 3-18mg/day in div.doses

NDA

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 3mg(23000)

ADR:

COMMON
ataxia, dizziness, drowsiness, sedation, hypotension, impairment of learning

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to bromazepam, other benzodiazepines, or any other ingredient, or components of the container; Myasthenia gravis ; Severe hepatic insufficiency ; Severe respiratory insufficiency ; Sleep apnea syndrome ; Narrow angle glaucoma ;

藥名相似:

外觀相似: 22865 Luminal * Phenobarbital

外觀描述: 粉紅圓扁錠，一面中間有一刻痕，有JCP及3字樣

14.14B Benzodiazepines

23002 **UK /**

ERISPAN-S* TABLETS 0.25MG "生達"癒利舒盼錠 0.25毫克

Fludiazepam 0.25mg tab

Dosage: 1常備品 23002

Adult
·Anxiety: 0.25mg tid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 0.25mg(23002)

ADR:

Depression, transient memory impairment, dizziness, drowsiness, headache, sedation, GI symptoms, nausea, unsteadiness, weakness.

NOTE: 室溫儲存

藥名相似: Tab: 0.25mg(23002)

外觀相似:

外觀描述: 白色圓扁錠，有SCP及017字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046729

14.14B Benzodiazepines

23005 **D / Unknown(有**

LARPAM TABLETS 2MG (LORAZEPAM) "S.D." "世達" 樂眠錠 2 毫克

Lorazepam 2mg tab

Dosage: 1常備品 23005

Adult
·Anxiety: PO, 2-6mg/day div.into 2-3 doses with the largest dose taken at night, Max. 10mg/day
·Insomnia: PO, 2-4mg hs

Pediatric
·Safety and efficacy have not been established in patients less than 12 years old.
·Anxiety(≧12yrs): PO, initial 2-3 mg/day div. into 2-3 doses. maintenance, 2-6 mg/day div. into 2-3 doses; dose may vary from 1-10 mg/day.
·Insomnia, due to anxiety or situational stress(≧12yrs): PO, 2-4 mg hs.

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 0.5mg(23015), 2mg(23005); Inj: 2mg/1mL Amp(32601)

ADR:

COMMON
Depression, transient memory impairment; dizziness, drowsiness, headache, sedation, GI symptoms, nausea, unsteadiness, weakness.

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to benzodiazepines or any component of the product (oral and injection) , polyethylene glycol, propylene glycol, or benzyl alcohol (injection) ; Intraarterial

administration; may produce arteriospasm resulting in gangrene (injection) ; Narrow-angle glaucoma, acute ; Premature infants; injection formulation contains benzyl alcohol ; Respiratory insufficiency, severe; in the absence of resuscitative equipment (injection) ; Sleep apnea syndrome (injection) ;

藥名相似:

外觀相似:

外觀描述: 黃色圓扁錠，一面有S.D字樣，另一面有十字溝痕

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1033929

14.14B Benzodiazepines

23015 **D / Unknown(有**

LOWEN TABLETS 0.5MG (LORAZEPAM) "C.C.P." "中國化學" 樂穩錠 0．5 公絲（樂耐平）

Lorazepam 0.5mg tab

Dosage: 1常備品 23015

Adult
·Anxiety: PO, 2-6mg/day div.into 2-3 doses with the largest dose taken at night, Max. 10mg/day
·Insomnia: PO, 2-4mg hs

Pediatric
·Safety and efficacy have not been established in patients less than 12 years old.
·Anxiety(≧12yrs): PO, initial 2-3 mg/day div. into 2-3 doses. maintenance, 2-6 mg/day div. into 2-3 doses; dose may vary from 1-10 mg/day.
·Insomnia, due to anxiety or situational stress(≧12yrs): PO, 2-4 mg hs.

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 0.5mg(23015), 2mg(23005); Inj: 2mg/1mL Amp(32601)

ADR:

COMMON
Depression, transient memory impairment, dizziness, drowsiness, headache, sedation, GI symptoms, nausea, unsteadiness, weakness.

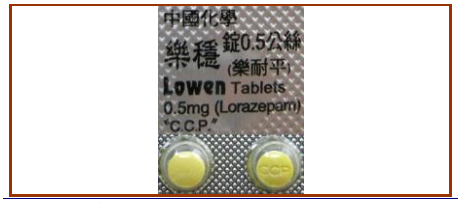
NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to benzodiazepines or any component of the product (oral and injection) , polyethylene glycol, propylene glycol, or benzyl alcohol (injection) ; Intraarterial administration; may produce arteriospasm resulting in gangrene (injection) ; Narrow-angle glaucoma, acute ; Premature infants; injection formulation contains benzyl alcohol ; Respiratory insufficiency, severe; in the absence of resuscitative equipment (injection) ; Sleep apnea syndrome (injection) ;

藥名相似: Oxazepam Tab 15mg(23019)

外觀相似: Donison* 5mg Tab (25602), Tofranil* 25mg t

外觀描述: 黃色圓扁錠，有CCP字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1027849

14.14B Benzodiazepines

23017 **D /**

KINAX TABLETS 0.5MG (ALPRAZOLAM) 景安寧錠0.5毫克（三氮二氮平）

Alprazolam 0.5mg tab

Dosage: 1常備品 23017

Adult
·Anxiety : initial 0.25-0.5mg tid; Max. 4mg/day
·Panic disorder or agoraphobia : initial 0.5mg tid, the dosage being increased as needed, Max.10mg/day

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

0.25mg bid-tid, the dose may be gradually increased as needed and as tolerated.

Dosing adjustments in renal impairment:

NDA

P: Tab: 0.5mg(23017)

ADR:

COMMON
Decrease in appetite, Increased appetite, Weight increased, Constipation, Reduced salivation, Xerostomia, Cognitive disorder, Confusion, Dysarthria, Incoordination, Lightheadedness, Memory impairment, Sedated, Somnolence, Irritability, Reduced libido, Fatigue.
SERIOUS
Stevens-Johnson syndrome, Liver failure, Seizure co-occurrent and due to drug withdrawal.

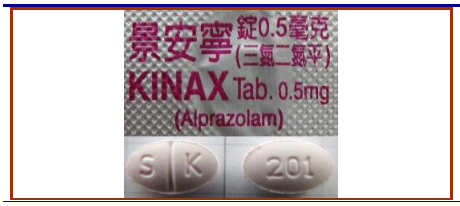
NOTE: 室溫儲存

·《Contraindications》Acute narrow angle glaucoma; Concomitant use with itraconazole or ketoconazole; Hypersensitivity to benzodiazepines ;
·仿單內容變更(版本CDS 20130709-1)與其他藥物之交互作用：曾有報告指出服用本藥有增加digoxin血中濃度的情形，特別是在老人族群(>65歲)。因此對於併服本藥與digoxin者，應監測digoxin毒性相關的徵象與症狀。不良反應增列光敏感反應(頻率不明)。

藥名相似:

外觀相似:

外觀描述: 粉紅橢圓扁錠，一面有有" S | K "，另一面有 "201" 字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1042686

14.14B Benzodiazepines

23061 **ɔt be ruled out / Infant risk can**

LIMIN* TABLETS (NITRAZEPAM) "YU SHENG" "優生" 寧眠錠（耐妥眠）

Nitrazepam 5mg tab

Dosage: 1常備品 23061

Adult
·Insomnia: PO, 5-10mg hs

Pediatric
·Epilepsy: PO, initial 1- 6 mg/day, Max. 60 mg/day.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 5mg(23061)

ADR:

Confusion, dependence, dizziness, dysphagia, drooling.

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to nitrazepam；

藥名相似:

外觀相似:

外觀描述: 黃色圓扁錠，一面有中央刻痕及YS及LM字樣)

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1019579

14.14B Benzodiazepines

23063 **c / Caution**

Fallep* Tablets 2mg 服爾眠錠2毫克

Flunitrazepam 2mg tab

Dosage: 1常備品 23063

Adult
·Insomnia: 1-2mg hs

Pediatric
·For oral premedication: PO, 1 mg (in children weighing 31-40 kg), 1.5 mg (41-50 kg), 2 mg (≥50 kg), has been effective when administered 90 minutes before surgery.
·For sedation: PO, 0.1-2 mg/kg has been used for sedation 90 minutes prior to IV fentanyl analgesia in children undergoing bone marrow aspiration and needle biopsy.

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

NDA

P: Tab: 2mg(23063,瑞士)，(23067,政德)

ADR:

Hypotension, drowsiness, memory impairment, respiratory depression, dependence

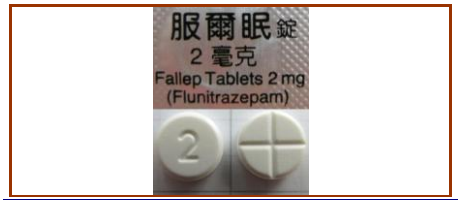
NOTE: 室溫儲存

臺北市政府衛生局函(2017.07.3)北市衛食藥字第10644324100號，請醫師依「苯二氮平類(Benzodiazepines)藥品用於鎮靜安眠之使用指引」相關規定，改善處方用藥行為，成人一般睡前最多不超過2mg。

藥名相似: Fluanxol* 3mg tab (22967)

外觀相似:

外觀描述: 白色圓扁錠，一面有十字刻痕，一面有 2 字樣



14.14B Benzodiazepines

23065 **X / Caution**

HALCION TABLETS 0.25MG 酣樂欣錠0.25毫克

Triazolam 0.25mg tab

Dosage: 1常備品 23065

Adult
·Insomnia: PO, initial 0.125-0.25 mg hs; Max. 0.5 mg hs

Pediatric
·Safety and efficacy have not been established in patients less than 18 years old.

Dosing adjustments in hepatic impairment:

Severe liver dysfunction: initial 0.125 mg hs

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 0.25mg(23065)

ADR:

COMMON
Dizziness, Feeling nervous, Headache, Lightheadedness, Somnolence.
SERIOUS
Cholestatic jaundice syndrome, Jaundice, Liver failure, Hypersensitivity reaction, Amnesia, Dystonia, Abnormal behavior, Complex mannerisms - behavior, Depression, Worsening, Suicidal thoughts, Apnea, Respiratory depression, Excitability, Paradoxical, Withdrawal symptom.

NOTE: 室溫儲存25℃以下

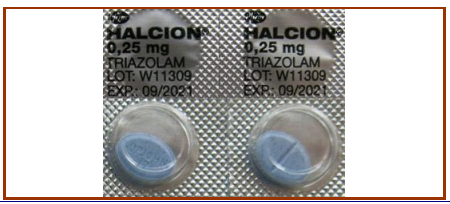
·《Contraindications》Concomitant use with potent CYP 3A inhibitors including itraconazole, ketoconazole, nefazodone, or several HIV protease inhibitors (ie, indinavir, lopinavir, nelfinavir, ritonavir,

or saquinavir , efavirenz, or elvitegravir/cobicistat) ;
Hypersensitivity to triazolam or other benzodiazepines ;
1.Contraindications: concomitant administration of itraconazole or ketoconazole, pregnancy.
2.Grapefruit juice has been reported to increase bioavailability of triazolam, resulting in an increase in sedation.
3.仿單內容變更，摘述如下：(版本CDS 20130906-2)
(1)中文品名重量單位標示由"公絲"改為"毫克"。
(2)加註調劑本藥應依管制藥品專用處方箋為之。
(3)禁忌：增列本藥禁止併用ketoconazole、itraconazole、nefazodone及HIV蛋白酉每抑制劑。
(4)藥物交互作用：加註HIV蛋白酉每抑制劑(如ritonavir)與本藥間的交互作用複雜且與用藥時間長短相關。短期低劑量服用ritonavir使得本藥清除率大為減少，排除半衰期延長且臨床效果增強。Triazolam禁止併用HIV蛋白酉每抑制劑。
(5)不良反應：加註協調功能不良、跌倒。
(6)過量：加註曾有呼吸中止的報告。
4.久裕公司來文，Triazolam 0.25mg tab藥品資訊仿單內容變更，摘述如下：(版本 CDS 20170531-2)
(1)Benzodiazepines類藥物併用鴉片類藥物會產生加成的CNS抑制效果，可能引起深度鎮靜、呼吸抑制、昏迷和死亡。應將劑量和療程限制在所需的最低程度。
(2)用於老年及/或虛弱病人，推薦本錠0.125 mg劑量開始治療，以降低出現鎮定過度，頭昏眼花，或協調能力受損的可能。
(3)服用本品可能出現夢遊行為，例如開車、打電話及準備與食用食物。曾有病人服用鎮靜安眠藥(包括triazolam)後，在不完全清醒的狀態下發生複雜的睡眠行為相關事件的報告，例如「夢駕」(即服食鎮靜安眠藥之後，在不完全清醒的狀態下駕駛，事後毫無記憶)。(2018.04.18)
5.仿單內容變更，摘述如下：(版本CDS CDS 20180802-1)
安全性資料增列麻醉和鎮靜藥物的影響-非臨床研究已顯示，在幼年動物腦部發育高峰期間給予阻斷NMDA受體及/或增強GABA活性的麻醉和鎮靜藥物，會增加腦部神經元細胞的死亡，並造成長期的認知和行為缺陷。根據非臨床物種間的比較，這些影響被認為與人類在大腦脆弱期(孕期第三期至出生後第一年間)的接觸有關，而且可能延長至大約3歲。儘管有關本藥影響的資訊有限，但由於作用機制包括增強GABA活性，因此可能產生類似效果。這些非臨床結果於人類用途的相關性仍未知。

藥名相似: Trileptal* 300mg Tab(22877)

外觀相似:

外觀描述: 藍色橢圓扁錠，一面有UPJOHN 17字樣，另一面中央有刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021726

14.14B Benzodiazepines

23066 **X / Unknown(有**

ESZO* TABLETS 2MG (ESTAZOLAM)"S.T." "信東" 艾斯樂錠 2 毫克（伊塔諾浪）

Estazolam 2mg tab

Dosage: 1常備品 23066

Adult
·Insomnia: 1-2mg hs

Pediatric
·Safety and efficacy have not been established in patients less than 18 years old.

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 2mg(23066)

ADR:

COMMON
Abnormal coordination, hypokinesia, asthenia, dizziness, somnolence

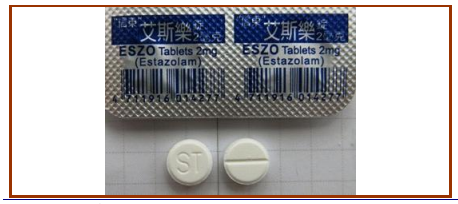
NOTE: 室溫儲存

·《Contraindications》Concomitant use of ketoconazole or itraconazole ; Pregnancy ;

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠,有ST字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1042646

14.14B Benzodiazepines

32605 **D / Unknown(有**

MIDATIN* INJECTION 5MG/ML "N.K." "南光" 美得定注射液5毫克/毫升

■Midazolam HCl inj 15mg/3mL amp

Dosage: 1常備品 32605

Adult
·Preoperative sedation : IM, 0.07-0.08mg/kg (5mg) 0.5-1hr before surgery.
·Sedation: Slow IV over 2min, LD 0.01- 0.05 mg/kg, then IV infusion, MD 0.02-0.1 mg/kg/hr (1-7 mg/hr).
·Induction and maintenance of anesthesia: IV, 0.15-0.35mg/kg over 20-30 sec depending upon age and presence of premedication, incremental of 25% the induction dose may be given as necessary, Max. total dose 0.6mg/kg.

Pediatric
·Preoperative sedation:
IM, 0.1-0.15 mg/kg; total dose does not exceed 10mg
IV, over 2-3 mins
6m-5yrs: initial 0.05-0.1 mg/kg, wait an additional 2-3 mins to evaluate the sedative effect ,or repeating a dose; total dose up to 0.6mg/kg (Max. 6 mg)
6-12yrs:initial 0.025-0.05 mg/kg, wait an additional 2-3 mins to evaluate the sedative effect ,or repeating a dose; total dose up to 0.4mg/kg (Max. 10 mg)
12-16yrs: dose as adults; Max. 10 mg

·Sedation: IV Infusion, neonates<32wks: 0.03 mg/kg/hr; neonates>32wks: 0.06 mg/kg/hr; Non-neonatal: LD 0.05-0.2 mg/kg over 2-3 mins, MD 0.06-0.12 mg/kg/hr

Dosing adjustments in hepatic impairment:

Decreased dose by 50%.

Dosing adjustments in renal impairment:

Clcr< 10 mL/min: decreased dose by 50%.

P: Inj: 5 mg/1mL(32603);15 mg/3mL(32605)

ADR:

COMMON
Nausea, vomiting, excessive somnolence, headache, somnolence, cough, hiccoughs
SERIOUS
Cardiac arrest (usually in combinations with CNS depressant drug (rare)), hypotensive episode (rare), desaturation of blood (pediatric patients), involuntary movement, agitation, apnea, respiratory arrest (with CNS depressant drugs (rare)), respiratory depression, respiratory obstruction (rare)

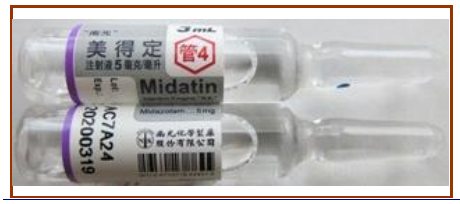
NOTE: 室溫儲存

■輕中度鎮靜止痛
IV loading doses should not be used in neonates.

藥名相似:

外觀相似:

外觀描述: 3mL透明注射液透明安瓿，頸部有藍點



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046285

14.14B Benzodiazepines

32606 **D / Unsafe**

MIDATIN* INJECTION 5MG/ML "N.K." "南光" 美得定注射液5毫克/毫升

■Midazolam HCl inj 5mg/1mL

Dosage: 1常備品 32606

Adult
·Preoperative sedation : IM, 0.07-0.08mg/kg (5mg) 0.5-1hr before surgery.
·Sedation: Slow IV over 2min, LD 0.01- 0.05 mg/kg, then IV infusion, MD 0.02-0.1 mg/kg/hr (1-7 mg/hr).
·Induction and maintenance of anesthesia: IV, 0.15-0.35mg/kg over 20-30 sec depending upon age and presence of premedication, incremental of 25% the induction dose may be given as necessary, Max. total dose 0.6mg/kg.

Pediatric
·Preoperative sedation:
IM, 0.1-0.15 mg/kg; total dose does not exceed 10mg
IV, over 2-3 mins
6m-5yrs: initial 0.05-0.1 mg/kg, wait an additional 2-3 mins to evaluate the sedative effect ,or repeating a dose; total dose up to 0.6mg/kg (Max. 6 mg)
6-12yrs:initial 0.025-0.05 mg/kg, wait an additional 2-3 mins to evaluate the sedative effect ,or repeating a dose; total dose up to 0.4mg/kg (Max. 10 mg)
12-16yrs: dose as adults; Max. 10 mg
·Sedation: IV Infusion, neonates<32wks: 0.03 mg/kg/hr; neonates>32wks: 0.06 mg/kg/hr; Non-neonatal: LD 0.05-0.2 mg/kg over 2-3 mins, MD 0.06-0.12 mg/kg/hr

Dosing adjustments in hepatic impairment:

Decreased dose by 50%.

Dosing adjustments in renal impairment:

Clcr< 10 mL/min: decreased dose by 50%.

P: Inj: 5 mg/1mL(32603)

ADR:

COMMON
Nausea, vomiting, excessive somnolence, headache, somnolence, cough, hiccoughs
SERIOUS
Cardiac arrest (usually in combinations with CNS depressant drug (rare)), hypotensive episode (rare), desaturation of blood (pediatric patients), involuntary movement, agitation, apnea, respiratory arrest (with CNS depressant drugs (rare)), respiratory depression, respiratory obstruction (rare)

NOTE: 室溫儲存

■輕中度鎮靜止痛
IV loading doses should not be used in neonates.

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液，白底紫色字標籤透明安瓿

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046285

14.14C Non-Benzodiazepines Hypnotic

23068 **C / Caution**

ZOLON* FILM COATED TABLETS 7.5MG (ZOPICLONE) "信東" 樂比克膜衣錠 7 · 5 公絲

Zopiclone 7.5mg tab

Dosage: 1常備品 23068

Adult
·Insomnia: PO, 5-7.5 mg hs, Patients with chronic respiratory insufficiency: 3.75 mg, may increase up to 7.5 mg with caution in appropriate cases.
Elderly: initial 3.75 mg, may increase to 5-7.5 mg

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

3.75 mg, may increase up to 7.5 mg with caution in appropriate cases.

Dosing adjustments in renal impairment:

NDA

P: Tab: 7.5 mg(23068)

ADR:

Dryness of the mouth and a bitter taste, residual sedation/psychomotor impairment, rebound insomnia.

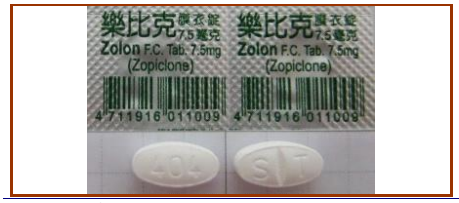
NOTE: 室溫儲存

1.Eszopiclone(S-enantiomer of zopiclone)，FDA Pregnancy Category: Category C

藥名相似: Zolpi * 10mg FC tab (23069), Zoloft* 50mg Ta

外觀相似:

外觀描述: 白色長橢圓形錠，有"S" "T"及"404"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046013

14.14C Non-Benzodiazepines Hypnotic

23069 C / Infant risk is

ZOLPIDEM* F.C. TABLETS 10MG "CYH" 柔拍膜衣錠10毫克

Zolpidem hemitartrate10mg FC tab

Dosage: 1常備品 23069

Adult

·Insomnia: PO, 10mg hs, Max. 10mg/day.

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

5 mg hs

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 10mg(23069), 10mg(23072), 6.25mg CR(23071)

ADR:

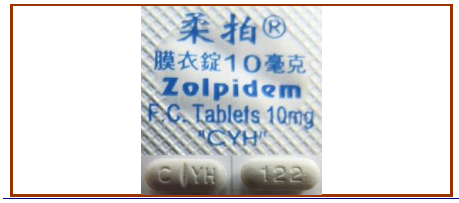
COMMON
Diarrhea, nausea, allergy, dizziness, drugged state, headache, somnolence, visual disturbance
SERIOUS
Chest pain, tachycardia, anaphylaxis, hepatic encephalopathy, depression, worsening, suicidal thoughts, angioedema (rare)

NOTE: 室溫儲存

藥名相似: Tab: 10mg(23069)

外觀相似: Coxine* 20mg Tab(22530), STROCAIN* (220

外觀描述: 白色長橢圓形錠，一面有"122"字樣，另一面中央有刻痕及"C | YH"字樣



14.14C Non-Benzodiazepines Hypnotic

23071 ɔt be ruled out / Infant risk can

Stilnox* CR Tablet 6.25 mg 使蒂諾斯長效錠6.25毫克

Zolpidem tartrate 6.25mg CR tab

Dosage: 1常備品 23071

Adult

·Insomnia: PO, 6.25mg hs(藥委會決議每日限一粒)

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

6.25mg hs (dosing adjustment required)

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 10mg(23069), 10mg(23072), 6.25mg CR(23071)

ADR:

COMMON
Diarrhea, Nausea, Allergic reaction, Dizziness, Drugged state, Headache, Somnolence, Visual disturbance, Fatigue.
SERIOUS
Chest pain, Tachycardia, Hepatic encephalopathy, Anaphylaxis, Hepatic encephalopathy, Complex mannerisms-behavior, Sleep, worsening of Depression, , Suicidal, Suicidal thoughts, Angioedema.

NOTE: 室溫儲存

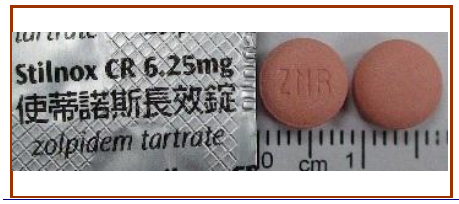
·《Contraindications》Hypersensitivity to zolpidem tartrate; Patients who have experienced complex sleep behaviors after taking zolpidem, eszopiclone, or zolpidem ;
·《仿單禁忌》對zolpidem或本要其他任何非活性成分過品; 嚴重肝功能不全; 急性及/或嚴重呼吸功能不全; 睡眠呼吸暫止徵候群; 肌無力(myasthenia gravis) ;
·Swallow whole; do not divide, crush or chew. It's a coated two-layer tablet: one layer releases immediately, another layer releases slower.
·接受此類藥品治療，無論有無憂鬱症，其自殺與企圖自殺的發生率會增加，但因果關係尚未建立。
·於先天性長QT症候群的病人給予治療時，應慎重評估利益與風險。
·本藥不宜長期使用且不可用於18歲以下之病人。
·藥委會決議:限精神科使用，且每日限一粒
·懷孕期間不建議使用(仿單)。
·使用本藥後，應小心避免從事駕駛或操作機械能力之行為；且次日早晨可能會有思睡之風險，在服藥後需有7-8小時的睡眠時間。
·本藥可引起思睡及意識降低的情形，可能導致跌倒而造成嚴重外傷。
·併用本藥與鴉片類藥物，須儘可能地減低劑量及使用時間，並密切注意病人呼吸抑制和鎮靜的徵象和症狀。
·藥物交互作用：(A)酒精(酒精會增加本藥的鎮靜作用)。(B)中樞神經系統抑制劑(與抗精神病劑、安眠藥、抗焦慮劑/鎮靜劑、抗鬱劑、麻醉性止痛藥、抗癲癇藥、麻醉劑及鎮靜的抗組織胺劑併用會增強中樞神經系統抑制作用。就麻醉性止痛藥而言，也可能出現欣快感增強，導致心理依賴性增加。(C)併用ketoconazole可能增強鎮靜作用，併用時應考慮使用較低劑量的zolpidem。(D)不建議與聖約翰草(St John’ s wort)併用，會降低zopidem血中濃度。
·不宜長期服用，應盡量縮短治療期，不可超過4週。未經反覆再評估病人狀況，不可持續治療超過建議的治療期間，因為濫用和依賴性風險隨治療延長而增高。
·精神運動障礙-具有中樞神經系統(CNS)抑制作用。

·濫用及/或生理或心理依賴性-隨劑量及治療期間增加而增加。超過4週，依賴性病例的報導較為頻繁。有精神障礙及/或酒精或藥物濫用史的病人濫用和依賴性風險也較高。對於目前有酒精或藥物濫用史者，使用本藥應格外謹慎。

藥名相似:

外觀相似:

外觀描述: 淺磚紅色圓形錠，一面有ZMR字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024677

14.14D Miscellaneous

23012 **B / Caution**

Sepirone Tablets 5mg 怡必隆錠5毫克

Buspirone HCl 5mg tab

Dosage: 1常備品 23012

Adult
·Anxiety: PO, Initial 10-15 mg/day in 2-3 div. doses. The dosage may be increased 5 mg/day every 2-3 days as needed. MD 15-30 mg/day in 2-3 div. doses. Max. 60 mg/day

Pediatric
·Safety and efficacy have not been established in patients less than 18 years old.
·Anxiety: PO, 5 mg/day, may increase by 5-10 mg/day every 3 days as needed (usual dose 30 mg/day), Max. 50 mg/day.

Dosing adjustments in hepatic impairment:

Dosage adjustment needed

Dosing adjustments in renal impairment:

Dosage adjustment needed

P: Tab: 5mg(23012)

ADR:

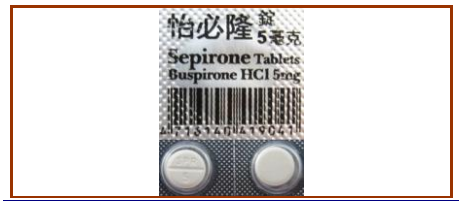
COMMON
Blurred vision, dizziness, headache, nausea, nervousness, excitement, anger/hostility, confusion, numbness, weakness
SERIOUS
Cerebrovascular accidents (rare), congestive heart failure (rare), myocardial infarction (rare).

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，有SPR 5字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1040134

14.14D Miscellaneous

28562 **a / Infant risk is**

Clodrin Oral Solution "CENTER" "晟德" 可律靜內服液劑

■Chloral hydrate soln 10%(100mg/mL)

Dosage: 1常備品 28562

Adult
·Hypnotic: PO, Rectal, 0.5-1g hs, Max. 2g/day
·Sedation: PO, Rectal, 250mg tid, Max. 2g/day
·Preoperative sedation: PO, 0.5-1g 30min before surgery

Pediatric
·Hypnotic: PO, Rectal, 50mg/kg hs, Max.1g/dose; Max. 1g/day for infants and 2g/day for children
·Procedural sedation: PO, Rectal, 25-100mg/kg/dose; Max. 1g for infants and 2g for children
·Premedication before EEG: PO, Rectal, 20-25mg/kg/dose
·Sedation: PO, Rectal, 25-50mg/kg/day div. in 3-4 doses, Max.500mg/dose

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr > 50 mL/min: No dosage adjustment need
Clcr < 50 mL/min: Avoid use

P: Soln: 100mg/mL(28562)

ADR:

COMMON
Clumsiness or unsteadiness, dizziness, lightheadedness, diarrhea, nausea, stomach pain, vomiting, drowsiness, hangover effect
SERIOUS
Confusion, hallucinations, unusual excitement, skin rash or hives (allergic reaction)

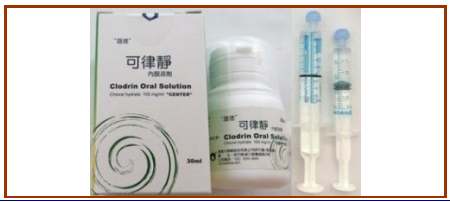
NOTE: 避光室溫

·《仿單禁忌》(依文獻記載)1.明顯肝或腎功能損害者。2.患有嚴重心臟疾病。3.嚴重胃炎、食道炎、胃潰瘍或十二指腸潰瘍。4.紫質症。5.對 Chloral hydrate 或對其中任何賦形劑有過敏反應者。6.由於呼吸道阻塞的風險進而影響到生命安全，患有嚴重阻塞性睡眠呼吸中止症的兒童禁用；
·以mg開處方，藥局以100mg/ml 發藥。
·開封後室溫可放至1個月(晟德藥廠安定性試驗報告2015.08.24)。
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 透明液體，依用量以餵藥器裝 或 整瓶塑膠瓶30mL裝



14.14D Miscellaneous

32542 C / Caution

PRECEDEX* INJECTION 100MCG/ML 普利斯德注射劑 100微公絲/公撮

■Dexmedetomidine 200mcg/2mL vial

Dosage: 1常備品 32542

Adult

· Sedation of mechanically ventilated patients in ICU: IV, LD 1mcg/kg over 10 mins, followed by a maintenance infusion of 0.2-0.7mcg/kg/hr for a maximum of 24 hours

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Dosage reduction may need to be considered

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 200mcg/2mL Vial(32542)

ADR:

COMMON

Nausea, xerostomia

SERIOUS

Atrial fibrillation, atrioventricular block, bradyarrhythmia, cardiac arrest, aggravated hypertension, hypotension, supraventricular tachycardia, ventricular arrhythmia, ventricular tachycardia, acidosis, hyperkalemia, anemia, leukocytosis, oliguria, apnea, bronchospasm, dyspnea, hypercapnia, hypoventilation, hypoxia, pleural effusion, pulmonary congestion, pulmonary edema, respiratory acidosis, infectious disease

NOTE:

■輕中度鎮靜止痛

· It should be diluted with NS prior to administration

藥名相似:

外觀相似:

外觀描述: 2mL透明注射液『寶藍』蓋透明玻璃瓶，蓋上有FLIP及OFF字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024002

14.16 Respiratory and Central Stimulants

23031 C / Caution

CONCERTA* EXTENDED RELEASE TABLETS 18MG 專思達長效錠１８毫克

Methylphenidate HCl 18mg ER tab

Dosage: 1常備品 23031

Adult

·Attention deficit hyperactivity disorder (ADHD) :
No prior methylphenidate therapy: initial, 18 or 36 mg orally once daily in the morning; may adjust dosage at weekly intervals in 18 mg increments; Max 72 mg/day .
Conversion from prior methylphenidate therapy, taken 2 or 3 times a day (priory therapy of 10 to 15 mg/day), 18 mg orally in morning; (prior therapy of 20 to 30 mg/day); 36 mg in morning; (prior therapy of 30 to 45 mg/day), 54 mg in morning; (prior therapy of 40 to 60 mg/day), 72 mg in morning .

Pediatric

·Attention deficit hyperactivity disorder (ADHD) :
No prior methylphenidate (IR) therapy:
6 to 12 years:18mg qd AM, may adjust dosage at weekly intervals in 18mg increments; Max 54mg/day.
13 to 17 years:18 mg orally once daily in the morning; may adjust dosage at weekly intervals in 18 mg increments; MAX 72 mg/day or 2 mg/kg/day.
Patients taking methylphenidate (IR) may be switched to ER:
6 to 17 years:Conversion from prior methylphenidate therapy taken 2 or 3 times a day, (prior therapy of 10 to 15 mg/day), 18 mg orally in morning; (prior therapy of 20 to 30 mg/day), 36 mg in morning; (prior therapy of 30 to 45 mg/day), 54 mg in morning.
13 to 17 years:Conversion from prior methylphenidate therapy taken 2 or 3 times a day (prior therapy of 40 to 60 mg/day), 72 mg orally in the morning.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: IR tab: 10mg(23039); LA cap: 20mg(23038) ;ER tab:18mg(23031) , 27mg(23040), 36mg(23032), 54mg(23035)

ADR:

COMMON

Erythema, weight decreased, decrease in appetite, loss of appetite, nausea, vomiting, headache, insomnia, labile affect, nasal congestion, nasopharyngitis

SERIOUS

Contact dermatitis, decreased body growth, lowered convulsive threshold (Tic), psychotic disorder, drug dependence

NOTE: 室溫儲存

· 《Contraindications》Angina pectoris; Cardiac arrhythmias; Concomitant use of MAOIs, or use within 14 days of MAOI discontinuation; Concomitant use with halogenated anesthetics; do not take on day of surgery; Family history or diagnosis of Tourette syndrome; Fructose intolerance, glucose-galactose malabsorption, or sucrase-isomaltase insufficiency; contains sucrose; Glaucoma; Heart failure; Hypersensitivity to methylphenidate or other components of the product; Marked agitation, anxiety, and tension; may aggravate symptoms; Motor tics; Recent myocardial infarction; Severe hypertension ;
(1)IR: Immediate-release
(2)Concerta extended-release(ER) tablet uses osmotic pressure to deliver methylphenidate at a constant rate. The tablet must be swallowed whole with the aid of liquids, and must not be chewed, divided, or crushed.

(3)仿單內容變更，摘述如下：(版本USPI Dec2013_v1501)
1.增列藥物依賴性之紅框警語。
2.適應症變更並更新13-17歲青少年及18-65歲成人病患之使用說明、劑量、警語及注意事項、不良反應及臨床試驗之相關資訊。
3.用法用量：更新正服用Methylphenidate每日10-60mg每日二或三次者，CONCERTA*的建議劑量。
4.禁忌症增列動作型不自主抽動之病人。
5.增列藥物濫用和依賴性之相關資訊。
6.產品說明加註製劑成分及作用方式。
7.其他部分則修改敘述方式。
(4)仿單內容變更，摘述如下：(版本USPI Jan2017_v1702)
適應症變更為「治療6歲(含)以上及65歲(含)以下患有注意力不足過動症之兒童、青少年及成人病患」。
1.用法用量：(A)13-17歲青少年及18-65歲成人劑量範圍由每日18-54毫克變更為每日18-72毫克。(B)對於目前正在服用Methylphenidate者，轉換的劑量不應超過每日72毫克。(C)更新劑量調整之相關資料。
2.不良反應：上市後用藥經驗增列肝細胞損傷、急性肝衰竭。
3.增列病患諮詢須知(陰莖勃起異常、手指與腳趾的周邊循環問題、一般注意事項、藥物投予說明、駕駛與操作重型機械)。

藥名相似:

外觀相似:

外觀描述: 土黃色圓柱錠,有alza 18字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023731

14.16 Respiratory and Central Stimulants

23032 **C / Caution**

CONCERTA* EXTENDED RELEASE TABLETS 36MG 專思達長效錠36毫克

Methylphenidate HCl 36mg ER tab

Dosage: 1常備品 23032

Adult
·Attention deficit hyperactivity disorder (ADHD) :
No prior methylphenidate therapy: initial, 18 or 36 mg orally once daily in the morning; may adjust dosage at weekly intervals in 18 mg increments; Max 72 mg/day .
Conversion from prior methylphenidate therapy, taken 2 or 3 times a day (priory therapy of 10 to 15 mg/day), 18 mg orally in morning; (prior therapy of 20 to 30 mg/day); 36 mg in morning; (prior therapy of 30 to 45 mg/day), 54 mg in morning; (prior therapy of 40 to 60 mg/day), 72 mg in morning
.

Pediatric
·Attention deficit hyperactivity disorder (ADHD) :
No prior methylphenidate (IR) therapy:
6 to 12 years:18mg qd AM, may adjust dosage at weekly intervals in 18mg increments; Max 54mg/day.
13 to 17 years:18 mg orally once daily in the morning; may adjust dosage at weekly intervals in 18 mg increments; MAX 72 mg/day or 2 mg/kg/day.
Patients taking methylphenidate (IR) may be switched to ER:
6 to 17 years:Conversion from prior methylphenidate therapy taken 2 or 3 times a day, (prior therapy of 10 to 15 mg/day), 18 mg orally in morning; (prior therapy of 20 to 30 mg/day), 36 mg in morning; (prior therapy of 30 to 45 mg/day), 54 mg in morning.
13 to 17 years:Conversion from prior methylphenidate therapy taken 2 or 3 times a day (prior therapy of 40 to 60 mg/day), 72 mg orally in the morning.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: IR tab: 10mg(23039); LA cap: 20mg(23038) ;ER tab:18mg(23031) , 27mg(23040), 36mg(23032), 54mg(23035)

ADR:

COMMON
Erythema, weight decreased, decrease in appetite, loss of appetite, nausea, vomiting, headache, insomnia, labile affect, nasal congestion, nasopharyngitis
SERIOUS
Contact dermatitis, decreased body growth, lowered convulsive threshold (Tic), psychotic disorder, drug dependence

NOTE: 室溫儲存

·《Contraindications》Angina pectoris; Cardiac arrhythmias; Concomitant use of MAOIs, or use within 14 days of MAOI discontinuation; Concomitant use with halogenated anesthetics; do not take on day of surgery; Family history or diagnosis of Tourette syndrome; Fructose intolerance, glucose-galactose malabsorption, or sucrase-isomaltase insufficiency; contains sucrose; Glaucoma; Heart failure; Hypersensitivity to methylphenidate or other components of the product; Marked agitation, anxiety, and tension; may aggravate symptoms; Motor tics; Recent myocardial infarction; Severe hypertension ;
·IR: Immediate-release
·Concerta extended-release(ER) tablet uses osmotic pressure to deliver methylphenidate at a constant rate. The tablet must be swallowed whole with the aid of liquids, and must not be chewed, divided, or crushed.
·仿單內容變更，摘述如下：(版本USPI Jan2017_v1702)
適應症變更為「治療6歲(含)以上及65歲(含)以下患有注意力不足過動症之兒童、青少年及成人病患」。
1.用法用量：(A)13-17歲青少年及18-65歲成人劑量範圍由每日18-54毫克變更為每日18-72毫克。(B)對於目前正在服用Methylphenidate者，轉換的劑量不應超過每日72毫克。(C)更新劑量調整之相關資料。
2.不良反應：上市後用藥經驗增列肝細胞損傷、急性肝衰竭。
3.增列病患諮詢須知(陰莖勃起異常、手指與腳趾的周邊循環問題、一般注意事項、藥物投予說明、駕駛與操作重型機械)。

藥名相似:

外觀相似:

外觀描述: 白色圓柱錠,有alza 36字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023880

14.16 Respiratory and Central Stimulants

23035 C / Caution

CONCERTA* EXTENDED RELEASE TABLETS 54MG 專思達長效錠54毫克

Methylphenidate HCl 54mg ER tab

Dosage: 1常備品 23035

Adult

·Attention deficit hyperactivity disorder (ADHD) :
No prior methylphenidate therapy: initial, 18 or 36 mg orally once daily in the morning; may adjust dosage at weekly intervals in 18 mg increments; Max 72 mg/day .
Conversion from prior methylphenidate therapy, taken 2 or 3 times a day (priory therapy of 10 to 15 mg/day), 18 mg orally in morning; (prior therapy of 20 to 30 mg/day); 36 mg in morning; (prior therapy of 30 to 45 mg/day), 54 mg in morning; (prior therapy of 40 to 60 mg/day), 72 mg in morning
.

Pediatric

·Attention deficit hyperactivity disorder (ADHD) :
No prior methylphenidate (IR) therapy:
6 to 12 years:18mg qd AM, may adjust dosage at weekly intervals in 18mg increments; Max 54mg/day.
13 to 17 years:18 mg orally once daily in the morning; may adjust dosage at weekly intervals in 18 mg increments; MAX 72 mg/day or 2 mg/kg/day.
Patients taking methylphenidate (IR) may be switched to ER:
6 to 17 years:Conversion from prior methylphenidate therapy taken 2 or 3 times a day, (prior therapy of 10 to 15 mg/day), 18 mg orally in morning; (prior therapy of 20 to 30 mg/day), 36 mg in morning; (prior therapy of 30 to 45 mg/day), 54 mg in morning.
13 to 17 years:Conversion from prior methylphenidate therapy taken 2 or 3 times a day (prior therapy of 40 to 60 mg/day), 72 mg orally in the morning.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: IR tab: 10mg(23039); LA cap: 20mg(23038) ;ER tab:18mg(23031) , 27mg(23040), 36mg(23032), 54mg(23035)

ADR:

COMMON
Erythema, weight decreased, decrease in appetite, loss of appetite, nausea, vomiting, headache, insomnia, labile affect, nasal congestion, nasopharyngitis
SERIOUS
Contact dermatitis, decreased body growth, lowered convulsive threshold (Tic), psychotic disorder, drug dependence

NOTE: 室溫儲存

·《Contraindications》Angina pectoris; Cardiac arrhythmias; Concomitant use of MAOIs, or use within 14 days of MAOI discontinuation; Concomitant use with halogenated anesthetics; do not take on day of surgery; Family history or diagnosis of Tourette syndrome; Fructose intolerance, glucose-galactose malabsorption, or sucrase-isomaltase insufficiency; contains sucrose; Glaucoma; Heart failure; Hypersensitivity to methylphenidate or other components of the product; Marked agitation, anxiety, and tension; may aggravate symptoms; Motor tics; Recent myocardial infarction; Severe hypertension ;
(1)IR: Immediate-release
(2)Concerta extended-release(ER) tablet uses osmotic pressure to deliver methylphenidate at a constant rate. The tablet must be swallowed whole with the aid of liquids, and must not be chewed, divided, or crushed.
(3)仿單內容變更，摘述如下：(版本USPI Jan2017_v1702)
適應症變更為「治療6歲(含)以上及65歲(含)以下患有注意力不足過動症之兒童、青少年及成人病患」。
1.用法用量：(A)13-17歲青少年及18-65歲成人劑量範圍由每日18-54毫克變更為每日18-72毫克。(B)對於目前正在服用Methylphenidate者，轉換的劑量不應超過每日72毫克。(C)更新劑量調整之相關資料。
2.不良反應：上市後用藥經驗增列肝細胞損傷、急性肝衰竭。
3.增列病患諮詢須知(陰莖勃起異常、手指與腳趾的周邊循環問題、一般注意事項、藥物投予說明、駕駛與操作重型機械)。

藥名相似:

外觀相似:

外觀描述: 磚紅色圓柱錠,有alza 54字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024229

14.16 Respiratory and Central Stimulants

23038 C / Caution

RITALIN LA CAPSULES 20MG 利長能持續性藥效膠囊20毫克

Methylphenidate HCl 20mg LA cap

Dosage: 1常備品 23038

Adult(≦60yrs)
·Attention deficit hyperactivity disorder (ADHD):initial, 20 mg once daily,dosage may be adjusted in weekly 10 mg increments to a maximum of 60 mg/day.

Pediatric(>6yrs)
·Attention deficit hyperactivity disorder (ADHD): PO, 10mg qd in the morning. Dosage may be adjusted in weekly 10mg increments to maximum of 40mg/day.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: IR tab: 10mg(23039); LA cap: 20mg(23038) ;ER tab:18mg(23031) , 27mg(23040), 36mg(23032), 54mg(23035)

ADR:

COMMON
Tachycardia, diaphoresis, weight decreased, abdominal pain, decrease in appetite, loss of appetite, nausea, vomiting, xerostomia, dizziness, headache, insomnia, anxiety, depression, irritability
SERIOUS
Myocardial infarction, Raynaud's phenomenon, sudden cardiac death, decreased body growth, gastrointestinal obstruction, abnormal liver function, cerebral artery occlusion, cerebral hemorrhage, cerebrovascular accident, seizure, blurred vision, aggressive behavior, mania, psychotic disorder, priapism

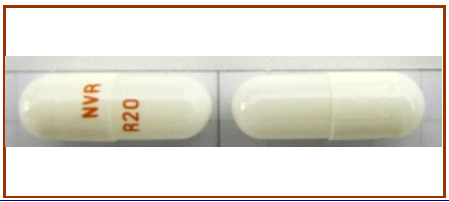
NOTE: 室溫儲存

·《Contraindications》Angina pectoris; Cardiac arrhythmias; Concomitant use of MAOIs, or use within 14 days of MAOI discontinuation; Concomitant use with halogenated anesthetics; do not take on day of surgery; Family history or diagnosis of Tourette syndrome; Fructose intolerance, glucose-galactose malabsorption, or sucrase-isomaltase insufficiency; contains sucrose; Glaucoma; Heart failure; Hypersensitivity to methylphenidate or other components of the product; Marked agitation, anxiety, and tension; may aggravate symptoms; Motor tics; Recent myocardial infarction; Severe hypertension ;
· When coadministration with other methylphenidate IR,the sum of methylphenidate dose form different form < 60mg /day

藥名相似:

外觀相似:

外觀描述: 白色膠囊，上面印有 NVR 及 R20字樣



14.16 Respiratory and Central Stimulants

23039 C / Caution

Ritalin Tablets 10mg 利他能錠10毫克

Methylphenidate HCl 10mg tab

Dosage: 1常備品 23039

Adult

·Narcolepsy: PO, ac 30-45 min, 10 mg bid-tid, Max. 60 mg/day.

Pediatric(>6yrs)
·Attention deficit hyperactivity disorder (ADHD): PO, ac, initial 5mg before breakfast & lunch, increase by 5-10mg/day at weekly intervals, Max. 2mg/ kg/day or 60mg/day.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: IR tab: 10mg(23030); ER tab: 54mg(23035), 36mg(23032), 18mg(23031)

ADR:

COMMON
Restlessness, behavior disturbances, slurred speech, loss of appetite
SERIOUS
Hallucinations,hypertension, tachycardia, thrombocytopenia, thrombocytopenia

NOTE: 室溫儲存30°C以下

· 《Contraindications》Angina pectoris; Cardiac arrhythmias; Concomitant use of MAOIs, or use within 14 days of MAOI discontinuation; Concomitant use with halogenated anesthetics; do not take on day of surgery; Family history or diagnosis of Tourette syndrome; Fructose intolerance, glucose-galactose malabsorption, or sucrase-isomaltase insufficiency; contains sucrose; Glaucoma; Heart failure; Hypersensitivity to methylphenidate or other components of the product; Marked agitation, anxiety, and tension; may aggravate symptoms; Motor tics; Recent myocardial infarction; Severe hypertension ;
· Take last daily dose early in the evening (prior to 6 pm) to avoid insomnia.
· Contraindications: concomitant use of MAO inhibitors and within 14 days following discontinuation of MAO inhibitors, glaucoma, motor tics or family history or diagnosis of Tourette's syndrome, patients with marked anxiety or agitation.

藥名相似:

外觀相似: Tofranil*(22934)

外觀描述: 白色圓扁錠，一面有有"A | B"，另一面有"C G"字樣

14.16 Respiratory and Central Stimulants

23040 C / Caution

CONCERTA* EXTENDED RELEASE TABLETS 27MG 專思達長效錠27毫克

急用Methylphenidate HCl 27mg ER tab

Dosage: 2急用藥 23040

Adult
·Attention deficit hyperactivity disorder (ADHD) :
No prior methylphenidate therapy: initial, 18 or 36 mg orally once daily in the morning; may adjust dosage at weekly intervals in 18 mg increments; Max 72 mg/day .
Conversion from prior methylphenidate therapy, taken 2 or 3 times a day (priory therapy of 10 to 15 mg/day), 18 mg orally in morning; (prior therapy of 20 to 30 mg/day); 36 mg in morning; (prior therapy of 30 to 45 mg/day), 54 mg in morning; (prior therapy of 40 to 60 mg/day), 72 mg in morning .

Pediatric
·Attention deficit hyperactivity disorder (ADHD) :
No prior methylphenidate (IR) therapy:
6 to 12 years:18mg qd AM, may adjust dosage at weekly intervals in 18mg increments; Max 54mg/day.
13 to 17 years:18 mg orally once daily in the morning; may adjust dosage at weekly intervals in 18 mg increments; MAX 72 mg/day or 2 mg/kg/day.
Patients taking methylphenidate (IR) may be switched to ER:
6 to 17 years:Conversion from prior methylphenidate therapy taken 2 or 3 times a day, (prior therapy of 10 to 15 mg/day), 18 mg orally in morning; (prior therapy of 20 to 30 mg/day), 36 mg in morning; (prior therapy of 30 to 45 mg/day), 54 mg in morning.
13 to 17 years:Conversion from prior methylphenidate therapy taken 2 or 3 times a day (prior therapy of 40 to 60 mg/day), 72 mg orally in the morning.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: IR tab: 10mg(23039); LA cap: 20mg(23038) ;ER tab:18mg(23031) , 27mg(23040), 36mg(23032), 54mg(23035)

ADR:

COMMON
Erythema, weight decreased, decrease in appetite, loss of appetite, nausea, vomiting, headache, insomnia, labile affect, nasal congestion, nasopharyngitis
SERIOUS
Contact dermatitis, decreased body growth, lowered convulsive threshold (Tic), psychotic disorder, drug dependence

NOTE: 室溫儲存25°C以下

· 《Contraindications》Angina pectoris; Cardiac arrhythmias; Concomitant use of MAOIs, or use within 14 days of MAOI discontinuation; Concomitant use with halogenated anesthetics; do not take on day of surgery; Family history or diagnosis of Tourette syndrome; Fructose intolerance, glucose-galactose malabsorption, or sucrase-isomaltase insufficiency; contains sucrose; Glaucoma; Heart failure; Hypersensitivity to methylphenidate or other components of the product; Marked agitation, anxiety, and tension; may aggravate symptoms; Motor tics; Recent myocardial infarction; Severe hypertension ;
· IR: Immediate-release
· Concerta extended-release(ER) tablet uses osmotic pressure to deliver methylphenidate at a constant rate. The tablet must be swallowed whole with the aid of liquids, and must not be chewed, divided, or crushed
· 仿單內容變更 · 摘述如下：(版本USPI Jan2017_v1702)
適應症變更為「治療6歲(含)以上及65歲(含)以下患有注意力不足過動症之兒童、青少年及成人病患」。
1.用法用量：(A)13-17歲青少年及18-65歲成人劑量範圍由每日18-54毫克變更為每日18-72毫克。(B)對於目前正在服用Methylphenidate者 · 轉換的劑量不應超過每日72毫克。(C)更新劑量調整之相關資料。
2.不良反應：上市後用藥經驗增列肝細胞損傷、急性肝衰竭。
3.增列病患諮詢須知(陰莖勃起異常、手指與腳趾的周邊循環問題、一般注意事項、藥物投予說明、駕駛與操作重型機械)。

藥名相似:

外觀相似:

外觀描述: 灰色圓柱錠,有alza 27字樣

14.16 Respiratory and Central Stimulants

27540 **C / Infant risk can**

PROVIGIL TABLETS 200MG 普衛醒錠 200毫克

急用Modafinil 200mg tab

Dosage: 2急用藥 27540

Adult
·Excessive daytime sleepiness associated with the narcoleptic syndrome, obstructive sleep apnea/hypopnea syndrome (OSAHS): PO, 200mg as a single dose in the morning
·Shift work sleep disorder (SWSD): PO, 200mg 1hr before start of work shift

Pediatric
·Safety and efficacy have not been established in patients less than 16 years old.

Dosing adjustments in hepatic impairment:

Severe hepatic impairment: Decrease dose by 50%

Dosing adjustments in renal impairment:

NDA

P: Tab: 200mg(27540)

ADR:

COMMON
Rash, nausea, dizziness, headache, insomnia, anxiety, feeling nervous
SERIOUS
Hypertension, hypersensitivity syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis, multi-organ hypersensitivity reaction, mania

NOTE: 室溫儲存

·Doses of 400mg/day, given as a single dose, have been well tolerated, but there is no consistent evidence that this dose confers additional benefit.
·食藥署藥品安全資訊風險溝通表(108/07)：醫療人員注意事項
1.Modafinil禁用於懷孕或計畫懷孕之婦女。
2.應與所有接受過modafinil治療或將要接受modafinil治療的女性病人討論於懷孕期間使用modafinil與胎兒相關的潛在風險。
3.應確定所有育齡婦女於開始使用modafinil治療前一週內的妊娠試驗結果為陰性。
4.告知所有育齡婦女於使用modafinil治療期間與停藥後2個月內須採用有效避孕措施。且因modafinil可能會降低固醇類避孕藥的有效性，使用固醇類避孕藥的病人須於modafinil治療期間與治療後2個月內採用替代或額外的避孕方法。

藥名相似:

外觀相似:

外觀描述: 白色長橢圓錠，有PROVIGIL及200 MG字樣

14.16 Respiratory and Central Stimulants

27552 **C / Caution**

PROVIGIL TABLETS 200MG 普衛醒錠 200毫克

急用Modafinil 200mg tab

Dosage: 2急用藥 27552

Adult
·Excessive daytime sleepiness associated with the narcoleptic syndrome, obstructive sleep apnea/hypopnea syndrome (OSAHS): PO, 200mg as a single dose in the morning
·Shift work sleep disorder (SWSD): PO, 200mg 1hr before start of work shift

·Shift work sleep disorder (SWSD): PO, 200mg 1hr before start of work shift

Pediatric
·Safety and efficacy have not been established in patients less than 16 years old.

Dosing adjustments in hepatic impairment:

Severe hepatic impairment: Decrease dose by 50%

Dosing adjustments in renal impairment:

NDA

P: P Tab: 200mg(27552)

ADR:

COMMON
Rash, nausea, dizziness, headache, insomnia, anxiety, feeling nervous
SERIOUS
Hypertension, hypersensitivity syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis, multi-organ hypersensitivity reaction, mania

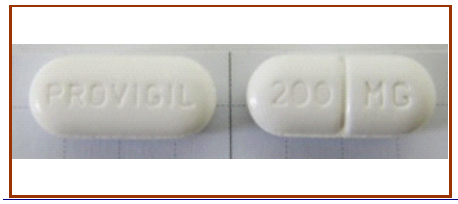
NOTE:

·Doses of 400mg/day, given as a single dose, have been well tolerated, but there is no consistent evidence that this dose confers additional benefit.

藥名相似:

外觀相似:

外觀描述: 白色長橢圓錠，有PROVIGIL及200 MG字樣



14.16 Respiratory and Central Stimulants

32615 **C / Infant risk is**

PEYONA* 20mg/ml solution for infusion and oral solution 啡那輸注溶液及口服液

急用Caffeine citrate inj & oral 20mg/1mL amp

Dosage: 2急用藥 32615

Adult
·No data available

Pediatric
·Apnea of prematurity: LD: IV, 20 mg/kg over 30 mins, MD: PO, 5mg/kg or IV over 10min Q24H beginning 24 hrs after LD

Dosing adjustments in hepatic impairment:

依據 caffeine 血漿濃度監測資料來調整劑量

Dosing adjustments in renal impairment:

依據 caffeine 血漿濃度監測資料來調整劑量

P: P Inj: 20mg/1mL(32615)

ADR:

COMMON
Irritability, Feeding problem symptom
SERIOUS
Acidosis, Hyperglycemia, Hypoglycemia, Impaired wound healing, Gastritis (rare), Gastrointestinal hemorrhage, Necrotizing enterocolitis in fetus OR newborn, Disseminated intravascular coagulation, Hemorrhage, Central nervous system stimulation, Excessive, Cerebral hemorrhage, Retinopathy of prematurity, Renal failure, Dyspnea, Pulmonary edema, Sepsis

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to any component of the product ；
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 1mL透明藥液，透明玻璃安瓿，頸部有綠色及白色線條，白底 紫字/粉紅字/黑字 標籤

14.18 Antimigraine Agents

22104 C / Infant risk is

Imigran FDT Tablets 50mg 英明格速溶錠50毫克

Sumatriptan succinate 50mg FDT tab

Dosage: 1常備品 22104

Adult
·Migraine: PO, initial, 25-100mg (base) as a single dose. If necessary, additional doses up to 100mg may be taken at intervals of at least 2 hrs. Max. 200mg/day.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Initial 25 -50 mg, may repeat after 2 hours if headache returns, Max. 50mg/dose;100mg/24hrs

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 50mg(22104)

ADR:

COMMON
Chest or throat pain/pressure, dizziness, fatigue, asthenia, dyspnea, flushing, numbness, sweating, burning sensation, myalgia, nausea/vomiting, diarrhea,
phonophobia, photophobia
SERIOUS
Myocardial infarction, angina, arrhythmias (rare);transient myocardial ischemia, coronary artery vasospasm, hypertensive crises.

NOTE: 室溫儲存

1.Each tab contains sumatriptan succinate 70mg. Dosage and strength are expressed in terms of sumatriptan base(50 mg/tab).
2.Contraindications: ergot agent or serotonin agonist 5HT1 within 24hr, hemiplegic/basilar migraine, ischemic cardiac, cerebrovascular or peripheral vascular syndromes, MAOI therapy within 2 wk (oral tablets), severe hepatic impairment, uncontrolled hypertension, underlying cardiovascular disease

藥名相似: Tab: 50mg(22104)

外觀相似:

外觀描述: 淡橘色三角形錠，一面有"GS" "1YM"，另一面有"50"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024380

14.18 Antimigraine Agents

23160 C /

Rizatan tablet 5mg "Union" "聯邦" 羅莎疼錠 5 毫克

Rizatriptan tab 5mg

Dosage: 1常備品 23160

Adult
·Migraine, acute, with or without aura: PO, 5 or 10 mg; may repeat after 2 hours, Max. 30 mg/24 hour.
·Concomitant propranolol: PO, 5 mg; Max. 3 doses in 24-hour period.

Pediatric
·Safety and efficacy have not been established in patients less than 6 years old.
·Migraine, acute, with or without aura(6-17yrs), <40 kg, PO 5 mg; Max. 1 dose/24 hr.
·Migraine, acute, with or without aura(6-17 yrs), ≧40 kg, PO 10 mg; Max. 1 dose/24 hr.

Dosing adjustments in hepatic impairment:

Mild or moderate hepatic faiilure: use with caution
Severe hepatic failure: not recommended

Dosing adjustments in renal impairment:

Mild or moderate renal faiilure: use with caution
Severe renal failure: not recommended

P: Tab: 5mg(23160)

ADR:

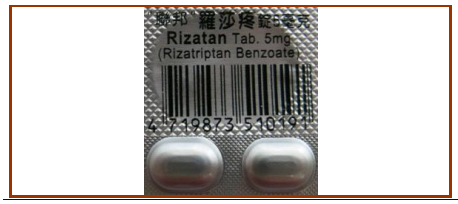
COMMON
Nausea, asthenia, dizziness, somnolence, fatigue.
SERIOUS
Chest pain, coronary artery spasm, hypertension, myocardial infarction, peripheral ischemia, ventricular arrhythmia, ischemic colitis, anaphylaxis, angioedema, analgesic overuse headache, cerebrovascular accident, serotonin syndrome.

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色長橢圓形錠，一面有488字樣，另一面UN字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1052537

14.18 Antimigraine Agents

37681 ɔt be ruled out / Infant risk can

EMGALITY injection 恩疼停 注射劑

急用Galcanezumab 120mg/1mL pre-filled syringe

Dosage: 2急用藥 37681

Adult
· Migraine; prophylaxis: SC, 240 mg (2 consecutive 120-mg doses) once as a loading dose, followed by 120 mg once monthly

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Inj: 120mg/1mL prefilled syringe(37681)

ADR:

COMMON
Injection site reaction
SERIOUS
Anaphylaxis, hypersensitivity reaction, angioedema

NOTE: 冰箱冷藏，不可冷凍

·《Contraindications》Serious hypersensitivity to galcanezumab-gnlm or to any of the components of the product

藥名相似:

外觀相似:

外觀描述:

14.20 Miscellaneous

22027 **B / Caution**

EXMEM* FILM-COATED TABLETS 10 MG 拾憶膜衣錠 10 毫克

Memantine 10mg FC tab

Dosage: 1常備品 22027

Adult
· Moderate to severe dementia of the Alzheimer's disease: PO, initial 5mg qd, increased by 5mg daily at intervals of not less than 1 week. Recommended target dosage is 10mg bid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Mild to moderate renal impairment: No dosage adjustment needed
Severe renal impairment (Clcr 5-29mL/min): A target dose of 5mg bid is recommended

P: Tab: 10mg(22027)

ADR:

COMMON
Hypertension, constipation, dizziness, headache, pain

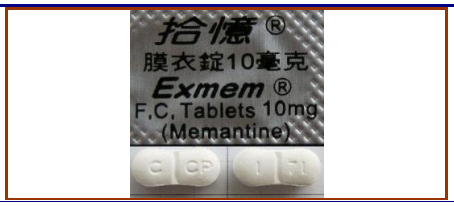
NOTE: 室溫儲存30℃以下

· Doses above 5mg/day should be given in 2 divided doses

藥名相似:

外觀相似:

外觀描述: 白色長橢圓型錠，一面有刻痕及"C | CP"字樣，另一面有刻痕及"1 | 71"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1055939

14.20 Miscellaneous

23033 **C / Caution**

Strattera* 25mg Hard Capsules 思銳膠囊

Atomoxetine 25mg Cap

Dosage: 1常備品 23033

Adult
· Attention deficit hyperactivity disorder: PO, initial 40mg/day, increase after a minimum of 3 days to a target dose of approximately 80mg/day, may administer as either a single daily dose or 2 divided doses in morning and late afternoon/early evening. May increase to Max. of 100mg/day in 2-4 additional weeks to achieve optimal response

Pediatric
·Attention deficit hyperactivity disorder: PO, ≦70kg: initial 0.5mg/kg/day, increase after minimum of 3 days to a target dose 1.2mg/kg/day, may administer as either a single daily dose or 2 divided doses in morning and late afternoon/early evening; Max.1.4mg/kg/day or 100mg/day; >70kg:same as adult

Dosing adjustments in hepatic impairment:

Moderate hepatic insufficiency (Child-Pugh class B): All doses should be reduced to 50% of normal
Severe hepatic insufficiency (Child-Pugh class C): All doses should be reduced to 25% of normal

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: 25mg(23033), 40mg(23034), 60mg(23036)

ADR:

COMMON
Increased systolic/diastolic arterial pressure, palpitations, tachycardia, pruritus, rash, weight loss, constipation, indigestion, loss of appetite, nausea, vomiting, xerostomia, dizziness, headache, insomnia, paresthesia, somnolence, mood swings, difficulty passing urine, urinary retention, disorder of ejaculation, dysmenorrhea, erectile dysfunction, prostatitis, reduced libido
SERIOUS
Severe injury of liver(rare), dyskinesia, seizure, suicidal thoughts, priapism(rare)

NOTE: 室溫儲存

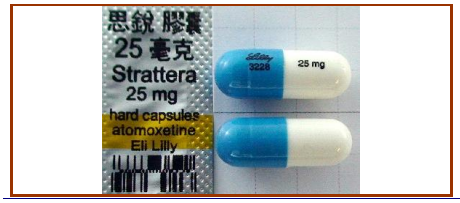
· 《Contraindications》Do not administer atomoxetine during therapy with or within 2 weeks of discontinuing an MAOI; do not administer MAOI within 2 weeks of discontinuing atomoxetine; Hypersensitivity to atomoxetine or to other components of the product; arrow angle glaucoma; Pheochromocytoma, current or history of; Severe cardiac or vascular disorders when at risk for deterioration with clinically important increase of blood pressure (eg, 15 to 20 mm Hg) or heart rate

(eg, 20 beats per minute)；

藥名相似:

外觀相似:

外觀描述: 白/藍色膠囊，有25mg及Lilly 3228字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024516

14.20 Miscellaneous

23034 **C / Caution**

Strattera* 40mg Hard Capsules 思銳膠囊40毫克

Atomoxetine 40mg Cap

Dosage: 1常備品 23034

Adult

· Attention deficit hyperactivity disorder: PO, initial 40mg/day, increase after a minimum of 3 days to a target dose of approximately 80mg/day, may administer as either a single daily dose or 2 divided doses in morning and late afternoon/early evening. May increase to Max. of 100mg/day in 2-4 additional weeks to achieve optimal response

Pediatric

·Attention deficit hyperactivity disorder: PO, ≦70kg: initial 0.5mg/kg/day, increase after minimum of 3 days to a target dose 1.2mg/kg/day, may administer as either a single daily dose or 2 divided doses in morning and late afternoon/early evening; Max.1.4mg/kg/day or 100mg/day; >70kg:same as adult

Dosing adjustments in hepatic impairment:

Moderate hepatic insufficiency (Child-Pugh class B): All doses should be reduced to 50% of normal
Severe hepatic insufficiency (Child-Pugh class C): All doses should be reduced to 25% of normal

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: 40mg(23034), 25mg(23033), 60mg(23036)

ADR:

COMMON
Increased systolic/diastolic arterial pressure, palpitations, tachycardia, pruritus, rash, weight loss, constipation, indigestion, loss of appetite, nausea, vomiting, xerostomia, dizziness, headache, insomnia, paresthesia, somnolence, mood swings, difficulty passing urine, urinary retention, disorder of ejaculation, dysmenorrhea, erectile dysfunction, prostatitis, reduced libido
SERIOUS
Severe injury of liver(rare), dyskinesia, seizure, suicidal thoughts, priapism(rare)

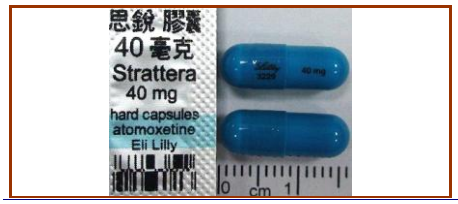
NOTE: 室溫儲存

· 《Contraindications》Do not administer atomoxetine during therapy with or within 2 weeks of discontinuing an MAOI; do not administer MAOI within 2 weeks of discontinuing atomoxetine; Hypersensitivity to atomoxetine or to other components of the product; arrow angle glaucoma; Pheochromocytoma, current or history of; Severe cardiac or vascular disorders when at risk for deterioration with clinically important increase of blood pressure (eg, 15 to 20 mm Hg) or heart rate (eg, 20 beats per minute)；

藥名相似:

外觀相似:

外觀描述: 藍色膠囊，有40mg及Lilly 3229字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024517

14.20 Miscellaneous

23036 **C / Caution**

STRATTERA* 60mg cap 思銳膠囊

Atomoxetine 60mg Cap

Dosage: 1常備品 23036

Adult

· Attention deficit hyperactivity disorder: PO, initial 40mg/day, increase after a minimum of 3 days to a target dose of approximately 80mg/day, may administer as either a single daily dose or 2 divided doses in morning and late afternoon/early evening. May increase to Max. of 100mg/day in 2-4 additional weeks to achieve optimal response

Pediatric

·Attention deficit hyperactivity disorder: PO, ≦70kg: initial 0.5mg/kg/day, increase after minimum of 3 days to a target dose 1.2mg/kg/day, may administer as either a single daily dose or 2 divided doses in morning and late afternoon/early evening; Max.1.4mg/kg/day or 100mg/day; >70kg:same as adult

Dosing adjustments in hepatic impairment:

Moderate hepatic insufficiency (Child-Pugh class B): All doses should be reduced to 50% of normal
Severe hepatic insufficiency (Child-Pugh class C): All doses should be reduced to 25% of normal

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: 60mg(23036), 25mg(23033), 40mg(23034)

ADR:

COMMON
Increased systolic/diastolic arterial pressure, palpitations, tachycardia, pruritus, rash, weight loss, constipation, indigestion, loss of appetite, nausea, vomiting, xerostomia, dizziness, headache, insomnia, paresthesia, somnolence, mood swings, difficulty passing urine, urinary retention, disorder of ejaculation, dysmenorrhea, erectile dysfunction, prostatitis, reduced libido
SERIOUS
Severe injury of liver(rare), dyskinesia, seizure, suicidal thoughts, priapism(rare)

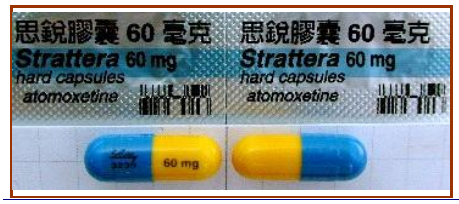
NOTE: 室溫儲存

·《Contraindications》Do not administer atomoxetine during therapy with or within 2 weeks of discontinuing an MAOI; do not administer MAOI within 2 weeks of discontinuing atomoxetine; Hypersensitivity to atomoxetine or to other components of the product; arrow angle glaucoma; Pheochromocytoma, current or history of; Severe cardiac or vascular disorders when at risk for deterioration with clinically important increase of blood pressure (eg, 15 to 20 mm Hg) or heart rate (eg, 20 beats per minute) ;

藥名相似:

外觀相似:

外觀描述: 黃/藍色膠囊，有60mg及Lilly 3239字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024518

14.20 Miscellaneous

23037 X / No report(毫

Priligy* film-coated tablet 30mg 必利勁膜衣錠30毫克

Dapoxetine 30mg tab

Dosage: 1常備品 23037

Adult

·Treatment of premature ejaculation in men 18 to 64 years of age：PO,30 mg ,1 to 3 hours prior to sexual activity. The maximum recommended dosing frequency is once every 24 hours.

Pediatric

·Should not be used in individuals below 18 years of age.

Dosing adjustments in hepatic impairment:

Contraindicated in patients with moderate and severe hepatic impairment (Child-Pugh Class B and C).

Dosing adjustments in renal impairment:

Caution is advised in patients with mild or moderate renal impairment.
Not recommended for use in patients with severe renal impairment.

P: Tab: 30mg (23037)

ADR:

COMMON
Headache, dizziness, nausea, diarrhea, insomnia, fatigue, anxiety, agitation, libido decreased, abnormal dreams, restlessness, blurred vision, erectile dysfunction, somnolence, disturbance in attention
SERIOUS
Syncope, loss of consciousness, orthostatic hypotension

NOTE: 室溫儲存

Tablet should be swallowed whole and taken with at least one full glass of water to avoid the bitter taste.

藥名相似:

外觀相似:

外觀描述: 淺灰色圓凸錠，一面有三角形刻痕，內有"30"字樣)

14.20 Miscellaneous

27513 C / Caution

LAIDEC FC TABLETS 50MG 解凍膜衣錠 5 0 毫克

急用Riluzole 50mg tab

Dosage: 2急用藥 27513

Adult

·Amyotrophic lateral sclerosis: PO, ac, 50mg q12h

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Hepatic disease or baseline transaminases >3X ULN is contraindicated
Baseline elevations of several liver function tests (especially elevated bilirubin) should preclude use

Dosing adjustments in renal impairment:

NDA. Not recommended for use

P: Tab: 50mg(27513)

ADR:

COMMON
Hypertension, tachyarrhythmia, circumoral paresthesia, abdominal pain, diarrhea, loss of appetite, nausea, vomiting, arthralgia, asthenia, dizziness, somnolence, vertigo, pneumonia
SERIOUS
Cardiac arrest, neutropenia, ALT (SGPT) level raised, jaundice(rare), respiratory depression

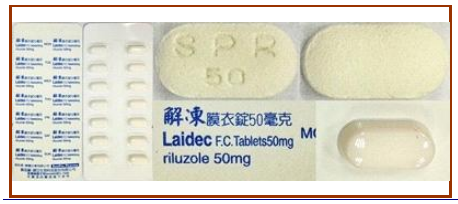
NOTE: 室溫儲存

·Because food decreases oral bioavailability, please take riluzole at least 1 hour before or 2 hours after a meal

藥名相似:

外觀相似:

外觀描述: 白色長橢圓錠，有SPR 50字樣



14.20 Miscellaneous

27559 C / Unsafe

Xenazine 25mg 止蹈劑25毫克

急用Tetrabenazine 25mg tab

Dosage: 2急用藥 27559

Adult

· Huntington's chorea: PO, initial 12.5 mg qd, then increase to 12.5 mg bid after 1 wk; dosage may be increased in 12.5-mg increments at weekly intervals. Daily dose ≧37.5 mg should be given in 3 divided doses.

Pediatric

· Safety and efficacy not established in children

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 25mg(27559)

ADR:

COMMON
Nausea, Insomnia, Sedated, Somnolence, Anxiety, Fatigue.
SERIOUS
Orthostatic hypotension, Prolonged QT interval, Syncope, Hyperprolactinemia, Dysphagia, Akathisia, Parkinsonism, Depression, Suicidal thoughts, Neuroleptic malignant syndrome.

NOTE: 室溫儲存

· Patients should be observed closely for worsening or emergence of depression, suicidal thoughts or behavior
· Max dose for CYP2D6 extensive/intermediate metabolizers: 37.5 mg/dose, 100 mg/day; for poor metabolizers: 25 mg/dose, 50 mg/day
· If treatment is interrupted for >5 days, retitration is recommended

藥名相似:

外觀相似:

外觀描述: 暗黃色圓柱錠，一面有CL 25字樣，一面有一刻痕

14.20 Miscellaneous

27620 ɔt be ruled out / Infant risk can

TECFIDERA* 120mg Gastro-resistant Hard Capsule 泰福德膠囊120毫克

急用Dimethyl fumarate 120mg cap

Dosage: 2急用藥 27620

Adult

· relapsing remitting multiple sclerosis : PO, initial 120 mg bid .After 7 days, MD 240 mg bid.(give with food to decrease flushing)

Pediatric

· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: P Cap: 120mg(27620), 240mg(27621)

ADR:

COMMON
Flushing, Rash, Abdominal pain, Diarrhea, Nausea, Vomiting
SERIOUS
Lymphocytopenia, AST/SGOT level raised, Injury of liver, Anaphylaxis, Infectious disease, Progressive multifocal leukoencephalopathy, Angioedema

NOTE: 室溫儲存

· Temporary dose reduction to 120 mg twice a day may reduce the occurrence of flushing and gastrointestinal adverse reactions. Within 1 month, the recommended maintenance dose of 240 mg twice a day should be resumed.

藥名相似:

外觀相似:

外觀描述: 淺綠色/白色硬膠囊，有BG-12 120 mg 字樣。

14.20 Miscellaneous

27621 ɔt be ruled out / Infant risk can

TECFIDERA* 240mg Gastro-resistant Hard Capsule 泰福德膠囊240毫克

急用Dimethyl fumarate 240mg cap

Dosage: 2急用藥 27621

Adult

· relapsing remitting multiple sclerosis : PO, initial 120 mg bid .After 7 days, MD 240 mg bid .(give with food to decrease flushing)

Pediatric

· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: P Cap: 120mg(27620), 240mg(27621)

ADR:

COMMON
Flushing, Rash, Abdominal pain, Diarrhea, Nausea, Vomiting
SERIOUS
Lymphocytopenia, AST/SGOT level raised, Injury of liver, Anaphylaxis, Infectious disease, Progressive multifocal leukoencephalopathy, Angioedema

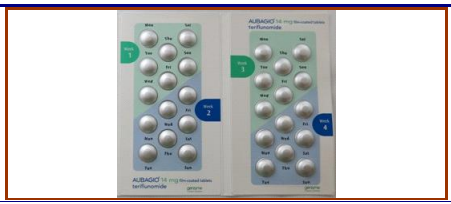
NOTE: 室溫儲存

· Temporary dose reduction to 120 mg twice a day may reduce the occurrence of flushing and gastrointestinal adverse reactions. Within 1 month, the recommended maintenance dose of 240 mg twice a day should be resumed.

藥名相似:

外觀相似:

外觀描述: 淺綠色硬膠囊，有BG-12 240 mg 字樣。



14.20 Miscellaneous

27623 **demonstrated / Infant risk can**

AUBAGIO* film coated tablet 14 mg 歐博捷膜衣錠14毫克

急用Teriflunomide 14mg tab

Dosage: 2急用藥 27623

Adult

· Multiple sclerosis, Relapsing forms : PO,7mg or 14 mg QD.

Pediatric

· Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

mild or moderate: No adjustment necessary
severe: Use contraindicated

Dosing adjustments in renal impairment:

P: P: tab (27623)

ADR:

COMMON
alopecia, diarrhea, nausea, increased liver enzymes, headache
SERIOUS
Stevens-Johnson syndrome, toxic epidermal necrolysis, neutropenia, liver failure, drug reaction with eosinophilia and systemic symptoms, peripheral neuropathy, serum creatinine raised, interstitial lung disease

NOTE: 室溫儲存

1.Prior to therapy initiation, rule out pregnancy in women with reproductive potential.
2.Discontinuation of therapy: Without an accelerated elimination procedure, it may take an average of 8 months and up to 2 years to achieve blood levels less than 0.02 mg/L.
3.Accelerated elimination procedure: To achieve nondetectable serum concentrations (<0.02 mg/L) of teriflunomide administer either of the following
· Cholestyramine 8g is administered 3 times daily for a period of 11 days, or cholestyramine 4g three times a day can be used, if cholestyramine 8g three times a day is not well tolerated.
· alternatively, 50g of activated powdered charcoal is administered every 12 hours for a period of 11 days.

藥名相似:

外觀相似:

外觀描述: 淡藍五角膜衣錠，一面有"14"，另一面印公司商標

16.10 Ophthalmic Practice

32864 C / Unknown(有

DIAGNOGREEN INJECTION 循血綠注射劑

Indocyanine green (ICG) 25mg vial

Dosage: 1常備品 32864

Adult
· Arterial blood flow test, Hepatic: IV, 0.5mg/kg.
· Cardiac output monitoring: IV, 5 mg via a cardiac catheter, an average of 5 dilution curves are needed in a diagnostic cardiac catheterization; not to exceed 2 mg/kg.
· Liver function tests - general: IV, 0.5 mg/kg.
· Ophthalmic fluorescence imaging: up to 40 mg in 2 mL of aqueous solvent IV; inject bolus into the antecubital vein, followed by a 5 mL bolus of normal saline .

Pediatric
· Arterial blood flow test, Hepatic: IV, 0.5 mg/kg.
· Cardiac output monitoring: IV rapidly, via a cardiac catheter, an average of 5 dilution curves are needed in a diagnostic cardiac catheterization; not to exceed 2 mg/kg. Children, 2.5 mg. Infants, 1.25 mg.
· Liver function tests - general: IV, 0.5 mg/kg.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj : 25mg pow in vial (with 10ml sterile water for inj) (32864)

ADR:

Anaphylactoid reactions, local skin discoloration

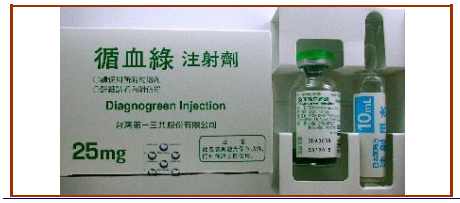
NOTE: 室溫保存

Contraindications: Allergy to iodide, Patients at higher risk for anaphylactic reactions

藥名相似:

外觀相似:

外觀描述: 暗綠青色乾粉、『綠』蓋透明玻璃小瓶附10ml稀釋液透明安瓿



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2018254

16.14 Radiographic Examination of the G-I Tract

35321 B / Unknown(有

GLUCAGEN 1 MG 昇糖精

Glucagon 1mg (1 IU)

Dosage: 1常備品 35321

·Hypoglycemia :>20kg IM;IV;SC :1mg
·Diagnostic use
for examination of the stomach, duodenum and small intestine : IM, 1-2mg or IV,0.25-2mg 10min before the examination
for examination of the colon : IM, 2mg 10 min before the examination
·Assessing of β-cell secretion:IV,1mg into fasting patients plasma C-peptide is measured before and 6 min after injection

·Hypoglycemia:
< 20Kg IM, IV, SC: 0.5 mg or the equivalent of 20 to 30 mcg/kg.
> 20Kg IM, IV, SC: 1mg.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 1mg(1 unit) pow in vial with 1ml of diluting solution (35321)

ADR:

COMMON
nausea, vomiting
SERIOUS
necrolytic migratory erythema, anaphylaxis.

NOTE: 冰箱保存2-8℃

1.Glucagon should not be administered at concentrations greater than 1 mg/ml. Glucagon should be reconstituted with the diluting solution provided . Reconstituted solutions should be used immediately; any unused portion should be discarded.
2.Contraindications: (1)Hypersensitivity to glucagon, lactose, or any other components of the product. (2)Insulinoma. (3)Pheochromocytoma.

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『橙』蓋透明玻璃小瓶，1mL稀釋液『白』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000735

16.18 Thyroid Function

32896 UK / Unknown(有

THYROGEN 1.1MG/VIAL 適諾進凍晶注射劑 1.1毫克

Thyrotropin alfa inj 1.1mg vial

Dosage: 1常備品 32896

Adult
· Adjunctive diagnostic tool for differentiated thyroid cancer: IM, 0.9mg q24h for 2 doses or q72h for 3 doses

Pediatric(> 16yrs)
· Adjunctive diagnostic tool for differentiated thyroid cancer: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 1.1mg Vial(32896)

ADR:

COMMON
Nausea, vomiting, asthenia, headache
SERIOUS
Anaphylactoid reaction (with repeated administration)

NOTE: 冰箱避光

· After reconstitution with 1.2mL sterile water for injection, 1mL of the resulting solution(0.9mg/mL) should be administered into the buttock
· For radioiodine imaging, radioiodine administration should be given 24hrs following final Thyrogen* injection. Scanning should be performed 48hrs after radioiodine administration.
· For serum testing, serum thyroglobulin should be obtained 72hrs after final injection of Thyrogen*.

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『藍』蓋透明玻璃小瓶

16.22 Ovulation test

29044 **/ Unknown(有**

"BIOTRON" ONE STEP LH TEST "立知圓" 排卵測試

LH ovulation test

Dosage: 1常備品 29044

For in vitro gualitative determination of human luteinizing hormone in urine to predict the time of ovulation

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Device:6 tests(29044)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=44001130

16.26 Radiopharmaceutical Agents

32906 **X / Infant risk has**

PPhB Sodium Iodide【131I】Capsules 士宣放射性碘化鈉【131I】膠囊

(建檔)■PPhB Sodium Iodide (I-131) Cap 100 uCi

Dosage: 1常備品 32906

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and

discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

16.26 Radiopharmaceutical Agents

32907 **X / Infant risk has**

PPhB Sodium Iodide【131I】Capsules 士宣放射性碘化鈉【131I】膠囊

(建檔)■PPhB Sodium Iodide (I-131) Cap 2 mCi

Dosage: 1常備品 32907

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

16.26 Radiopharmaceutical Agents

32908 **X / Infant risk has**

PPhB Sodium Iodide【131I】Capsules 士宣放射性碘化鈉【131I】膠囊

(建檔)■PPhB Sodium Iodide (I-131) Cap 6 mCi

Dosage: 1常備品 32908

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

16.26 Radiopharmaceutical Agents

32909 X / Infant risk has

PPhB Sodium Iodide【131I】Capsules 士宣放射性碘化鈉【131I】膠囊

(建檔)■PPhB Sodium Iodide (I-131) Cap 10 mCi

Dosage: 1常備品 32909

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

16.26 Radiopharmaceutical Agents

32910 X / Infant risk has

PPhB Sodium Iodide 【131I】Capsules 士宣放射性碘化鈉【131I】膠囊

(建檔)■PPhB Sodium Iodide (I-131) Cap 30 mCi

Dosage: 1常備品 32910

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

16.26 Radiopharmaceutical Agents

32921 X / Infant risk has

SODIUM IODIDE (131 I) THERAPY CAPSULES 1 3 1 - I 碘化鈉治療膠囊

(建檔)■SODIUM IODIDE (I-131) Cap 6 mCi

Dosage: 1常備品 32921

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩

)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2R00063

16.26 Radiopharmaceutical Agents

32922 X / Infant risk has

SODIUM IODIDE (131 I) THERAPY CAPSULES 1 3 1 - I 碘化鈉治療膠囊

(建檔)■SODIUM IODIDE (I-131) Cap 10 mCi

Dosage: 1常備品 32922

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2R00063

16.26 Radiopharmaceutical Agents

32923 X / Infant risk has

SODIUM IODIDE (131 I) THERAPY CAPSULES 1 3 1 - Ⅰ碘化鈉治療膠囊

(建檔)■SODIUM IODIDE (I-131) Cap 30 mCi

Dosage: 1常備品 32923

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2R00063

16.26 Radiopharmaceutical Agents

32924 X / Infant risk has

SODIUM IODIDE (131 I) THERAPY CAPSULES 1 3 1 - Ⅰ碘化鈉治療膠囊

(建檔)■SODIUM IODIDE (I-131) Cap 100 uCi

Dosage: 1常備品 32924

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

16.26 Radiopharmaceutical Agents

32931 **X / Infant risk has**

SODIUM IODIDE (131 I) THERAPY CAPSULES 1 3 1 - I 碘化鈉治療膠囊

(建檔)■SODIUM IODIDE (I-131) Cap 2 mCi

Dosage: 1常備品 32931

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2R00063

16.26 Radiopharmaceutical Agents

32955 X / Infant risk has

SODIUM IODIDE (131 I) THERAPY CAPSULES 1 3 1 - I 碘化鈉治療膠囊

(建檔)■SODIUM IODIDE (I-131) Cap 75 mCi

Dosage: 1常備品 32955

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

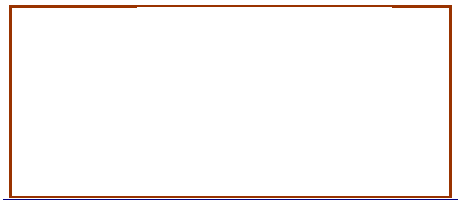
NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:



16.26 Radiopharmaceutical Agents

32956 X / Infant risk has

SODIUM IODIDE (131 I) THERAPY CAPSULES 1 3 1 - I 碘化鈉治療膠囊

(建檔)■SODIUM IODIDE (I-131) Cap 100 mCi

Dosage: 1常備品 32956

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

16.26 Radiopharmaceutical Agents

32957 **X / Infant risk has**

SODIUM IODIDE (131 I) THERAPY CAPSULES 1 3 1 - Ⅰ碘化鈉治療膠囊

(建檔)■SODIUM IODIDE (I-131) Cap 120 mCi

Dosage: 1常備品 32957

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

16.26 Radiopharmaceutical Agents

32958 **X / Infant risk has**

SODIUM IODIDE (131 I) THERAPY CAPSULES 1 3 1 - Ⅰ碘化鈉治療膠囊

(建檔)■SODIUM IODIDE (I-131) Cap 150 mCi

Dosage: 1常備品 32958

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue

antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

16.26 Radiopharmaceutical Agents

32959 **X / Infant risk has**

SODIUM IODIDE (131 I) THERAPY CAPSULES 1 3 1 - I 碘化鈉治療膠囊

(建檔)■SODIUM IODIDE (I-131) Cap 200 mCi

Dosage: 1常備品 32959

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months

after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

16.26 Radiopharmaceutical Agents

32966 /

TECHNELITE*(TECHNETIUM TC-99M GENERATOR FOR DIAGNOSTIC USE) 鎝ＴＣ－９９Ｍ孳生器

■Technetium Tc 99m Generator for Diagnostic Use

Dosage: 1常備品 32966

Adult

Pediatric

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P:

ADR:

NOTE: 室溫避光儲存

藥名相似:

外觀相似:

外觀描述:

16.26 Radiopharmaceutical Agents

32967 /

INER MIBI KIT 核研美必鎝心臟造影劑

(建檔)TETKIS(M.I.I)COPPER(1) TETRAFLUOROBORATE

Dosage: 1常備品 32967

Adult

Pediatric

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P:

ADR:

NOTE: 室溫避光儲存

藥名相似:

外觀相似:

外觀描述:

16.26 Radiopharmaceutical Agents

32970 X / Infant risk has

PPhB Sodium Iodide【131I】Capsules 士宣放射性碘化鈉【131I】膠囊

(建檔)■PPhB Sodium Iodide (I-131) Cap 75 mCi

Dosage: 1常備品 32970

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩

)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

16.26 Radiopharmaceutical Agents

32971 **X / Infant risk has**

PPhB Sodium Iodide【131I】Capsules 士宣放射性碘化鈉【131I】膠囊

(建檔)■PPhB Sodium Iodide (I-131) Cap 100 mCi

Dosage: 1常備品 32971

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

16.26 Radiopharmaceutical Agents

32972 X / Infant risk has

PPhB Sodium Iodide【131I】Capsules 士宣放射性碘化鈉【131I】膠囊

(建檔)■PPhB Sodium Iodide (I-131) Cap 120 mCi

Dosage: 1常備品 32972

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

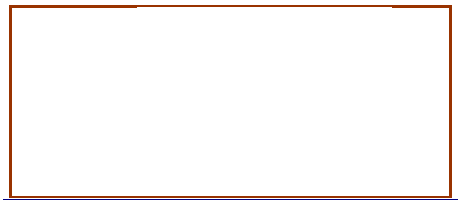
NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:



16.26 Radiopharmaceutical Agents

32973 X / Infant risk has

PPhB Sodium Iodide【131I】Capsules 士宣放射性碘化鈉【131I】膠囊

(建檔)■PPhB Sodium Iodide (I-131) Cap 150 mCi

Dosage: 1常備品 32973

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

16.26 Radiopharmaceutical Agents

32974 **X / Infant risk has**

PPhB Sodium Iodide【131I】Capsules 士宣放射性碘化鈉【131I】膠囊

(建檔)■PPhB Sodium Iodide (I-131) Cap 200 mCi

Dosage: 1常備品 32974

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

16.26 Radiopharmaceutical Agents

32981 **X / Infant risk has**

Sodium iodide Na131I POLATOM, capsules for therapeutic use "波特蘭" 碘-131治療用膠囊

(建檔)■POLATOM Sodium Iodide (I-131) Cap 100 mCi

Dosage: 1常備品 32981

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue

antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

16.26 Radiopharmaceutical Agents

32982 **X / Infant risk has**

Sodium iodide Na131I POLATOM, capsules for therapeutic use "波特蘭" 碘-131治療用膠囊

(建檔)■POLATOM Sodium Iodide (I-131) Cap 120 mCi

Dosage: 1常備品 32982

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

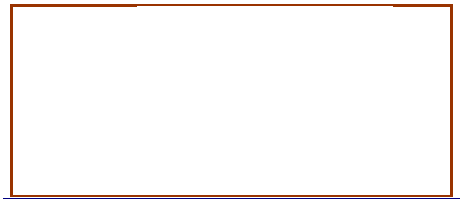
1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months

after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:



16.26 Radiopharmaceutical Agents

32983 **X / Infant risk has**

Sodium iodide Na131I POLATOM, capsules for therapeutic use "波特蘭" 碘-131治療用膠囊

(建檔)■POLATOM Sodium Iodide (I-131) Cap 150 mCi

Dosage: 1常備品 32983

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)
·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

16.26 Radiopharmaceutical Agents

32984 **X / Infant risk has**

Sodium iodide Na131I POLATOM, capsules for therapeutic use "波特蘭" 碘-131治療用膠囊

(建檔)■POLATOM Sodium Iodide (I-131) Cap 200 mCi

Dosage: 1常備品 32984

ADULT
·Hyperthyroidism: PO, 148-370 MBq (4-10 mCi); in severely hyperthyroid patients, discontinue antithyroid therapy 3 or 4 days prior to administration of radioiodide
·Radionuclide thyroid imaging, for evaluation of thyroid function: PO, for thyroid uptake, 0.185-0.555 MBq (5-15 uCi); for scintiscanning, 1.85-3.7 MBq (50-100 uCi)
·Thyroid cancer: PO, initial, 1.1-3.7 GBq (30-100 mCi); for subsequent doses, administer 3.7-7.4 GBq (100-200 mCi)

·Thyroid cancer, metastases localization; diagnosis: PO, 37 MBq (1000 uCi)

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 100uCi(32924,新吉美碩)(32906,士宣); 2mCi(32931,新吉美碩)(32907,士宣); 6mCi(32921,新吉美碩)(32908,士宣); 10mCi(32922,新吉美碩)(32909,士宣); 30mCi(32923,新吉美碩)(32910,士宣); 75mCi(32955,新吉美碩)(32970,士宣); 100mCi(32956,新吉美碩)(32971,士宣)(32981,泰歷); 120mCi(32957,新吉美碩)(32972,士宣)(32982,泰歷); 150mCi(32958,新吉美碩)(32973,士宣)(32983,泰歷); 200mCi(32959,新吉美碩)(32974,士宣)(32984,泰歷)

ADR:

COMMON
Chest pain, tachycardia, hives, pruritus, rash, disorder of salivary gland, nausea, vomiting, disorder of lacrimal gland
SERIOUS
Thyroid storm, acute leukemia, disorder of hematopoietic structure, leukopenia, hypersensitivity reaction

NOTE: 室溫儲存

1. Contraindications: concurrent antithyroid therapy within 3 to 4 days of radioiodide administration, diarrhea, thyroid malignancies shown to have no iodide uptake (including most medullary and anaplastic carcinomas), vomiting.
2. Females and males of childbearing potential; rule out pregnancy prior to treatment; two effective methods of contraception for at least 6 months after treatment, or longer (eg, one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated, is advised.
3. Thyroiditis may occur and may cause new onset or exacerbation of hyperthyroidism or thyroid storm; consider pretreatment with antithyroid medication in patients with hyperthyroidism and discontinue antithyroid medication at least 3 days prior to administration; also consider beta blocker therapy prior to administration to minimize risk.
4. Renal function impairment; risk of decreased radioiodide excretion and increased radiation exposure; monitoring recommended.
5. Serum chlorides, low; may increase thyroid uptake of sodium iodide.

藥名相似:

外觀相似:

外觀描述:

16.28 Miscellaneous

37660 ɔt be ruled out / Infant risk can

SONAZOID* 8ul/ml, powder and solvent for dispersion for injection 立梭影注射劑8微升/毫升

Perfluorobutane Microbubbles inj 16uL/ 2mL/ vial

Dosage: 1常備品 37660

Adult
·Detection and characterization of focal liver lesions: 0.12 uL/kg up to 1 vial in a single administration.

Pediatric
·The saftey has not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 2ml/ vial(37725 捐贈), 2ml/ vial(37660)

ADR:

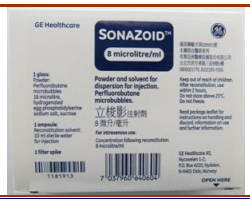
COMMON
Headache, diarrhea, nausea, vomiting, abdominal pain, transient altered taste, fever
SERIOUS
Anaphylactoid reaction, anaphylactoid shock

NOTE: 室溫儲存25℃以下，不可冷藏。

藥名相似:

外觀相似:

外觀描述: 含一注射乾粉小瓶、注射用水、刺針過濾器



18.02 Alkalinzing Agents

23601 C / Infant risk is

SODIUM BICARBONATE TABLETS 0.3 GM "F.Y." "福元" 碳酸氫鈉片 0 . 3 克

Sodium bicarbonate (NaHCO3) tab 300mg

Dosage: 1常備品 23601

Adult
·Urine alkalinization: PO, initial 48 mEq (4g); then 12- 24 mEq (1-2g) q4h; dose should be titrated to desired urinary pH
·Distal renal tubular acidosis: PO, 0.5-2 mEq/kg/day div into 4-5 doses
·Proximal renal tubular acidosis: PO, 5-10 mEq/kg/day in div doses; MD: increase as required to maintain serum bicarbonate in the normal range

Pediatric
·Urine alkalinization: PO, 1-10 mEq (84-840 mg)/kg/day in div doses; dose should be titrated to desired urinary pH
·Distal renal tubular acidosis: PO, 2-3 mEq/kg/day in div doses
·Proximal renal tubular acidosis: PO, 5-10 mEq/kg/day in div doses; MD: increase as required to maintain serum bicarbonate in the normal range

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Dosage adjustment required

P: Tab: 300mg(23601), Inj: 7%(16.7 mEq) 20 mL(33200), 7% 250mL(33455)

ADR:

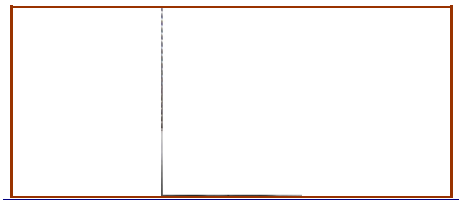
NOTE: 儲存25℃以下

Sodium bicarbonate 1 gram equals 11.9 mEq sodium and 11.9 mEq bicarbonate.(300mg=3.6mEq)

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有FY T021字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12005225

18.02 Alkalinzing Agents

23605 C / Infant risk can

DESTONE TABLETS 540MG "N.K."(POTASSIUM CITRATE) "南光"去石寧錠 5 4 0 毫克(檸檬酸鉀)

Potassium citrate 540 mg (5mEq) tab

Dosage: 1常備品 23605

Adult
·Mild-moderate hypocitraturia: PO, initial 30 mEq/day div into 3 doses with meals; Max. 100 mEq/day
·Severe hypocitraturia: PO, initial 60 mEq/day div into 3-4 doses with meals; Max. 100 mEq/day

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Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 540 mg (5 mEq) (23605)

ADR:

SERIOUS
alkalosis, electrocardiographic abnormalities (associated with hyperkalemia), hyperkalemia

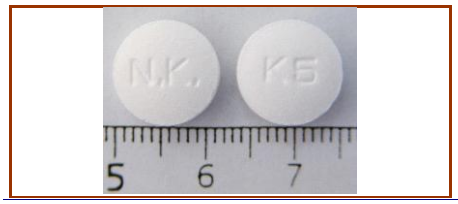
NOTE: 室溫儲存

1.Swallow whole; do not crush or chew
2.Contraindications: untreated Addison's disease, adynamia episodica hereditaria , anuria , acute dehydration, heat cramps, hyperkalemia, severe myocardial damage, severe renal impairment with oliguria or azotemia

藥名相似:

外觀相似:

外觀描述: 白色圓錠,有NK及K5字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1041577

18.02 Alkalinzing Agents

23606 C / Caution

U-CITRA GRANULES "鎰浩" 優暢粒劑

Potassium citrate monohydrate 3.3g, Citric acid monohydrate 1.002g, 5g/pk

Dosage: 1常備品 23606

ADULT
· 1pk(30mEq) tid-qid/day (in 180mL water or juice)

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Granules:3300 mg (30 mEq)(23606)

ADR:

SERIOUS
alkalosis, electrocardiographic abnormalities (associated with hyperkalemia), hyperkalemia

NOTE: 室溫儲存25℃以下

· 《Contraindications》Addison's disease, untreated; adynamia episodica hereditaria; anuria; dehydration, acute; heat cramps; hyperkalemia; myocardial damage, severe; severe renal impairment with oliguria or azotemia ;
· 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 5公克鋁箔包裝

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1031113

18.02 Alkalinzing Agents

33200 C /

SODIUM BICARBONATE* INJECTION 70MG/ML "TAI YU" 碳酸氫鈉注射液 7 0 公絲/公撮

Sodium bicarbonate (NaHCO3) 7% (16.7 mEq) 20 mL amp

Dosage: 1常備品 33200

Adult
·Cardiac arrest: IV, initial 1 mEq/kg,.If need, repeat 0.5 mEq/kg every 10 min during continued arrest
·Metabolic acidosis: IV infusion
HCO3- (mEq) = 0.2 x weight (kg) x base deficit (mEq/L) or
HCO3- (mEq) = 0.5 x weight (kg) x [24 - serum HCO3- (mEq/L)]
If acid-base status is not available: 2-5 mEq/kg over 4-8 hr; subsequent doses should be based on patient's acid-base status

Pediatric
·Cardiac arrest: IV, initial 1 mEq/kg, 0.5 mEq/kg every 10 min of arrest
·Metabolic acidosis: IV infusion
HCO3- (mEq) = 0.3 x weight (kg) x base deficit (mEq/L) or
HCO3- (mEq) = 0.5 x weight (kg) x [24 - serum HCO3- (mEq/L)]

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Dosage adjustment required

P: Tab: 300mg(23601), Inj: 7%(16.7 mEq) 20 mL(33200), 7% 250mL(33455)

ADR:

GI cramps, flatulence, alkalosis, vomiting

NOTE: 室溫儲存

For direct IV administration (cardiac arrest) in neonates and infants, use the 1:1 dilution with D5W to avoid hypertonicity and infuse at a rate <10 mEq/min.

藥名相似:

外觀相似:

外觀描述: 20mL透明注射液透明安瓿，頸部有紅點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1026772

18.06A Thiazides Diuretics

23633 B / Infant risk can

INDAP S.R. TABLETS 1.5MG "STANDARD" "生達" 迅順持續釋放錠1.5毫克

Indapamide SR 1.5 mg FC tab

Dosage: 1常備品 23633

Adult
·Hypertension: PO, 1.5 mg qd; preferably in the morning.

--

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Dosage adjustment required

P: Tab: Natrilix* SR(23633), Bi-Preterax*(22489)

ADR:

COMMON
Postural hypotension, vasculitis, dizziness, headache, paresthesias, tiredness, electrolyte abnormalities, hyperuricemia
flushing, hives, pruritus, rash
SERIOUS
arrhythmias, Stevens-Johnson syndrome, toxic epidermal necrolysis

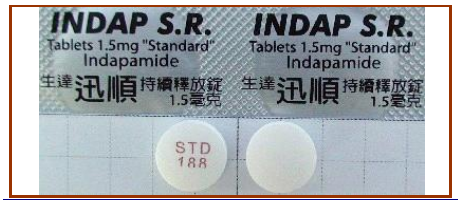
NOTE: 室溫儲存

1. 1.5 mg indapamide sustained release and 2.5mg immediate release are statistically and clinicaly equivalent in antihypertensive efficacy.
2. Swallow whole; do note or chew
3. Contraindications: anuria

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，有"STD"及"188"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1047372

18.06A Thiazides Diuretics

23640 C / Infant risk can

TRICOZIDE* TABLETS "JOHNSON" "強生"多利固財錠

Trichlormethiazide 2mg tab

Dosage: 1常備品 23640

Adult
·Edema or Hypertension: PO, 2-4mg/day

Pediatric (not approved by FDA)
·Edema & hypertension (children >6 months): PO, 0.07mg/kg/24hrs or 2mg/square meter/24hrs.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Not used in patients with a serum creatinine or urea nitrogen level greater than 2.5mg/dL

P: Tab: 2mg(23640)

ADR:

Hypokalemia, hyperuricemia, dizziness, headache

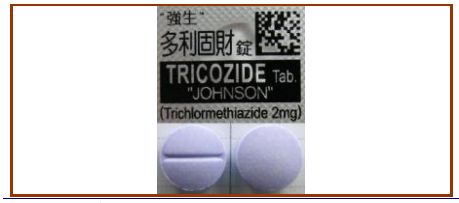
NOTE: 室溫儲存

·《Contraindications》Anuria; Hypersensitivity to trichlormethiazide or other sulfonamides；
·外露皮膚如發生紅疹建議停止治療，若需再用藥，應有防曬。

藥名相似: Tab: 2mg(23640)

外觀相似:

外觀描述: 粉紫色圓扁錠，一面中間有刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12008138

18.06B Loop Diuretics

23634 C / Unsafe

URETROPIC TABLETS 通舒錠

Furosemide 40mg tab

Dosage: 1常備品 23634

Adult
·Edema: PO, initial 20-80 mg as a single dose, may be increased by 20-40 mg q6-8h as needed; Max. 600 mg/day
·Hypertension: PO, 40 mg bid

Pediatric
·Edema: PO
Neonates: 1-4 mg/kg/dose qd-bid
Infants & children: 1-6 mg/kg/day div q6-12h

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Patients in renal failure may require higher than usual doses to induce diuresis.

P: Tab: 40mg(23634), Soln: 10mg/mL, 30mL/B(28803, 專案進口用藥), 120mL/B(28807, 急用藥), Inj: 20mg/2mL amp(33262)

ADR:

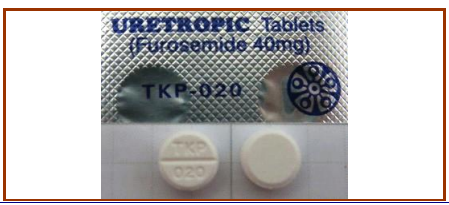
NOTE: 室溫儲存

Contraindications: anuria

藥名相似:

外觀相似: Diazepam 2mg Tab(23009), Colchicine 0.5mg

外觀描述: 白色圓扁錠，一面中間有刻痕，並有TKP及020字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1001047

18.06B Loop Diuretics

27544 C / Unsafe

BUSIX TABLETS 1.0MG "信東" 必得寧錠 1 毫克

Bumetanide 1mg tab

Dosage: 1常備品 27544

Adult
·Edema: PO, initial 1mg/day as a single dose, may be repeated at 6-8 hr intervals as needed; Max. 40mg/day

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P: Tab: 1mg(27544); Inj: 2mg/4mL Amp(33265)

ADR:

COMMON
Hypotension, Hyperuricemia, Hypochloremia, Hypokalemia, Nausea, Cramp, Dizziness, Headache, Azotemia
SERIOUS
Stevens-Johnson syndrome, Thrombocytopenia, Encephalopathy

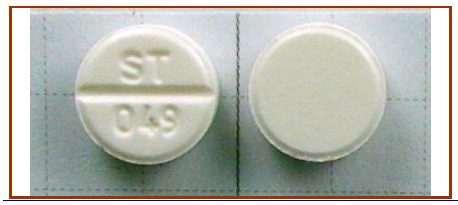
NOTE: 室溫儲存

·Bumetanide 1mg is approximately equivalent to furosemide 40mg

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面中間有刻痕、有 ST 及 049 字樣。



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1028079

18.06B Loop Diuretics

28807 C / Unsafe

FUMIDE OREAL SOLUTION 10MG/ML "PURZER" "瑞安" 福滿內服液劑 1 0 公絲/公撮

Furosemide oral soln 10mg/mL, 120mL/bot

Dosage: 1常備品 28807

ADULT
·

Pediatric
· Edema: PO, Initial 1-2mg/kg/dose, dosage may be increased by 1-2mg/kg every 6-8 hour; Max. 6mg/kg/dose

Dosing adjustments in hepatic impairment:

Cirrhotic patients have a diminished diuretic effect and may require high dose

Dosing adjustments in renal impairment:

Patients in renal failure may require high doses

P: Tab: 40mg(23634), Soln: 10mg/mL, 30mL/B(28803, 專案進口用藥), 10mg/mL, 120mL/B(28807, 急用藥), Inj: 20mg/2mL amp(33262)

ADR:

COMMON
Hyperuricemia, hypomagnesemia, loss of appetite, spasm of bladder
SERIOUS
Orthostatic hypotension, erythema multiforme, Stevens-Johnson syndrome, pancreatitis, agranulocytosis (rare), aplastic anemia (rare), thrombocytopenia

NOTE: 室溫避光儲存

·《Contraindications》Anuria; History of hypersensitivity to furosemide ；
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 120mL口服液，褐色玻璃瓶，白色紙盒裝，黑字及藍色圖紋

18.06B Loop Diuretics

33262 C / Unknown(有

ROSIS* IV INJECTION "VPP" "榮民"樂泄靜脈注射液

Furosemide inj 20 mg/2 mL amp

Dosage: 1常備品 33262

Adult
·Edema: IV(over 1-2 min)/IM, initial 20-40 mg; may repeat same dose 2 hr later or may be increased by 20 mg until desired response
·Edema: continuous IV infusion, 0.05 mg/kg/hr, titrate to effect.

Pediatric
·Edema: IV(over 1-2 min)/IM
Neonates: 1-2 mg/kg/dose q12-24h
Infants & children: 1-2 mg/kg/dose q6-12h
·Edema: continuous IV infusion, 0.05 mg/kg/hr, titrate to effect

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Patients in renal failure may require higher than usual doses to induce diuresis.

P: Tab: 40mg(23634), Soln: 10mg/mL, 30mL/B(28803, 專案進口用藥), 120mL/B(28807, 急用藥), Inj: 20mg/2mL amp(33262)

ADR:

NOTE: 室溫避光15-30℃

Contraindications: anuria

藥名相似:

外觀相似:

外觀描述: 2mL透明注射液『棕』色安瓿頸部有白點，白底藍字標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1027928

18.06B Loop Diuretics

33265 D /

BURINEX INJECTION 0.5MG/ML "理奧"必瑞注射液0.5毫克 / 毫升

Bumetanide inj 2mg/ 4mL amp

Dosage: 1常備品 33265

Adult
·Edema: IV/IM (over 1-2 min), initial 0.5-1 mg, repeated doses may be given at intervals of 2-3 hr, Max. 10 mg/day

Pediatric
·Edema: IV/IM (over 1-2 min)
> 6 mon: 0.015-0.1 mg/kg/dose qd-qod, Max. 10 mg/day

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 2mg/4mL(33265)

ADR:

COMMON
muscle cramps, dizziness, hypotension, headache, hypokalemia, hyperuricemia, nausea
SERIOUS
thrombocytopenia

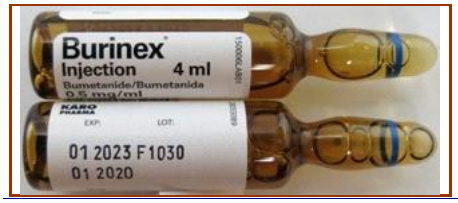
NOTE: 室溫儲存

Contraindications: anuria; hepatic coma; severe electrolyte depletion

藥名相似:

外觀相似:

外觀描述: 4mL透明注射液『棕』色安瓿頸部有一白點，一藍色線條。



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2019109

18.06C Potassium- Sparing Diuretics

23636 ɔt be ruled out / Infant risk can

SPIRONOLACTONE* TABLETS "ROYAL" "皇佳" 歐得通錠（蘇拉通）

Spironolactone 25mg tab

Dosage: 1常備品 23636

Adult
·Edema: PO, initial 100mg/day (range 25-200mg/day) in single or divided doses. Max. 400mg/day; administered at least 5 days when used

alone
·Congestive heart failure: PO, initial 12.5-25mg daily, increased to 50mg daily after 8 wks with no hyperkalemia(< 5.5mEq/L). If hyperkalemia, decreased to 25mg every other day
·Hyperaldosteronism:Diagnosis test, PO, 100-400 mg/day div. Into 1-2doses , Treatmen, PO, initial 400mg daily & MD 100-300mg daily
·Hypertension: PO, initial 50-100mg/day single or twice daily for 2 wks, then adjust to response (Max. 400mg/day)
·Hypokalemia: PO, 25-100mg daily
·Hirsutism (in women): PO, 50-200mg/day

Pediatric
·Edema: PO, initial 3.3 mg/kg/day in single or divided doses.Max. 200mg/24hrs
Neonates: PO, 0.5-1 mg/kg q8h
·Hyperaldosteronism (diagnosis): PO, 125-375 mg/m(2) in divided doses over 24 hrs

Dosing adjustments in hepatic impairment:

Hepatic insufficiency: initial 100-200 mg qd, MD up to 400 mg qd or qod may be considered

Dosing adjustments in renal impairment:

GFR > 50mL/min: increasing the dosing interval to every 6 to 12 hrs
GFR 10 to 50mL/min: every 12 to 24 hrs
GFR < 10mL/min: Not recommended

P: Tab: 25mg(23636)

ADR:

COMMON
drowsiness, lethargy, gynecomastia, impotence, menstrual disorders, headache, mental confusion, hyperkalemia, nausea, vomiting, abdominal cramping, gastritis, diarrhea, rash, urticaria
SERIOUS
agranulocytosis, breast cancer(cause and effect not established), gastric bleeding, gastritis, ulceration, metabolic acidosis severe hyperkalemia, systemic lupus erythematosus

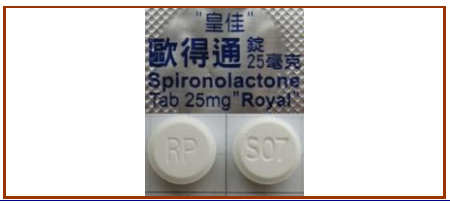
NOTE: 室溫儲存

Contraindications: anuria, hyperkalemia, acute renal insufficiency

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有"RP"，另一面有"S07"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1030526

18.06C Potassium- Sparing Diuretics

23642 **B / Unsafe**

Inspra F.C. Tablets 50mg 迎甦心 膜衣錠 50毫克

Eplerenone 50mg tab

Dosage: 1常備品 23642

Adult
· Heart failure - Post MI: PO, initial 25 mg QD; titration preferably within 4 weeks to 50 mg QD.

Pediatric
· Safety and effectiveness has not been established in pediatric patients.

Dosing adjustments in hepatic impairment:

Mild-to-Moderate Hepatic Impairment: No initial dosage adjustment is necessary.

Dosing adjustments in renal impairment:

Estimated GFR >= 50 mL/min/1.73 m(2): initial 25 mg QD. Maintenance dose, after 4 weeks with serum potassium <= 5 mEq/L, may be increased to 50 mg QD, If K+ levels increase up to 6 mEq/L or renal function worsens, hold dose until the K+ levels <= 5 mEq/L or renal impairment resolves for at least 72 hrs. Consider restarting at a reduced dose.

Estimate GFR 30 - 49 mL/min/1.73 m(2): initial 25 mg QOD. Maintenance dose, after 4 weeks with serum potassium <= 5 mEq/L, may be increased to 25 mg QD. If K+ levels increase up to 6 mEq/L or renal function worsens, hold dose until the K+ levels <= 5 mEq/L or renal impairment resolves for at least 72 hrs. Consider restarting at a reduced dose.

P: Tab: 50mg(23642)

ADR:

COMMON
Hyperkalemia, Diarrhea, Dizziness, Serum creatinine raised, Cough, Fatigue, Influenza-like illnes

NOTE: 室溫儲存

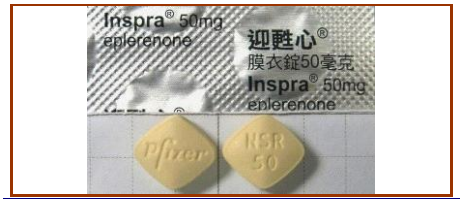
· 仿單內容變更，摘述如下： (版本USPI 201207-2)
(1)新增「NYHA第II級(慢性)心衰竭」之適應症，仿單新增有關此適應症之用法用量、不良反應及臨床研究的相關資訊。(如附件之許可證)
(2)用法用量：1.腎功能不全：(A)輕度：不須調整起始劑量(建議定期監測血鉀濃度)。(B)併有NYHA第II級(慢性)心衰竭及中度腎功能不全者(Clcr 30-60mL/min)：25mg qod並依據血鉀濃度調整劑量。c目前並無用於治療心肌梗塞後心衰竭且Clcr<50mL/min患者的經驗。這類患者使用本藥應謹慎。(D)目前尚未進行過對Clcr<50mL/min者使用劑量每天高於25mg的研究。(E)重度腎功能不全者(Clcr< 30mL/min)：禁用。
(3)禁忌：增列(A)重度腎功能不全(Clcr <30 mL/min)。(B)併用clarithromycin、telithromycin、nefazodone、nelfinavir者。c同時併用ACEI及ARB者。
(4)特殊警語及注意事項：加註(A)開始治療及劑量調整時，應監測血鉀濃度。具有高血鉀風險者，如年長者、腎功能不全者(包括有糖尿病性微量白蛋白尿的人)、糖尿病患者，應定期監測血鉀濃度。(B)本藥與ACEI及/或ARB併用時，可能會增加發生高鉀血症的風險。
(5)患者用藥須知：加註治療期間應避免併用鋰鹽(lithium)、cyclosporine及tacrolimus。
(6)藥品交互作用及其他交互作用：增列(A)不可用於接受鉀離子補充劑者。(B)本藥與ACEI及/或ARB併用時，發生高鉀血症的風險可能會增加。建議應密切監視血鉀與腎功能，尤其是有腎功能不全之風險者。不應併用ACEI、ARB及eplerenone三種藥物。c Cyclosporine及tacrolimus可能導致腎功能減退及增加高血鉀的風險，應避免與本藥併用；若須併用，則建議在合併治療期間嚴密監測血鉀及腎功能。(D)本藥併用trimethoprim會增加高血鉀的風險，應監測血鉀及腎功能。(E)當digoxin、warfarin的使用劑量接近療效範圍上限時，應小心。(F)本藥禁止併用強效CYP 3A4抑制劑如nelfinavir、clarithromycin、telithromycin、nefazodone等。

(G)本藥併用amiodarone或diltiazem時，劑量不可超過25mg。
(7)對駕駛及機械操作能力之影響：曾有少數患者發生暈眩及暈厥反應的報告。建議在初期治療的反應確定前，駕駛及操作機械時應多加小心。
(8)更新副作用之相關資訊。

藥名相似:

外觀相似:

外觀描述: 淡黃色菱型扁錠，一面有pfizer字樣，另一面有NSR及50字樣



18.06D Carbonic Anhydrase Inhibitors

23630 C / Infant risk can

ACETAZOLAMIDE* TABLETS 250MG "VPP" "榮民" 乙醯胺基硫唑嘧錠

Acetazolamide 250mg tab

Dosage: 1常備品 23630

Adult
·Diuresis : PO, 250-375 mg qd or qod, intermittently to avoid loss of diuretic effect
·Open-angle glaucoma: PO, 250 mg qd-qid
·Acute glaucoma: PO, initial 500 mg, followed by 125-250 mg q4h
·Anticonvulsant: PO, 375 mg-1g/day div. 1-4 doses
·Edema: PO, 250-375 mg daily (5 mg/kg) qd
·Acute high-altitude sickness: PO, 250 mg q 8-12h, begin 24-48h before and continued during ascent and for at least 48h after arrival at the high altitude
·Periodic paralysis: PO, 250 mg bid-tid, up to 1.5 g daily

Pediatric
·Anticonvulsant: PO, 8-30 mg/kg/day or 300-900 mg/m2/day, Max. 1 gram
·Glaucoma: PO, 8-30 mg/kg/day as divided doses q6-8h
·Edema: PO, 5 mg/kg or 150 mg/m2

Dosing adjustments in hepatic impairment:

1.Dosage adjustment required
2.If impending hepatic coma is evident, diuretics should not be used

Dosing adjustments in renal impairment:

Dosing interval increased
Clcr >50 mL/min, q6h
Clcr 10-50 mL/min, q12h
Clcr <10 mL/min should not receive the drug as it will be ineffective

P:

ADR:

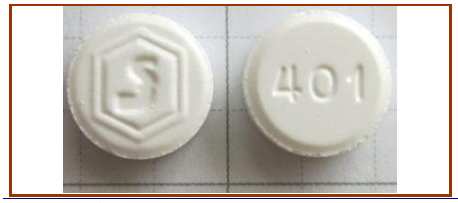
COMMON
confusion, depression, drowsiness, paresthesia, diarrhea, nausea, taste disturbances, vomiting, loss of appetite, weight loss, malaise, polyuria
SERIOUS
metabolic acidosis, sulfonamide reaction (including anaphylaxis, blood dyscrasias, erythema multiforme, fulminant hepatic necrosis, Stevens-Johnson syndrome, toxic epidermal necrolysis), tinnitus (frequent, early in therapy)

NOTE: 室溫儲存15-30℃

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有"401"字樣，另一面有商標圖案



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1003389

18.06E Osmotic Diuretics

33263 C / Unknown(有

MANITON INJECTION 滿乃通注射液

Mannitol inj 20% 100mL/bot

Dosage: 1常備品 33263

Adult
·Test dose (to assess adequate renal function): 0.2 g/kg/dose (Max. 12.5g) over 3-5 min to produce a urine flow of at least 30-50 mL/hr over the next 2-3 hrs
·Intracranial pressure (to reduce brain mass before/after neurosurgery): IV infusion(over 30-60 min), 0.5-2g/kg.
·Intraocular pressure: IV infusion(over 30-60 min), 1.5-2 g/kg, Max 6g/kg/24 hr
·Oliguria: IV infusion(over 30-60 min), initial 0.5-1 g/kg/dose, MD 0.25-0.5 g/kg q4-6h

Pediatric
>12 years: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Dosage adjustment required

P: Inj: 20% 100mL(33263), 20% 500mL(33266)

ADR:

NOTE: 室溫儲存

Contraindication: Chronic/severe renal failure or renal failure unresponsive to a test dose.

藥名相似:

外觀相似:

外觀描述: 100mL注射液，『紅』蓋玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1009633

18.06E Osmotic Diuretics

33266 C / Unknown(有

MANITON INJECTION 滿乃通注射液

Mannitol inj 20% 500 mL/bot

Dosage: 1常備品 33266

Adult
·Test dose (to assess adequate renal function):0.2 g/kg/dose (Max. 12.5g) over 3-5 min to produce a urine flow of at least 30-50 mL/hr over the next 2-3 hrs
·Intracranial pressure (to reduce brain mass before/after neurosurgery): IV infusion(over 30-60 min), 0.5-2g/kg.
·Intraocular pressure: IV infusion(over 30-60 min), 1.5-2 g/kg, Max 6g/kg/24 hr
·Oliguria: IV infusion(over 30-60 min), initial 0.5-1 g/kg/dose, MD 0.25-0.5 g/kg q4-6h

Pediatric
>12 years: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Dosage adjustmetn required

P: Inj: 20% 100mL(33263), Inj: 20% 300mL(33264)

ADR:

COMMON
chest pain, hypotension, palpitations, tachycardia, diarrhea, headache, fluid and electrolyte imbalance (eg, hypernatremia, hyponatremia, hyperkalemia) nausea, vomiting, rhinitis, xerostomia
SERIOUS
acidosis, pulmonary edema, renal failure, urinary retention, seizures, thrombophlebitis

NOTE: 室溫儲存

Contraindication: Chronic/severe renal failure or renal failure unresponsive to a test dose.

藥名相似:

外觀相似:

外觀描述: 500mL透明注射液,銀色鋁瓶口,紅色塑蓋,透明玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1009633

18.06E Osmotic Diuretics

37601 C / Safe

GLYCEROL* INJECTION "N.K." "南光" 固利壓注射液

Glycerin 100mg/mL, Fructose 50mg/mL, Sodium HCl 9mg/mL, 250mL/bag

Dosage: 1常備品 37601

Adult
·Reducing intracranial pressure secondary to head trauma, cerebral infarction, and Reye's syndrome: IV infusion, 250-500 mL qd-bid, for 1-2 wks.

Pediatric
·Intracranial Hypertension: 0.2-1 gm/kg/hr of glycerin.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 250ml(37601)

ADR:

Headaches, nausea, vomiting, hemolysis, hyperglycemia, and hyperosmolarity may occur with glycerin therapy.

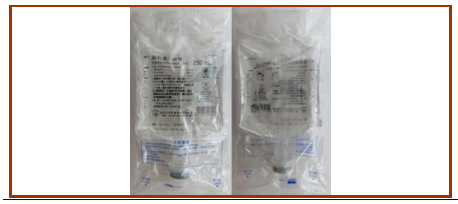
NOTE: 儲存15-30℃

Contraindication: Well-established anuria, severe dehydration, frank or impending acute pulmonary edema, severe cardiac decompensation

藥名相似:

外觀相似:

外觀描述: 250mL透明注射液，透明軟袋裝



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1024986

18.06H Miscellaneous

27548 C / Unsafe

Samsca Tablets 15mg 伸舒康錠15毫克

急用Tolvaptan 15mg tab

Dosage: 2急用藥 27548

Adult
· Euvolemic or hypervolemic hyponatremia: PO, initial 15mg once daily, may increase to 30mg once daily after at least 24 hours; Max. 60mg once daily

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 10-79mL/min: No dosage adjustment needed
Clcr<10mL/min: Not recommended

P: Tab: 15mg(27548)

ADR:

COMMON
Hyperglycemia, constipation, increased thirst, nausea, xerostomia, asthenia, dizziness, polyuria, dehydration
SERIOUS
Hypovolemia, gastrointestinal hemorrhage in cirrhotic patients

NOTE: 室溫儲存

· Avoid fluid restriction during the first 24 hours of therapy.
· Hyponatremia is corrected at a rate not to exceed 10-12mEq/L in the first 24 hours and not to exceed

18mEq/L in the first 48 hours.

藥名相似:

外觀相似:

外觀描述: 藍色三角形錠，有OTSUKA及15字樣

18.08A Dextrose and Electrolyte solutions, parenteral

33201 C /

VITACAL INJECTION "信東"美達加祿注射液

急用Ca chloride 2% & glucose10% 20mL (CaCl2 400mg=Ca 108.8mg=5.44mEq/Amp)

Dosage: 2急用藥 33201

Adult(Dosages are expressed in terms of calcium chloride salt)
· Hypocalcemia: IV infusion, 500mg-1g/dose repeated q4-6h if needed

Pediatric(Dosages are expressed in terms of calcium chloride salt)
· Hypocalcemia: IV infusion, 10-20mg/kg/dose repeated q4-6h if needed

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr< 25mL/min: Dosage adjustments may be necessary dependent on serum calcium levels

P: Inj: Ca chloride 2% & glucose10%, 20mL/Amp(33201)

ADR:

SERIOUS
Cardiac arrest(with rapid IV injection), cardiac dysrhythmia, hypercalcemia, hypotension, hypomagnesemia

NOTE: 室溫保存

僅供IV使用; avoid extravasation; IV calcium injections must be administered slowly (rate< 0.7-1.8mEq/min), and the injection should be stopped if the patient complains of discomfort. Following IV injections, the patient should remain recumbent for a short time. Close monitoring of serum calcium concentrations is essential during IV administration of calcium.

藥名相似:

外觀相似:

外觀描述: 20mL透明注射液透明安瓿

18.08B Electrolyte Supplement

23661 C / Infant risk can

CALCIUM CARBONATE TABLETS 500MG "U.L." "優良" 碳酸鈣錠５００毫克

Calcium carbonate 500mg (= 200mg Ca2+) tab

Dosage: 1常備品 23661

Adult
·RDA: PO, 2.5-3.0g (equal to 1.0-1.2g Ca2+/day)
·Antacid: PO, 0.5-1.5g as needed
·Hypocalcemia: PO, 2.5-5g (equal to 1-2g Ca2+) or more/day
·Prevention of osteoporosis: PO, 2.5-3.75g (equal to 1-1.5g Ca2+)/day
·Hyperphosphatemia: PO, 2.5-17g/day(mean 8.5g/day) in chronic renal failure patients maintained on dialysis

Pediatric
·RDA
Infants: PO, 525-675mg (equal to 210-270mg Ca2+/day)
Children: PO, 1.25-2g (equal to 500-800mg Ca2+/day)
·Antacid: PO, 0.5-1.5g as needed
·Hypocalcemia
Neonates: PO, 50-150mg/kg/day div q4-6h
Children: PO, 45-65mg/kg/day div into 4 doses

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr < 25mL/min: dosage adjustments may be necessary dependent on serum calcium levels

P: Tab:CaCO3 500mg(23661), Calcium acetate 667mg(23667), BIO-CAL* (23674), Caltrate* Plus(172605), Real-Gard*(172613), OS-Cal*(172612)

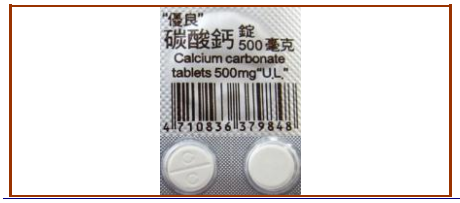
ADR:

NOTE: 室溫儲存

藥名相似: Tab:CaCO3 500mg(23661), Calcium acetate 6

外觀相似: Donison*5mg Tab (25602),

外觀描述: 白色圓扁錠，一面有"C | C"字樣及中間有刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1028939

18.08B Electrolyte Supplement

23674 ɔt be ruled out / Infant risk can

BIO-CAL PLUS Chewable Tablets 滋骨加強咀嚼錠

Tricalcium phosphate 1203mg, Cholecalciferol 330IU tab

Dosage: 1常備品 23674

ADULT
·Calium supplementation: PO, 1tab bid-tid, chewable.

NDA

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Plasma-calcium concentrations should be monitored closely in patients with renal impairment.

P: Tab:CaCO3 500mg(23661), Calcium acetate 667mg(23667), BIO-CAL* plus(23674), Caltrate* Plus(172605), Real-Gard*(172613), OS-Cal*(172612)

ADR:

NOTE: 室溫儲存

(1) Hypercalcemia; May potentiate effects of digoxin; May reduce absorption of tetracycline.
(2) Tricalcium phosphate 1203mg(=450mg Ca2+), Cholecalciferol 330IU (=1.56mcg)
(3) 1 mcg of colecalciferol or ergocalciferol is equivalent to 40 units of vitamin D.
(4)本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 粉紅色長橢圓錠，一面中央有刻痕，另一面有CA+D 字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=51058237

18.08B Electrolyte Supplement

23675 C / Infant risk can

RADI-K TABLETS (POTASSIUM GLUCONATE) "BOWLIN" 鉀順錠（葡萄酸鉀）

Potassium gluconate 595mg (= 2.54mEq) tab

Dosage: 1常備品 23675

Adult
·Daily requirement: PO, 40-80mEq/day
·Prevention of hypokalemia: PO, 20mEq/day
·Treatment of potassium depletion: PO, 40-100mEq/day in div doses (< 20mEq in a single dose)

Pediatric
·Daily requirement
Infants: PO, 2-3mEq/kg/day
·Prevention of hypokalemia
Neonates: PO, 1-2mEq/kg/day
Infants: PO, 2-3mEq/kg/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

1.Renal insufficiency: reduction in dose.
2.Severe renal impairment with oliguria or azotemia: probably should not receive potassium unless monitored under close supervision.

P: ab: 600mg(8mEq)(23671); Inj: 20 mEq/ 10mL(33323), 10 mEq / 500mL(33464)

ADR:

COMMON
diarrhea, flatulence, nausea, vomiting
SERIOUS
abdominal pain, cardiac arrest, ECG changes, GI ulceration, hyperkalemia

NOTE: 室溫儲存

1. Swallow whole; do not crush or chew.
2. Contraindications: severe renal impairment, untreated Addison's disease, adynamia episodica hereditoria, acute dehydration, heat cramps, hyperkalemia; structural, pathological, or pharmacologic cause for arrest or delay in tablet passage through the GI tract

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有PBF字樣，另一面刻有104字樣

18.08B Electrolyte Supplement

23676 C / Infant risk can

POTASSIUM CHLORIDE Extended-Release Tablets 750mg --

專案Potassium chloride (KCl) 750mg (= 10mEq) tab

Dosage: 1常備品 23676

ADULT
·Hypokalemia: PO, 40-100 mEq/day (or greater) ; divide daily dose as needed so that no more than 20 mEq is given as a single dose; take with meals and a full glass of liquid
·Hypokalemia; prophylaxis: PO, 20-25 mEq/day adjusted to patient needs

PEDIATRIC
·Hypokalemia: PO, 3-8 mEq/kg/day divided 1 to 5 times per day depending on tolerability and dose; start at lower dose and adjust based on serum potassium concentrations (study dose)

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Use with caution

P: P Tab: 750mg(10mEq)(23676, 專案), 600mg(8mEq)(23671), 595mg(2.54mEq)(23675); Inj: 20mEq/10mL(33323), 10mEq/ 500mL(33464)

ADR:

COMMON
Diarrhea, flatulence, nausea, vomiting
SERIOUS
Cardiac arrest, electrocardiogram abnormal, hyperkalemia, abdominal pain, gastrointestinal ulcer

NOTE: 室溫儲存

1. Do not chew, crush, or break. Swallow it whole with full glass of water.
2. Contraindications:
·anticholinergic agents; gastrointestinal tract passage restrictions or delay may inhibit extended-

release tablet passage.
·cardiac patients with esophageal compression; extended-release tablets may cause esophageal ulceration due to enlarged left atrium.
·concomitant pharmacologic agents in sufficient doses exerting anticholinergic effects; gastrointestinal tract passage restrictions or delay may inhibit extended-release tablet passage.
·structural or pathological conditions causing gastrointestinal tract passage restrictions or delay; may inhibit extended-release tablet passage.
·hyperkalemia; risk of cardiac arrest.

藥名相似:

外觀相似:

外觀描述: 黃色長橢圓形扁錠，有"P10"字樣

18.08B Electrolyte Supplement

27503 C / Infant risk can

ZINGA TABLETS (ZINC GLUCONATE) "BOWLIN" 鋅寶錠（葡萄酸鋅）

Zinc gluconate trihydrate 78mg (=10mg zinc) tab

Dosage: 1常備品 27503

ADULT
˙ RDA
Males (>14yrs): PO, ac, 11mg zinc/day
Females (>14yrs): PO, ac, 8~9mg zinc/day
Females (with pregnancy): PO, ac, 11~12mg zinc/day
Females (with lactation): PO, ac, 12~13mg zinc/day
˙ Wilson's disease: PO, ac, 5 tab.(equal to 50mg zinc) 3 times per day

Pediatric
˙ RDA
Infants: PO, ac, 2~3mg zinc/day
Children (1~8yrs): PO, ac, 3~5mg zinc/day
Children (9~13yrs): PO, ac, 8mg zinc/day
˙ Wilson's disease
Children (< 6yrs): PO, ac, 2.5 tab.(equal to 25mg zinc) twice daily
Adolescent (body weight< 60kg for males; < 45kg for females): PO, ac, 2.5 tab. 3 times daily

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: Zinc Acetate(Zn 50mg)(27529)急用; Tab: Zinc Gluconate(Zn 10mg)(27503)急用; Inj: Zinc Sulfate 29.7mg/5mL Amp(33294)

ADR:

COMMON
Indigestion, Nausea, Vomiting

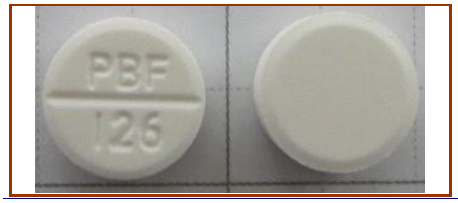
NOTE: 室溫儲存

需空腹服藥(飯前1小時或飯後2~3小時)

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠,有PBF及126字樣



18.08B Electrolyte Supplement

27529 /

ZINCA CAPSULES 50MG 鋅卡膠囊50毫克

急用Zinc Acetate (50mg Zn) cap

Dosage: 2急用藥 27529

·Wilson's disease: 50 mg tid
·Wilson's disease: ≧10 y/r 25mg tid.

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Cap: Zinc Acetate(Zn 50mg)(27529)急用; Tab: Zinc Gluconate(Zn 10mg)(27503)急用; Inj: Zinc Sulfate 29.7mg/5mL Amp(33294)

ADR:

Gastrointestinal irritation, Pancreatitis

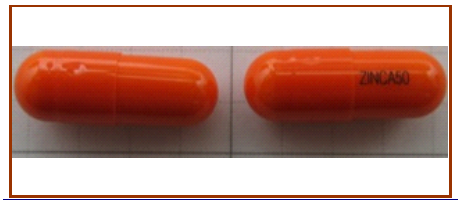
NOTE: 室溫儲存

需空腹服藥(飯前1小時或飯後2~3小時)

藥名相似:

外觀相似:

外觀描述: 橘色膠囊



18.08B Electrolyte Supplement

33289 /

Zelnite 西寧特

Sodium selenite pentahydrate 333mcg/2mL amp

Dosage: 1常備品 33289

ADULT
·Selenium deficiency: IVD, 100 ~ 200 micrograms selenium daily; if necessary this can be increased to 500 micrograms daily

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Inj: Sodium selenite pentahydrate 333mcg/2mL/Amp(33289)

ADR:

Loss of hair, nail changes, diarrhoea, dermatitis, metallic taste, garlic odour of breath, irritability, fatigue, peripheral neuropathy

NOTE: 室溫儲存

·Sodium selenite pentahydrate 333mcg = Selenium 100mcg
·The solution must not mixed with reducing agents (e.g. vitamin C) since a precipitation of elementary selenium could occur
·本品只能與確定能相容的靜脈營養輸注液互相混合。與本品相容之靜脈營養輸注液內容物包含脂肪乳劑、葡萄糖、胺基酸、電解質、微量元素等。
·靜脈導管給藥後使用 10 毫升的無菌 NS 沖洗管路。

藥名相似:

外觀相似:

外觀描述: 2mL透明注射液，透明安瓿頸部有藍點，白底黑字標籤有黃底區塊白色"西寧特"字樣

18.08B Electrolyte Supplement

33294 UK / Safe

ZINC SULFATE INJECTION 5.94MG/ML "TBC" "信東" 硫酸鋅注射液 5 . 9 4 毫克 毫升

Zinc sulfate 29.7mg/5mL amp

Dosage: 1常備品 33294

Adult
·Zinc deficiency, Prophylaxis: TPN, 2.5-4 mg/day (elemental zinc), added to TPN; in acute catabolic states, additional 2 mg zinc/day recommended; stable patients with small bowel fluid loss, add 12.2 mg zinc/L of fluid lost or 17.1 mg zinc/kg of stool or ileostomy output.

Pediatric
·Zinc deficiency, Prophylaxis:
Premature infants weighing up to 3 kg: TPN, 300 mcg elemental zinc/kg/day IV, added to TPN.
Full-term infants to age 5 yrs : TPN, 100 mcg elemental zinc/kg/day, added to TPN.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: Zinc Acetate(Zn 50mg)(27529)急用; Tab: Zinc Gluconate(Zn 10mg)(27503)急用; Inj: Zinc Sulfate 29.7mg/5mL (33294)

ADR:

Indigestion, nausea, vomiting

NOTE: 室溫儲存

1. Zinc sulfate 5.94mg =1.35mg elemental zinc
2. Excessive zinc can cause copper deficiency.

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液透明安瓿頸部有灰點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1037599

18.08B Electrolyte Supplement

33300 / Unknown(有

Addaven concentrate for solution for infusion 微達穩注射液

Trace elements inj 10mL vial

Dosage: 1常備品 33300

Adult
·Trace elements supplement in TPN solution: 10mL/day

Pediatric
Addaven must not be given to children less than 15 kg body weight.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: Trace elements 10mL(33300), Zinc sulfate 1mL(33324)

ADR:

NOTE: 室溫儲存

1.Addaven must not be given to children less than 15 kg body weight
2.if you have Wilson's disease (a genetic disorder in which copper builds up in the body) or hemochromatosis (accumulation of iron in the body).
3..Each mL contains:
Cr/Cu/Fe/Mn/I/F/Mo6+/Se4+/Zn = 0.001/0.038/0.11/0.0055/0.013/0.095/0.0019/0.0079/0.5 mg
鈉與鉀的含量等同於
鈉 120 mcg
鉀 3.9 mcg

藥名相似:

外觀相似:

外觀描述: 10mL透明注射液，透明塑膠方型安瓿，白底黑字標籤有黃色區塊及藍色線條

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=52026993

18.08B Electrolyte Supplement

33302 C / Safe

Calglon I.V. Injection 鈣克康靜脈注射液

■Calcium gluconate inj 10% 10mL(4.65mEq) amp

Dosage: 1常備品 33302

Adult
·Cardiac life support: IV, 5-20mL over 2-4 mL/min
·Hypocalcemia: IV, 5-20mL administered slowly (2mL/min)
·Cardiac arrest: IV, 5-8mL/dose q10min (Max. 30mL/dose)
·Black widow spider envenomation: IV, Max. 5-10mL, repeated every 1-4hr

Pediatric
·Cardiac life support: Slow IV push, 0.6-1.0mL/kg
·Hypocalcemia
Neonates: IV (rate< 1.5mL/min), 2-8mL/kg/day div q6h
Infants: IV (rate< 1.5mL/min), 2-5mL/kg/day div q6h
Children: IV (rate< 1.5mL/min), 2-5mL/kg/day div q6h
·Cardiac arrest
Infants & children: IV, 1mL/kg q10min
·Nutritional supplementation
Neonates: IV, MD 3-5mL/kg
Infants & children: IV, MD 1-2mL/kg
Adolescents: IV, MD 0.5-1mL/kg
·Black widow spider envenomation: IV, Max. 5-10mL, repeated every 1-4hr

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr< 25mL/min: Dosage adjustments may be necessary dependent on serum calcium levels

P:

ADR:

COMMON
constipation/nausea/vomiting, metallic taste
SERIOUS
cardiac arrest(with rapid IV injection), hypercalcemia, hypercalciuria, hypertension, hypomagnesemia, hypophosphatemia, milk-alkali syndrome, muscle weakness
vasodilation, hypotension, bradycardia, arrhythmias

NOTE: 室溫保存

1.僅供IV使用; IV calcium injections must be administered slowly (rate< 0.7-1.8mEq/min), and the injection should be stopped if the patient complains of discomfort. Following IV injections, the patient should remain recumbent for a short time. Close monitoring of serum calcium concentrations is essential during IV administration of calcium.
2.Contraindications: digitalis toxicity, hypercalcemia, blood hypercoagulability, renal failure, ventricular fibrillation.
3.The minimum dilution of intravenous CALCIUM GLUCONATE in patients 17 years and younger is 200mg/10ml administered over at least 30 minutes. In life-threatening situations, the drug may be administered by slow intravenous push over 3 to 5 minutes. Constant infusion is preferred over intermittent administration. Patients should be monitored for bradycardia, and extravasation of the intravenous solution should be avoided

藥名相似:

外觀相似:

外觀描述: 10mL透明液體、透明塑膠小瓶

18.08B Electrolyte Supplement

33318 C / Safe

POTASSIUM PHOSPHATE INJECTION "U.L." "優良" 磷酸鉀注射液

■Potassium phosphate inj 80mEq/20mL amp

Dosage: 1常備品 33318

Adult
·Serum phosphorus level 2.3-3mg/dl: IV infusion, 0.16-0.32 mM/kg over 4-6hrs.
·Serum phosphorus level 1.6-2.2mg/dl: IV infusion, 0.32-0.64 mM/kg over 4-6hrs.
·Serum phosphorus level <1.5mg/dl: IV infusion, 0.64-1 mM/kg over 8-12hrs.

..

Dosing adjustments in hepatic impairment:

Hepatic cirrhosis: Use with Caution .

Dosing adjustments in renal impairment:

Dosage adjustment required.

P: Inj: 20mL amp(33318)

ADR:

Diarrhea, hypotension, hyperphosphatemia, hypocalcemia, hypomagnesemia, nephrotoxicity

NOTE: 室溫儲存25℃以下

1.Each ml contains: K+ 4.4mEq & Phosphate 3mM
2.Must be diluted before use
3.Do not IV push

藥名相似:

外觀相似:

外觀描述: 20mL透明注射液，透明安瓿頸部有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1021343

18.08B Electrolyte Supplement

33323 C / Infant risk is

POTASSIUM CHLORIDE INJECTION 15% 氯化鉀注射液 1 5 %

■Potassium chloride (20mEq) 15% 10mL amp

Dosage: 1常備品 33323

Adult
·Hypokalemia: IV infusion, serum K less than 2

mEq/L, 20-40 mEq/hr, with continuous cardiac monitoring, Max. 400 mEq/day.Serum K greater than 2.5 mEq/L, 10-15 mEq/hr, Max. 200 mEq/day.

Pediatric
·Hypokalemia:Intermittent IV, 0.5-1 mEq/kg/dose; infuse at 0.3-0.5 mEq/kg/hr, Max.1 mEq/kg/hr and 30 mEq per dose; Max. 3 mEq/kg/day or 40 mEq/m(2)/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

1. Renal insufficiency: reduction in dose.
2. Severe renal impairment with oliguria or azotemia: probably should not receive potassium unless monitored under close supervision.

P: ab: 600mg(8mEq)(23671); Inj: 20 mEq/ 10mL(33323), 10 mEq / 500mL(33464)

ADR:

COMMON
diarrhea, flatulence, nausea, vomiting
SERIOUS
abdominal pain, cardiac arrest, ECG changes, GI ulceration, hyperkalemia

NOTE: 室溫儲存

1. Must dilute IV solution prior to use; max IV concentration = 40 mEq/L for peripheral IV line, to 80 mEq/L (with monitoring) through central line
2. Contraindications: severe renal impairment, untreated Addison's disease, adynamia episodica hereditoria, acute dehydration, heat cramps, hyperkalemia
3.Adult: Recommended maximum rates of potassium infusion: keep within 10~20mEq/hr(may range up to 50mEq/hr). Frequent biochemical and electrocardiographic monitoring is necessary when rates exceed 10 mEq/hr, and the faster rates should be continued for only short periods of time. Recommended maximum concentration of potassium IV infusion: 40mEq/L(ranges from 20~80mEq/L, higher potassium conc. May be needed initially in cases of severe hypokalemia, cardiac arrhythmias, diabetic ketoacidosis or the diuretic phase of acute renal failure.)
4.Pediatric: Recommended IV rate: diluted to 40mEq/L(max. 80mEq/L) and infused rate 20mEq/hr or 0.3mEq/kg/hr. Not recommended for direct IV push. Patients should be monitored for dysrhythmias and extravasation should be avoided. Recommended maximum intravenous dose: 1mEq/kg/hr. If the rate of infusion exceeds 0.5mEq/kg/hr, the patient should be continuously monitored.

藥名相似:

外觀相似:

外觀描述: 10mL黃色透明注射液透明安瓿頸部有紅點，瓶身標籤上下各有1條紅色粗線條

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1020573

18.08B Electrolyte Supplement

38502 /

WATER FOR INJECTION "SING TONE" "信東" 注射用水

■Distilled Water for inj. 500mL bot玻璃瓶

Dosage: 1常備品 38502

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P:

ADR:

NOTE:

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1032379

18.10A Amino Acid Supplement

23662 C / Unknown(有

KETOSTERIL TABLETS 吉多利錠

Keto analogues 630mg tab

Dosage: 1常備品 23662

Adult
·Amino acid supplement for renal dysfunction: PO: (70kg BW) 4-8 tab tid with meals.

PEDIATRIC
.

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Tab: 630mg

ADR:

Hypercalcaemia

NOTE: 室溫儲存

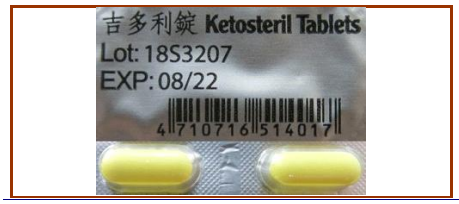
1. Each tablet contains: Calcium-3-methyl-2-oxo-valerate 67mg, Calcium-4-methyl-2-oxo-valerate 101mg, Calcium-2-oxo-3-phenylpropionate 68mg, Calcium-3-methyl-2-oxo-

butyrate 86mg, Calcium-DL-2-hydroxy-4-(methyl-thio)-butyrate 59mg, L-lysine acetate 105mg, L-threonine 53mg, L-tryptophan 23mg, L-histidine 38mg, L-tyrosine 30mg.
2. Total nitrogen 36mg, calcium 1.25mmol = 50mg.

藥名相似:

外觀相似:

外觀描述: 黃色橢圓形膜衣錠



18.10A Amino Acid Supplement

23672 B / Infant risk can

CARNITENE 1G CHEWABLE TABLETS 加力體能一公克咀嚼錠

L-Carnitine 1g tab

Dosage: 1常備品 23672

Adult
·Carnitine nutritional deficiency, primary/secondary: PO, 990 mg 2-3 times/day, depending on clinical response
·Hemodialysis : 2-4 g/day
·Angina pectoris & myocardial infarction: 2-6 g/day

Pediatric
·Carnitine nutritional deficiency, primary/secondary: PO, initial 50 mg/kg/day in divided doses, then 50-100 mg/kg/day depending on response, Max. 3 g/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Use with caution

P: Chewable tab: 1g(23672)

ADR:

Gastric discomfort, abdominal pain, diarrhea, nausea

NOTE: 室溫保存

·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=20000006

18.10A Amino Acid Supplement

33292 UK / No report(毫

CEREBROLYSIN* AMPOULES 速利清注射液

Cerebrolysin concentrate inj 2152g/10mL amp

Dosage: 1常備品 33292

Adult
· Amino acid supplement: IM or IV, 2mL/day then interval was extended to two or three days. Each course is 10 to 15 needles, and can be continued if necessary. High-dose: IV infusion, 5-40 mL/day.

Pediatric
·

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 2.152G/10mL amp(33292)

ADR:

COMMON
Diarrhea, nausea, stomach cramps, vomiting
SERIOUS
Seizure

NOTE: 室溫避光

Each ml contains: Cerebrolysin Concentrate 215.2mg
Alanine. 3.00mg
Arginine 0.25mg
Aspartic Acid 3.00mg
Cystine. 0.01mg
Glutamic Acid. 4.50mg
Glycine. 1.50mg
Histidine. 1.30mg
Isoleucine. 2.00mg
Methionine. 0. 50mg
Phenylalanine. 2. 00mg
Proline. 1. 60mg
Serine 0. 30mg
Threonine. 0. 30mg
Tryptophan. 0. 50mg
Tyrosine. 0. 24mg
Valine 2.00mg
Leucine 6.00mg
Lysine 5.80mg
sodium Hydroxide 4N q.s. (pH 7.1)
Water for injection q.s.

藥名相似:

外觀相似:

外觀描述: 10mL注射液『棕』色安瓿

18.10A Amino Acid Supplement

33296 B /

L-CARNIT* Injection 1G 優加力注射劑1公克

L-carnitine inj 1g/5mL amp

Dosage: 1常備品 33296

Adult
· Prophylaxis and treatment of carnitine deficiency secondary to hemodialysis: IV, 10-20mg/kg dry

body weight as a slow (2-3mins) bolus injection into the venous return line after dialysis; subsequent dose titration determined by predialysis levocarnitine concentrations
· Carnitine deficiency secondary to metabolic disorder: IV, 50mg/kg given as a slow (2-3mins) bolus or infusion; repeat 50mg/kg in divided dose over 24h (every 3-4 h and not less than every 6 h); repeat 50mg/kg/day if clinically indicated; Max. 300mg/kg

Pediatric
· Prophylaxis and treatment of carnitine deficiency secondary to hemodialysis or metabolic disorder: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Chewable tab: 1g(23672); Inj: 1g Amp(33296)

ADR:

COMMON
Diarrhea, nausea, stomach cramps, vomiting
SERIOUS
Seizure

NOTE: 室溫避光

藥名相似:

外觀相似:

外觀描述: 5mL注射液『棕』色安瓿，頸部有1條白色，頭部有紅色及黃色各1條線

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1052587

18.10A Amino Acid Supplement

33349 **C / Unknown(有**

MORIAMIN-SN INJECTION "中國化學" 蒙利安命賜源注射液

Amino acid injection 10% 200mL

Dosage: 1常備品 33349

Adult
·Nutrition support

Patient Condition	Protein Requirement (g/kg/day)
Unstressed	0.8-1.0
Low stress	1.0- 1.7
Critically ill	1.5 -2.0
Severe burn injury	2.0- 3.0

Dosing adjustments in hepatic impairment:

Unstressed severe chronic liver: 0.8- 1.1g/kg/day

Dosing adjustments in renal impairment:

1.Renal failure not receiving dialysis: 0.6 - 1.0g/kg/day
2.Receiving dialysis: 1.2-2.7g/kg/day

P: Inj: Moriamin-SN(33349),
Aminosteril N-Hepa 8% 500ml(33379),
Nephrosteril 7% 250ml(33381),
Aminosteril infant 10%(33383),
Aminosteril 5% 500ml(33390),
Aminoplasmal Hepa-10% 500mL(33456),
Aminoplasmal -10% E 500ml for TPN (38846)

ADR:

thrombophilebitis, encephalopathy, hyperammonia

NOTE: Protect from light

1.Each mL contains: L-Isoleucine 5.6mg, L-Leucine 12.5mg, Lysine Acetate 12.4mg, L-Methionine 3.5mg, L-Phenylalanine 9.35mg, L-Threonine 6.5mg, L-Tryptophan 1.3mg, L-Valine 4.5mg, L-Alanine 6.2mg, L-Arginine 7.9mg, L-Aspartic Acid 3.8mg, L-Cysteine 1mg, L-Glutamic Acid 6.5mg, L-Histidine 6mg, L-Proline 3.3mg, L-Serine 2.20mg, L-Tyrosine 0.35mg, Aminoacetic Acid 10.70mg
2.Total nitrogen content: 15.2mg/mL, pH 5.5-6.5

藥名相似:

外觀相似:

外觀描述: 200mL透明注射液『藍』蓋透明玻璃瓶，蓋上有CCP字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1024029

18.10A Amino Acid Supplement

33379 **UK / Unknown(有**

AMINOSTERIL N HEPA* 8% INFUSION SOLUTION 諾你健N靜脈輸注液8%

8% Branched chain enriched-amino acid 500mL/bot

Dosage: 1常備品 33379

Adult
·Hepatic encephalopathy, IV infusion: 80 to 120g/day
·Nitrogen loss, IV infusion: 1.5g/kg/day
·Nutritional support, IV infusion: 0.8 to 3g/kg/day

Pediatric
·Nutritional support, IV infusion:
children aged 1 to 10 years: 1 to 3.5g/kg/day
infants aged 0 to 1 years: 1.6 to 3.5g/kg/day

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Inj: Moriamin-SN(33349),
Aminosteril N-Hepa 8% 500ml(33379),
Nephrosteril 7% 250ml(33381),
PEDICARE* inj 10% 100mL(33383),
Aminoplasmal Hepa-10% 500mL(33456),
Aminoplasmal -10% E 500ml for TPN (38846)

ADR:

cholestasis, intrahepatic flushing,hyperammonemia,nausea,thrombocytopenia,thrombophlebitis

NOTE: 室溫儲存

1.Each mL contains: L-Isoleucine 10.4mg, L-Leucine 13.09mg, L-Lysine 6.88mg, L-Methionine 1.1mg, L-cysteine 0.52mg, L-Phenylalanine 0.88mg, L-Threonine 4.4mg, L-Tryptophan 0.70mg, L-Valine 10.08mg, L-Arginine 10.72mg, L-Histidine 2.80mg, Aminoacetic acid 5.82mg, L-Alanine 4.64mg, L-Proline 5.73mg, L-Serine 2.24mg, Glacial acetic acid 4.42mg.
2.Total nitrogen content: 12.9g/L

藥名相似:

外觀相似:

外觀描述: 透明玻璃瓶，半透明白蓋

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2020706

18.10A Amino Acid Supplement

33381 / Unknown(有

NEPHROSTERIL INFUSION SOLUTION 腎福諾輸注液

Essential enriched-amino acid inj 7% 250mL bot

Dosage: 1常備品 33381

·In renal failure not receiving dialysis: 0.6 -1.0 g/kg.
·In renal failure is receiving dialysis: 1.2 - 2.7 g/kg

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

ADULT
·in renal failure not receiving dialysis: 0.6 to 1.0 g/kg.
·in renal failure is receiving dialysis: 1.2 to 2.7 g/kg

P: Inj: Aminosteril infant 10%(33383), Moriamin-SN(33349), Aminosteril 5% 500ml(33390), Nephrosteril 7% 250ml(33381), Aminosteril N-Hepa 8% 500ml(33379), Aminoplasmal -10% E 500ml for TPN (38846)

ADR:

thrombophilebitis, encephalopathy, hyperammonia

NOTE: 儲存25℃以下

1.Each mL contains: L-Isoleucine 5.10mg, L-Leucine 10.30mg, L-Lysine monoacetate 10.01mg (=L-Lysine 7.1mg), L-Methionine 2.80mg, Acetylcysteine 0.50mg (=L-Cysteine 0.37mg), L-Phenylalanine 3.80mg, L-Threonine 4.80mg, L-Tryptophan1.90mg, L-Valine 6.20mg, L-Arginine 4.90mg, L-Histidine 4.30mg, Glycine 3.20mg, L-Alanine 6.30mg, L-Proline 4.30mg, L-Serine 4.50mg, L-Malic acid 1.50mg, Glacial acetic acid 1.30mg.
2.Total amino acid 70g/L, Total nitrogen content: 10.8g/L, Osmolarity 645mosm/L, Energy content 280Kcal/L
3.Essential amino acid: nonessential amino acid=6:4

藥名相似:

外觀相似:

外觀描述: 250mL透明注射液透明塑膠蓋透明玻璃瓶，蓋上有PP字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2017819

18.10A Amino Acid Supplement

33389 / Unknown(有

DIPEPTIVEN CONCENTRATED SLUTION FOR INFUSION 雙胜胺靜脈輸注液

■(N2)-L-alanyl-L-glutamine 20% 100mL bot

Dosage: 1常備品 33389

Adult
·Amino acid supplement: IV infusion, 1.5-2.0 mL/kg/day (0.3-0.4g/kg/day), Max. 2.0 mL/kg/day

Dosing adjustments in hepatic impairment:

Severe hepatic insufficiency : Not recommended.

Dosing adjustments in renal impairment:

Clcr < 25mL/min : Not recommended.

P: Inj: 20% 100mL/bot (33389)

ADR:

NOTE: 室溫保存

·It is not designed for direct administration. One volume part Dipeptiven* is to be mixed with at least 5 volume parts of compatible solution. Infusion rate should not exceed 0.1g amino acids/kg/hr.
·Each mL contains: L-alanine 82mg & L-glutamine 134.6mg.
·It should not exceed approx. 20% of total amino acids supply.
·Unused solution should be disposed off.

藥名相似:

外觀相似:

外觀描述: 100mL透明注射液透明塑膠蓋透明玻璃瓶，蓋上有bb字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023824

18.10A Amino Acid Supplement

33456 C / Unknown(有

AMINOPLASMAL HEPA 10% "B.BRAUN" "柏朗" 安命諾注射液１０％

10% Amino acid injection 500mL

Dosage: 1常備品 33456

Adult:
·Normal dose:7-10mL/kg b.w./day, corresponding to 0.7-1.0g of amino acids/kg b.w./day.
·Maximum dose:15mL/kg b.w./day, corresponding to 1.5g of amino acids/kg b.w./day.

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Inj: Moriamin-SN(33349), Aminosteril N-Hepa 8% 500ml(33379), Nephrosteril 7% 250ml(33381), Aminosteril infant 10%(33383), Aminosteril 5% 500ml(33390), Aminoplasmal Hepa-10% 500mL(33456), Aminoplasmal -10% E 500ml for TPN (38846)

ADR:

Cholestasis, intrahepatic flushing, hyperammonemia, nausea, thrombocytopenia, thrombophlebitis

NOTE: 室溫避光

1.Each mL contains: L-Isoleucine 8.8mg, L-Leucine 13.6mg, L-Lysine acetate 10.6mg, L-Methionine 1.2mg, L-Phenylalanine 1.6mg, L-Threonine 4.6mg, L-Tryptophan 1.5mg, L-Valine 10.6mg, L-Alanine 8.30mg, L-Arginine 8.80mg, L-Histidine 4.7mg, L-Proline 7.1mg, L-Serine 3.7mg, L-Aspartic Acid 2.5mg, L-Tyrosine 0.67mg, L-Cysteine 0.59mg, L-Glutamic Acid 5.7mg, L-Ornithine HCl 1.66mg, Glycine 63.mg, L-Asparagine monohydrate 0.55mg
2.Electrolyte (mmol/L): Acetate 51, Cl 10
3.Total amino acid 100g/L, Total nitrogen content: 15.3g/L, Caloric value 400kcal/L, Osmolarity 875mOsm/L

藥名相似:

外觀相似:

外觀描述: 500mL透明注射液『灰』蓋透明玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022393

18.10B Dextrose

33317 C / Caution

VITAGEN INJECTION 50% 美達研注射液 5 0 %

■Dextrose 50% 20mL amp

Dosage: 1常備品 33317

Adult
·Hypoglycemia: 25g (50mL of D50W) IV bolus
·Insulin induced hypoglycemia : IV infusion as needed

Pediatric
·Insulin induced hypoglycemia : IV infusion as needed

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Inj: 5% 500mL玻璃瓶(33341), 5% 500mL塑膠瓶(33331), 5% 1000mL(33329), 10% 500mL(33334), 20% 20mL(33332), 50% 20mL(33317), 50% 500mL(38842)

ADR:

rebound hypoglycemia, local vein irritation, hyperglycemia, glycosuria, and worsened neurologic outcome with hyperglycemia after ischemic brain injury.

NOTE: 室溫儲存

Do not use concentrated solutions in patients with anuria, hyperglycemia, intracranial or intraspinal hemorrhage, delirium tremens and dehydration or in patients with glucose-galactose malabsorption syndrome.

藥名相似:

外觀相似:

外觀描述: 20mL透明液體、透明塑膠小瓶白色標籤上有『黃』底紅字四方商標

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12006067

18.10B Dextrose

33332 C / Caution

VITAGEN INJECTION S.T 20% "信東"美達研液 2 0 %

■Dextrose 20% 20mL amp

Dosage: 1常備品 33332

Adult
·Caloric replacement with a minimum of fluids: IV, depends on the age, weight, clinical condition, and fluid, electrolyte, and acid-base balance of the patient.

Neonate and Infants:
·Acute symptomatic hypoglycemia: Slow IV, 2 mL/kg of 10-25% dextrose

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Inj: 5% 500mL玻璃瓶(33341), 5% 500mL塑膠瓶(33331), 5% 1000mL(33329), 10% 500mL(33334), 20% 20mL(33332), 50% 20mL(33317), 50% 500mL(38842)

ADR:

fever, infection at the site of injection, venous thrombosis, phlebitis extending from the site of injection, extravasation, hyperglycemia, glycosuria

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 20mL透明液體、透明塑膠小瓶白色標籤上有『黃』底藍字四方商標

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12003058

18.10C Fat Emulsion

33338 C /

LIPOFUNDIN MCT/LCT 20% I.V. INFUSION "柏朗"力保肪寧ＭＣＴ/ＬＣＴ注射液２０％

Fat emulsion MCT/LCT 20% 100mL bot

Dosage: 1常備品 33338

Adult
·Calorie supplementation: IV infusion, 1-2g/kg/day or 20-40% of the daily caloric intake, Max. 2.5g/kg/day or 60% of calorie intake
·Essential fatty acid deficiency, prevention: IV infusion, 8-10% of calorie intake

Pediatric
·Calorie supplementation: IV infusion, 0.5g/kg/day, Max. 3g/kg/day or 60% of calorie intake
·Essential fatty acid deficiency, prevention: IV infusion, 8-10% of calorie intake

Dosing adjustments in hepatic impairment:

Not appear necessary, but decreased doses should be considered in patients unable to tolerate fat emulsions who exhibit elevated triglyceride levels.

Dosing adjustments in renal impairment:

Use in normal doses. If fluids are restricted, it may be preferable to utilize a concentrated lipid emulsion.

P: Inj: Lipovenoes* MCT 20% 100mL(33338), Lipofundin MCT/LCT 20% 250mL(33342)

ADR:

COMMON
Flushing, hypertriglyceridemia, nausea, vomiting, headache
SERIOUS
Cholestasis, splenomegaly, thrombocytopenia (rare), hepatomegaly, dyspnea, pulmonary fat embolism

NOTE: 室溫25℃以下避光儲存

1.組成Each mL contains: Soybean oli 100mg, Medium-chain Triglycerides(MCT) 100mg.
2.賦形劑Each mL contains: Glycerol 25mg, Egg lecithin 12mg, all-rac-α-Tocopherol 0.17mg(±0.04mg), Sodium oleate (用於調節PH值), water for injection Q.S.
3.Caloric value 1935 Kcal/L, Osmolarity 380 mOsm/L, pH 6.5-8.5.
4.輸注應當在盡可能低的輸注速率下進行。
5.禁忌症：
(1)對雞蛋或大豆蛋白，大豆或花生產品過敏，或賦形劑過敏。
(2)嚴重之 高脂血症、凝血功能障礙、肝功能不全、出血傾向、腎功能不全且未接受腎臟替代療法。
(3)脂肪栓塞、急性血栓栓塞。
(4)一般靜脈營養禁忌：循環不穩定(衰竭及休克)、代謝不穩定(嚴重敗血症、不明原因昏迷)、急性心肌梗塞或中風、急性肺水腫、代償性心臟功能不全。
6.注意事項：給藥期間，血漿三酸甘油脂濃度超過4.6 mmol/L，建議降低輸注速率。血漿三酸甘油脂濃度超過11.4 mmol/L，必須中止輸注。
7.開封後，應立即使用。配製或稀釋後不得使用。

藥名相似:

外觀相似:

外觀描述: 100mL乳白注射液『灰』蓋透明玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2018307

18.10C Fat Emulsion

33384 C / Caution

SMOFlipid 20% Emulsion for Infusion 斯莫脂肪靜脈輸注液

Fat emulsion (soybean oil 30%, MCT 30%, olive oil 25%, fish oil 15%) 20% 250mL bot

Dosage: 1常備品 33384

ADULT
·1.0-2.0g fat/kg body weight (b.w.)/day, corresponding to 5-10ml/kg b.w./day. Infusion rate: 0.125g fat/kg b.w./hour, corresponding to 0.63 ml Smoflipid/kg b.w./hour, Max: 0.15g fat/kg b.w./hour, corresponding to 0.75 ml Smoflipid/kg b.w./hour

Pediatric
·Neonates and infants
Initial dose: 0.5-1.0g fat/kg b.w./day , increase by 0.5-1.0g fat/kg b.w./day up to 3.0g fat/kg b.w./day. Max: 3g fat/kg b.w./d, corresponding to 15 ml Smoflipid/kg b.w./day. Infusion rate: not exceed 0.125g fat/kg b.w./hour. In premature and low birthweight neonates, Smoflipid should be infused continuously over about 24 hours.
·Children
Max: 3 g fat/kg b.w./d, corresponding to 15 ml Smoflipid/kg b.w./day.
infusion rate: not exceed 0.15 g fat/kg b.w./hour.

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P: Inj: SMOFlipid* 20% 250mL(33384)

ADR:

COMMON
flushing, headache,hypertriglyceridemia
nausea, vomiting
SERIOUS
dyspnea, hepatomegaly, cholestasis, splenomegaly, intravascular fat accumulation in lungs (mainly preterm infants), thrombocytopenia (rare)

NOTE: 室溫儲存

1.Each 250mL contains: Soybean oil(refined) 15g, MCT 15g, Olive oil(refined) 12.5g, Fish oil(rich in omega 3 acids) 7.5g
2.Caloric value 500Kcal/250mL, pH 8

藥名相似:

外觀相似:

外觀描述: 250mL乳白注射液『灰』蓋透明玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024519

18.10C Fat Emulsion

33480 C / Unknown(有

Lipoplus 20% 力保加 20% 脂肪乳劑輸注液

Fat emulsion (soybean oil 40%, MCT 50%, fish oil 10%) 20% 250mL bot

Dosage: 1常備品 33480

ADULT
·Supply of fat: 1-2g fat/kg /day body weight (b.w.) equivalent to 5-10mL/kg b.w./day. Infusion rate: for the first 15 mins, should be only 50% of the maximum usable infusion rate. Max. up to 0.15g fat/kg b.w./hr, equivalent to 0.75 mL Lipoplus* 20%/kg b.w./hour

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P: Inj: LIPOPLUS* 20% 250mL(33480)

ADR:

COMMON
Flushing, hypertriglyceridemia, nausea, vomiting, headache
SERIOUS
Cholestasis, splenomegaly, thrombocytopenia (rare), hepatomegaly, dyspnea, pulmonary fat embolism

NOTE: 室溫儲存

1.Each 250mL contains: Soya-bean oil(refined) 20g, MCT 25g, Omega-3-acid triglycerides 5g.
2.Caloric value 475Kcal/250mL, Osmolality 410 mOsm/kg, pH 6.5-8.5.

藥名相似:

外觀相似:

外觀描述: 250mL乳白注射液『灰』蓋透明玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024919

18.10D TPN Solution

33365 C /

■Adult TPN-C 17.5% 1500mL Adult TPN-C 17.5% 1500mL

■Adult TPN-C 17.5% 1500mL(Clinimix, MVI, Combeplex)

Dosage: 1常備品 33365

Adult: IV infused via a central vein,
·The requirements range from 0.16g-0.35g nitrogen/kg/d (approximately 1-2g of amino acid/kg/d)
·The calorie requirements range from 25-40 kcal/kg/d, depending on the nutritional status of patient and the degree of catabolism
·Maximum infusion rate:1.4mL/kg/hr or 85-100 mL/hr (for a patient weighing 60-70 kg)
·Maximum daily dose:30mL/kg/day or 1800-2100 mL/day (for a patient weighing 60-70 kg)

Pediatric: IV infused via a central vein,
·The requirements range from 0.35g~0.45g nitrogen/kg/d (approximately 2~3g of amino acid/kg/d)

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 1.5L/Twin bag(33365)(38103, 原料藥或帶回居家輸注)

ADR:

NOTE: 冰箱保存

1.Do not freeze
2.After the peel seal activation, chemical and physical in-use stability has been demonstrated for 7 days at 2 to 8 degrees C or for 48 hours below 25 degrees C
3.After mixing both comparments, the composition of the mixture is:Glucose 263g, Amino acid 75g (Nitrogen 12.4g), Na 53mEq, K 45mEq, Mg 7.5mEq, Ca 6.8mEq, Acetate 113mEq, Cl 60mEq, Phosphate 23mM; total calories is 1350 kcal

藥名相似:

外觀相似:

外觀描述:

18.10D TPN Solution

33472 UK / Safe

■SMOFKABIVEN* PERIPHERAL EMULSION FOR INFUSION 斯莫克必恩周邊靜脈輸注液

■Glucose 7.1%, amino acid 3.2%, fat emulsion 2.8% inj 1448mL/bag

Dosage: 1常備品 33472

Adult
IV infusion through a central or peripheral vein.
·The nitrogen requirements are in the range of 0.10 - 0.25g nitrogen/kg/d (0.6 - 1.6g of amino acids/kg/d).
·Dosage range: 20 - 40mL/kg BW/d.
·Maximum daily dose: 40mL/kg BW.
·Maximum infusion rate: < 3mL/kg/hr of the emulsion for infusion.

> 2yrs

·Dosage range: 40mL/kg BW/d.
·Maximum daily dose: 40mL/kg BW.
·Maximum infusion rate: < 3mL/kg/hr of the emulsion for infusion.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 1.448L/bag(33472)

ADR:

NOTE: 室溫儲存25℃以下

·The mixture contain: Fat 41g(Soybean oil(refined) 12.3g, MCT 12.3g, Olive oil(refined) 10.1g, Fish oil(rich in omega-3-acids) 6.1g), Glucose 103g, Amino acid 46g (Nitrogen 7.4g), Na 36mmol, K 28mmol, Mg 4.6mmol, Ca 2.3mmol, Phosphate 11.9mmol, Zn 0.03mmol, sulphate 4.6mmol, Cl 32mmol, Acetate 96mmol; total calories is 1000kcal; Osmolality 850mOsm/L; pH 5.6
·禁忌症
- 對魚、蛋、大豆或花生的蛋白質過敏或對本品的任何有效成分或賦形劑過敏者。
- 嬰兒及兩歲以下之兒童。
·排除脂肪的能力因人而異，因此應列入臨床醫師的例行監測項目中，通常是測定三酸甘油酯濃度，輸注期間血清中三酸甘油酯濃度不得超過4毫莫耳 / 公升。用藥過量時可能導致脂肪超載症候群(特性為高血脂、發燒、脂肪浸潤、肝腫大合併黃疸或無黃疸、脾臟腫大、貧血、白血球減少症、血小板減少症、血液凝固疾病、溶血和網細胞增多、肝功能檢查異常和昏迷。)

藥名相似:

外觀相似:

外觀描述: 1448mL透明注射液被分隔為三部分的透明軟袋)

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025150

18.10D TPN Solution

33476 C /

OLICLINOMEL N7-1000E* EMULSION FOR INFUSION(依仿單含熱量1800KCAL) "百特"歐諾美N7-1000E輸注乳液

■Glucose 16%, amino acid 4% , fat 4%, with electrolyte 1500mL bag

Dosage: 1常備品 33476

Adult
IV infusion through a central vein.
·The nitrogen requirements are in the range of 0.16 - 0.35g nitrogen/kg/d (1-2g of amino acids/kg/d).
·Energy requirements vary depending on the patient's nutritional state and level of catabolism. On average these are 25-40kcal/kg/d.
·Maximum daily dose: 36mL/kg BW.
·Maximum infusion rate: < 1.5mL/kg/hr of the emulsion for infusion.

Pediatric (>2yrs)
IV infusion into a central vein.
·The nitrogen requirements are in the range of 0.35 - 0.45g nitrogen/kg/d (2-3g of amino acids/kg/d).
·Energy requirements vary depending on the patient's nutritional state and level of catabolism. On average these are 60-110kcal/kg/d.
·Maximum daily dose: 75mL/kg BW
·Maximum infusion rate: < 1.5mL/kg/hr of the emulsion for infusion.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 1.5L/bag(33476)

ADR:

NOTE: 室溫儲存

NOTE
The mixture contain: refined oliver oil + refined soya oil 60g, Glucose 240g, Amino acid 60g (Nitrogen 9.9g), Na 48mmol, K 36mmol, Mg 3.3mmol, Ca 3mmol, Phosphate 15mmol, Acetate 86mmol, Cl 72mmol; total calories is 1800kcal; Osmolality 1450mOsm/L; pH 6

藥名相似:

外觀相似:

外觀描述: 1500mL透明注射液被分隔為三部分的透明軟袋

18.10D TPN Solution

33490 ɔt be ruled out / Infant risk can

BFLUID INJECTION 必富力得注射液

■Glucose 7.5%, amino acid 3% with electrolyte 1L in twin bag

Dosage: 1常備品 33490

ADULT (IV infusion via peripheral or central line)
·Nutritional supplementation: IV infusion, 500 mL/dose, Max: 2500 mL/day, usual infusion rate > 250 mL/hr

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Inj: Bfluid* 1L/Twin bag(33490), Clinimix* N17G35E 1.5L/Twin bag(33365)

ADR:

SERIOUS
Aluminum toxicity, electrolyte imbalance, hyperammonemia, hyperglycemia, hyperosmolar coma due to diabetes mellitus, hypervolemia, increased ammonia level, refeeding syndrome,

thrombosis, parenteral nutrition associated disease of liver, injury of liver, hypersensitivity reaction, infusion reaction, pulmonary embolism, death, infectious disease

NOTE: 室溫保存

·After mixing both comparments, the composition of the mixture is: Glucose 75g, Amino acid 30g (Nitrogen 4.7g), Na 35mEq, K 20mEq, Mg 5mEq, Ca 5mEq, Acetate 16mEq, Cl 35mEq, Phosphate 10mM, Zn 5umol(0.33mg), Thiamine 1.5mg; total calories is 420 kcal

藥名相似:

外觀相似:

外觀描述: 1000mL透明注射液被分隔為兩部分的透明軟袋

18.12 Irrigating Solutions

29287 / Unknown(有

BSS STERILE IRRIGATING SOLUTION "愛爾康" 均衡鹽溶液

Balanced salt sterile irrigating soln 15mL

Dosage: 1常備品 29287

Adult

·For irrigation during various surgical procedures of the eyes, ears, nose and/or throat: The adapter plug is designed to accept an irrigating needle. Tissue may be irrigated by attaching the needle to the DROP-TAINER? bottle. External irrigation may be done without the irrigating needle.

Pediatric

same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph Soln: 15mL(29287), Soln: BSS PLUS 250mL(PART I 240mL+PART II 10mL)(33403), BSS PLUS 500mL(PART I 480mL+PART II 20mL)(33404)

ADR:

bullous keratopathy, corneal edema and corneal decompensation (post-operative inflammatory reactions)

NOTE: 室溫儲存2-25℃

1. Irrigation only, not for injection.
2. Cautions: intraocular irrigating solutions used in diabetic patients undergoing vitrectomy since intropeative lens changes have been observed
3. No preservative containing and use for one patient only.
4. Prior to use, check the following: tip should be firmly in place, irrigating needle should be properly seated; squeeze out several drops before inserting into anterior chamber.
5. The needle should be removed from the anterior chamber prior to releasing pressure to prevent suction.
6. The addition of any medication to BSS solution may result in damage to intraocular tissue.
7.Each mL contains: NaCl 0.64%, KCl 0.075%, CaCl2 0.048%, MgCl2 0.03%, sodium acetate 0.39%, sodium citrate 0.17% (sodium hydroxide and/or hydrochloric acid to adjust pH)

藥名相似:

外觀相似:

外觀描述: 15mL透明點眼液，『白』蓋半透明眼藥水瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022849

18.12A Peritoneal dialysis

33422 C / Unknown(有

DIANEAL PD-2, PERITONEAL DIALYSIS SOLUTION WITH 1.5% DEXTROSE "BAXTER" P D - 2 含 1 · 5 %葡萄糖腹膜透析液 "百特"

■Dianeal* PD-2 peritoneal dialysis solution with 1.5% dextrose 2L

Dosage: 1常備品 33422

ADULT

Peritoneal dialysis, 1.5 to 2L is dwelled for 4-8 hrs. Excessive body fluid ≦1 kg/day, 3-4 exchanges a day with DIANEAL 1.5%. Excessive body fluid >1 kg/day, 3-5 exchanges a day, 1-4 exchanges with DIANEAL 2.5% or 1-2 exchanges of DIANEAL 4.25% combination with DIANEAL 1.5%. Dosage may be adjusted as needed.

Pediatric

Safety and effectiveness have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Adjusted as needed

P: Soln:1.5% 1L(33416),1.5L(33419), 2L(33422), 2.5L(33425), 5L(33427); 2.5% 1L(33417),1.5L(33420), 2L(33423), 2.5L(33426), 5L(33428); 4.25% 1L(33418), 1.5L(33421), 2L(33424), 5L(33429); 2.5% low Ca 5L(33415)

ADR:

Peritonitis, hernias, hyperglycaemia, protein malnutrition, catheter complications

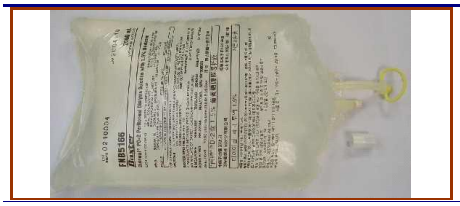
NOTE: 室溫儲存

1.Ionic concentration: Na/Ca/Mg/Cl/Lactate are 132/3.5/0.5/96/40 mEq/L
2.Osmolarity = 346 mOsm/L
3.Each liter contain anhydrous dextrose : 15g

藥名相似:

外觀相似:

外觀描述:



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022199

18.12F Miscellaneous

29045 /

NORMAL SALINE SOLUTION "CHI SHENG" 沖洗用生理食鹽水

Sodium chloride solution for irrgation 0.9% 500mL

Dosage: 1常備品 29045

·Topical irrigation : As needed.

·Topical irrigation : As needed.

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Inj: 0.45% 500mL軟袋(33328), 0.9% 20mL(33310), 0.9% 250mL塑膠瓶, 0.9% 500mL軟袋(33327), 0.9% 500mL塑膠瓶(33304), 0.9% 500mL玻璃瓶(33314), 0.9% 1000mL軟袋(33299), 3% 500mL塑膠瓶(33313), 23.5% 200mL(33312); Irrigation soln: 0.9% 500mL(29045) , 0.9% 1000mL(29137)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 藍色上蓋，500mL透明塑膠瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1035833

18.12F Miscellaneous

29137 /

N.S. IRRIGATION "Y.F." "永豐"生理食鹽水沖洗液

Sodium chloride solution 0.9% 1000mL (irrgation)

Dosage: 1常備品 29137

Adult

·Topical irrigation : As needed.

Pediatric

·Topical irrigation : As needed.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 0.45% 500mL軟袋(33328), 0.9% 20mL(33310), 0.9% 250mL塑膠瓶, 0.9% 500mL軟袋(33327), 0.9% 500mL塑膠瓶(33304), 0.9% 500mL玻璃瓶(33314), 0.9% 1000mL軟袋(33299), 3% 500mL塑膠瓶(33313), 23.5% 200mL(33312); Irrigation soln: 0.9% 500mL(29045) , 0.9% 1000mL(29137)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 1000mL白色塑膠瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1035639

18.14 Ion-removing Agents

23701 /

KALIMATE* POWDER 加利美粉

Calcium polystyrene sulfonate 5g pack (=calcium 7-9%)

Dosage: 1常備品 23701

Adult

·Hyperkalemia: PO, 15-30g/day div. 2-3 doses, (15g suspended in 30-50ml water); Enema, 30g/dose suspended in 100ml of water, 5% dextrose or 2% methylcellulose soln. The enema is retained for 30-60 mins.

Pediatric

·Hyperkalemia: 0.5-1g/kg/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Dosage adjustment required.

P: Pow: 5g(23701)

ADR:

constipation, anorexia, nausea, vomiting, electrolyte abnormalities, hypopotassemia.

NOTE: 室溫儲存

1.15-30g of resin binds about 1mEq/L of serum potassium.
2.Kalimate should be administered with care in the patients with hyperparathyroidism or multiple myeloma.
3.Not mixed with fruit juices having high potassium content.

藥名相似:

外觀相似:

外觀描述: 銀色鋁箔包裝，上印有紅色中、英、日文之"商品名"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2013086

18.14 Ion-removing Agents

28404 C / Safe

Kuzem Powder 順鉀美散

Sodium polystyrene sulfonate powder

Dosage: 1常備品 28404

Adult
·Hyperkalemia: PO, 15g suspended in 20-100mL of water or 70% sorbitol qd-qid; Rectal, 30-50g suspended in 100-200ml of water, 10% Dextrose, 25% Sorbitol or 1% Methylcellulose. The enema should if possible be retained for at least 9 hrs, then the colon should be irrigated to remove the resin.

Pediatric
·Hyperkalemia: PO, initial 1 g/kg/day in divided dose, MD 0.5g/kg/day; Rectal, same as oral dosage.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Pow: 15g pack (28404)

ADR:

COMMON
Constipation, nausea, vomiting
SERIOUS
Hypocalcemia, hypokalemia, fecal impaction, gastrointestinal hemorrhage, gastrointestinal necrosis, gastrointestinal obstruction, gastrointestinal perforation, ischemic colitis, acute bronchitis, bronchopneumonia

NOTE: 室溫儲存

◎本品具吸附作用，可能干擾其他藥品作用，請至少間隔3小時；患有胃輕癱或其他延遲胃排空者，則服用間隔應延長至6小時。

1. 1g resin binds about 1mEq of potassium in vivo.
2. 1g resin contains 4.1 mEq Na, and 1/3 will be absorbed.
3. The powder should not be mixed with foods or liquids that contain a large amount of potassium such as bananas or orange juice.
4. Magnesium hydroxide should not be used as a laxative for the treatment of sodium polystyrene sulfonate-induced constipation.
5. Suspension freshly prepared, not stored beyond 24 hours.
6. 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 15克粉末，鋁箔包裝，一面白底黑字有廠牌標誌，另一面綠底黑字

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049416

18.14B Phosphate-Removing Agents

23667 C /

PROCAL TABLETS 667MG (CALCIUM ACETATE) "PL" "培力" 普羅鈣錠６６７毫克（醋酸鈣)

Calcium acetate (=169mg Ca2+) tab

Dosage: 1常備品 23667

·Hyperphosphatemia: PO, initial 1334mg tid with meal, may be increased gradually to obtain serum phosphate levels below 6mg/dL; MD 2001-2668mg tid with meal

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr < 25mL/min: dosage adjustments may be necessary dependent on serum calcium levels

P: Tab:CaCO3 500mg(23661), Calcium acetate 667mg(23667), BIO-CAL* (23674), Caltrate* Plus(172605), Real-Gard*(172613), OS-Cal*(172612)

ADR:

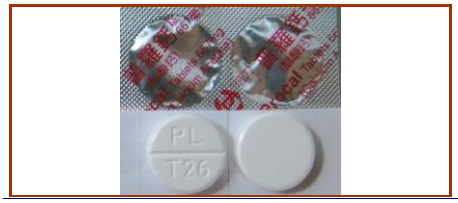
Nausea, hypercalcemia

NOTE: 室溫儲存

藥名相似: Tab:CaCO3 500mg(23661), Calcium acetate 6

外觀相似:

外觀描述: 白色圓扁錠，一面中間有一刻痕有PL及T26 字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1036794

18.14B Phosphate-Removing Agents

23702 C / Unknown(有

FOSRENOL CHEWABLE TABLET 750MG 福斯利諾咀嚼錠750公絲

Lanthanum carbonate 750mg chewable tab

Dosage: 1常備品 23702

ADULT
·End stage renal disease - Hyperphosphatemia: Initial, PO 1500 mg per day in divided doses with meals, then titrate in increments of 750 mg/day at intervals of 2 to 3 weeks. Maintenance, PO 1500 to 3000 mg per day in divided doses with meals.

Pediatric
·Use in pediatric patients is not recommended

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab:Fosrenol(23702)

ADR:

COMMON
Abdominal pain, Diarrhea, Nausea, Vomiting.
SERIOUS
Dialysis Vascular graft occlusion, Bowel obstruction, Fecal impaction, Gastrointestinal obstruction,

Gastrointestinal perforation, Ileus.

NOTE: 室溫儲存

·《Contraindications》·Bowel obstruction, including ileus or fecal impaction ;
·chew completely or crush tablets to aid chewing before swallowing; do not swallow intact tablets
·take with meals
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有S405 750字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024494

18.14B Phosphate-Removing Agents

23704 **C / Unsafe**

Renvela powder for oral suspension 磷減樂口服懸液用粉劑

Sevelamer carbonate 800mg sachet

Dosage: 1常備品 23704

Adult
·End stage renal disease - Hemodialysis - Hyperphosphatemia:
serum phosphorus > 5.5 and < 7.5 mg/dL: PO, 800 mg tid with meals.
serum phosphorus >= 7.5 mg/dL: PO, 1600 mg tid with meals.
dose titration, increase or decrease by 800 mg tid with meals at 2 week intervals, with a target serum phosphorus goal of 3.5 mg/dL to 5.5 mg/dL

Pediatric
safety and efficacy of sevelamer carbonate in pediatric patients have not been established

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Powder: 800mg(23704)

ADR:

COMMON
Abdominal pain, Constipation, Diarrhea, Flatulence, Indigestion, Nausea, Vomiting
SERIOUS
Bowel obstruction, Perforation of intestine, Peritonitis

NOTE: 室溫避光

1.Switching from Calcium Acetate, a similar reduction was seen with equivalent dose. Calcium Acetate 667mg = Renvela powder 0.8g
2.本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 淡黃色粉末，裝於白色鋁箔小包

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025733

20.00 Enzymes

24006 /

BROEN-C ENTERIC F.C. TABLETS "N.K." "南光"撲炎喜腸溶膜衣錠

Bromelain 20000 U, L-cysteine 20mg tab

Dosage: 1常備品 24006

Adult
Treatment of soft-tissue inflammatory and edema associated with trauma and surgery: PO, 3-6 tabs/day divided in 3-4 doses according to patient's condition

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Severe liver impairment: Contraindicated

Dosing adjustments in renal impairment:

Severe kidney impairment: Contraindicated

P: P Tab: BROEN-C* (24006)

ADR:

Increase in heart rate, palpitations, stomach ache, diarrhea, bronchial asthma, erythema, pruritus

NOTE: 室溫儲存

Swallow whole; do not crush or chew

藥名相似:

外觀相似:

外觀描述: 橙黃色圓扁錠，一面有"NK"字樣，另一面有"C"字樣

20.00 Enzymes

33602 / Unknown(有

FOY FOR INJECTION 胰活愛注射劑

Gabexate mesylate 100 mg inj pow in vial

Dosage: 1常備品 33602

Adult
·Pancreatitis : IV infusion, initial 100-300mg/day, an additional dose of 100-300mg as needed
·Disseminated intravascular coagulation (DIC): continuous IV infusion, 20-39mg/kg/day

--

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 100mg vial(33602)

ADR:

·Cardiovascular Effects: Hypotension, Thrombophlebitis.
·Dermatologic Effects: Local injection site irritation (reddening, swelling, induration, inflammation), SKIN RASH and/or PRURITUS.
·Gastrointestinal Effects: NAUSEA, DIARRHEA, VOMITING, ANOREXIA, and ABDOMINAL DISTENSION.
·Hematologic Effects: Leukopenia.
·Hepatic Effects: Hepatotoxicity.
·Immunologic Effects: Hypersensitivity reaction.
·Neurologic Effects: HEADACHE and PARESTHESIAS, Exacerbation of NEUROSIS.
·Ophthalmic Effects:BLURRED VISION.
·Renal Effects: Nephrotoxicity.
·Respiratory Effects: BRONCHOSPASM.

NOTE: 室溫儲存

Contraindications: cerebral aneurysm, cerebrovascular hemorrhage, hypertension (severe, uncontrolled), uncontrolled bleeding (except for disseminated intravascular coagulation or hemodialysis patients with active bleeding sites/hemostatic function impairment)

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『綠』蓋透明玻璃小瓶，蓋上有FOY及100字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2018669

20.00 Enzymes

33610 C / Unknown(有

FASTURTEC POWDER AND SOLVENT FOR CONCENTRATE FOR SOLUTION FOR INFUSION 1.5MG/ML 法舒克注射劑1.5毫克/毫升

Rasburicase inj 1.5mg pow in vial with 1mL solvent

Dosage: 1常備品 33610

Adult
·Chemotherapy-induced hyperuricemia: IV infusion over 30 min, 0.15 or 0.2 mg/kg/day for 1-10 days

Pediatric
·Chemotherapy-induced hyperuricemia: IV infusion over 30 min, 0.15 or 0.2 mg/kg/day for 3-5 days

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 1.5mg/vial (with 1 mL solvent)

ADR:

COMMON
abdominal pain, mucositis, constipation, diarrhea, nausea, vomiting, fever, rash
SERIOUS
anaphylaxis, hemolysis, neutropenia, methemoglobinemia, respiratory distress, sepsis

NOTE: 冰箱儲存2-8℃，不可冷凍。

1. Contraindications: patients with prior hypersensitivity reactions or anaphylaxis, hemolytic

reactions or methemoglobinemia, patients with G6PD deficiency
2. Chemotherapy should be initiated 4-24 hours after the first dose of rasburicase
3. Do not use any glucose solution for dilution due to potential incompatibility.
4. Blood samples must be immediately immersed in ice water bath to prevent the degradation of uric acid.

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『淺綠』蓋透明玻璃小瓶，附1ml稀釋液透明安瓿頸部有2條白色線條

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000761

20.00 Enzymes

33612 C / Caution

Vimizim 1 mg/ml concentrate for solution for infusion 衛尼吉 酉每 1毫克/毫升濃縮輸注液

急用 Elosulfase alfa inj 5mg/5mL vial

Dosage: 2急用藥 33612

Adult
·Mucopolysaccharidosis (MPS IVA; Morquio A syndrome): IV infusion over 3.5-4.5 hrs, 2 mg/kg once weekly

Pediatric (5 yrs and older)
·Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Inj: 5mg/5mL vial (33612)

ADR:

COMMON
Abdominal pain, nausea, vomiting, headache, fatigue, fever, shivering
SERIOUS
Anaphylaxis, hypersensitivity reaction

NOTE: 冰箱冷藏 2-8℃

·Pretreat with antihistamines (with or without antipyretics) 30-60 mins prior to infusion
·Administer using a 0.2-micrometer in-line filter

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液『白』蓋透明玻璃瓶

20.00 Enzymes

37517 C / Caution

Cerezyme 400U 雪瑞素 400U

急用Imiglucerase inj 400U vial

Dosage: 2急用藥 37517

Adult
·Gaucher disease, type 1: usual dosage is 60 units/kg IV over 1-2 hours every 2 weeks, but may range from 2.5 units/kg 3 times a week to 60 units/kg once every 2 weeks; disease severity may dictate that treatment be initiated at a relatively high dose or with relatively frequent administration

Pediatric(≧2yrs)
·Gaucher disease, type 1: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 400U Vial(37517, 專案進口)(31135, 捐贈)

ADR:

COMMON
Hypotension, tachyarrhythmia, cyanosis, flushing, pruritus, rash, urticaria, shivering, abdominal pain, diarrhea, nausea, backache, dizziness, headache, chest discomfort, disorder of respiratory system, angioedema, fatigue, fever
SERIOUS
Anaphylactoid reaction (rare)

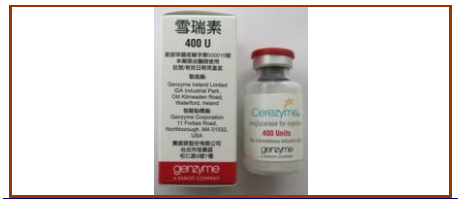
NOTE: 冰箱冷藏，不可冷凍

An enzyme unit (U) of IMIGLUCERASE is defined as the amount of enzyme that catalyzes the hydrolysis of one micromole of the synthetic substrate para-nitrophenyl beta-D-glucopyranoside (Pnp-Glc) per minute at 37 degrees C

藥名相似:

外觀相似:

外觀描述: 白色乾粉，紅蓋玻璃小瓶



20.00 Enzymes

37680 B / Infant risk can

FABRAZYME INJECTION 35MG/VIAL 法布瑞酶凍晶注射劑

急用Agalsidase beta 35mg Vial

Dosage: 2急用藥 37680

Adult
· Fabry's disease: IV infusion 1 mg/kg q 2 wks

Pediatric
· Fabry's disease (≧ 8 yrs): Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Inj: 35mg Vial(37680)

ADR:

COMMON
Hypertension, Hypotension, Tight chest, Pruritus, Urticaria, Nausea, Antibody development, Anti-agalsidase beta, Complication of infusion, Fever, Arthritis/arthrosis, Musculoskeletal pain, Myalgia, Headache, Rigor, Anxiety, Depression, Dyspnea, Pharyngitis, Rhinitis
SERIOUS
Cardiac arrest, Cardiomegaly, Cerebrovascular accident

NOTE:

· Antipyretics should be administered prior to infusion.

藥名相似:

外觀相似:

外觀描述: 白色乾粉，紅蓋玻璃小瓶

20.00 Enzymes

37772 C /

ELAPRASE (idursulfase) Injection 移黏寶脢靜脈輸液

急用Idursulfase 6mg/3mL vial

Dosage: 2急用藥 37772

Adult
·Mucopolysaccharidosis II (MPS-II): IV infusion over 1-3 hrs, 0.5mg/kg once a week

Pediatric (5 yrs and older)
·Mucopolysaccharidosis II (MPS-II): Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 6mg/3mL Vial(37875, 37763捐贈)

ADR:

COMMON
Hypertension, Infusion-site edema, pruritic rash, pruritus, urticaria, arthralgia, chest wall musculoskeletal pain, headache, visual disturbance, abscess, complication of infusion, fever, malaise
SERIOUS
Hypersensitivity, cardiac dysrhythmia, infectious disease, cyanosis, hypoxia, pulmonary embolism, respiratory failure

NOTE: 冰箱保存

· Use an infusion set with a 0.2 micrometer filter is recommended.
· Start infusion at a rate of 8 mL/h for the first 15 mins. If tolerated, it may be increased by 8 mL/h increments every 15 mins. Do not exceed a rate of 100 mL/h.
· Withdraw the calculated volume and dilute in 100mL NS, mix gently, do not shake.

藥名相似:

外觀相似:

外觀描述: 3mL透明注射液『藍』蓋透明玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=22000011

20.00 Enzymes

37841 B /

Aldurazyme Concentrated Solution 艾德脢靜脈注射用溶液

急用Laronidase inj 2.9mg/5mL vial

Dosage: 2急用藥 37841

Adult
· Mucopolysaccharidosis I: IV infusion over 3-4 hrs, 0.58 mg/kg once a week

Pediatric (5 yrs and older)
·Mucopolysaccharidosis I: same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 2.9mg/5ml vial (37841)

ADR:

COMMON
absess, flushing, injection site reactions, rash, corneal opacity,dependent edema, facial edema, hypotension, development of antibodies to laronidase, fever, headache, hyperreflexia, paresthesia,upper respiratory infection.
SERIOUS
anaphylactic reaction, bronchospasm, dyspnea, angioedema, bilirubinemia, chest pain, vein disorders, thrombocytopenia.

NOTE: 冰箱保存

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液『橙』蓋透明玻璃瓶

20.00 Enzymes

37873 B /

NAGLAZYME* (galsulfase) Injection 那加硫酉每注射劑

急用Galsulfase inj 5mg/5mL vial

Dosage: 2急用藥 37873

Adult
·Mucopolysaccharidosis VI (MPS VI; Maroteaux-Lamy syndrome): IV infusion over at least 4 hrs, 1 mg/kg once weekly

Pediatric (5 yrs and older)
Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 5mg/5mL vial (37873)

ADR:

COMMON
Abdominal pain, diarrhea, vomiting, immunology finding, antibody development, arthralgia, headache, otalgia, otitis media, cough, upper respiratory infection, fever
SERIOUS
Urticaria (face and neck), complication of infusion, apnea, bronchospasm, respiratory distress

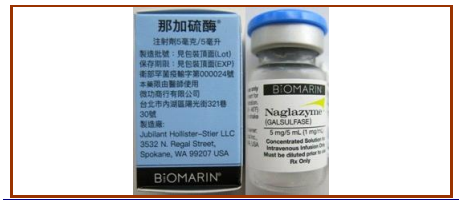
NOTE: 冷藏儲存2-8℃

· Pretreat with antihistamines with or without antipyretics 30-60 mins prior to infusion
· Initial infusion rate should be 6 mL/hr for the first hour. If tolerated, it may be increased to 80 mL/hr for the remaining 3 hours
· Infusion time can be extended up to 20 hours if infusion reactions occur
· Administer with a polyvinyl chloride (PVC) infusion set equipped with an in-line, low-protein-binding 0.2 micrometer filter

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液，『藍』蓋透明玻璃瓶



22.02 Antitussives

28597 UK /

COUGH MIXTURE 〝生達〞鎮咳祛痰液

Platycodon fluidextract 0.2mL/mL, 120mL/bot

Dosage: 1常備品 28597

Adult
·Cough: PO, 5-15mL tid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Soln: 120mL/Bot(28597)

ADR:

NOTE: 室溫儲存

· 《仿單禁忌》曾因本藥成分引起過敏者。
· 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 120cc塑膠瓶，暗褐色液體

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1030862

22.02A Narcotic Antitussives

24431 UK /

OPIUM AND GLYCYRRHIZA MIXTURE TABLETS "ASTAR" 複方鴉片甘草合劑錠

Opium powder[C] 2.5mg, glycyrrhiza fluid extract 0.48mL, antimony potassium tartrate 1mg tab

Dosage: 1常備品 24431

Adult
·Cough: PO, 2-3 tabs tid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: OPIUM and GLYCYRRHIZA mixture (24431)

ADR:

·For ingredient of opium
COMMON
Constipation, nausea, vomiting, asthenia, dizziness, sedation, somnolence
SERIOUS
Seizure, respiratory depression

NOTE: 室溫儲存

·屬第四級管制藥

藥名相似:

外觀相似:

外觀描述: 棕色圓扁錠，一面有"AS 308"字樣，另一面中央有刻痕

22.02B Non-Narcotic Antitussives

24403 ɔt be ruled out / Infant risk can

ROMICON-A* CAPSULES 樂滅咳複方膠囊

Dextromethorphan HBr 20mg [A], Potassium cresolsulfonate 90mg[UK], Lysozyme Cl 20mg[UK] cap

Dosage: 1常備品 24403

Adult
·Cough: PO, 10-20 mg q4h or 30mg q6-8h; Max. 120mg/day

Pediatric
(Dextromethorphan)
·Cough: PO
1-3 months: 0.5-1 mg every 6-8 hours
3-6 months: 1-2 mg every 6-8 hours
7 months to 1 year: 2-4 mg every 6-8 hours
2-6 yr: 2.5-7.5 mg q4-8h; Max. 30mg/day
7-12 yr: 5-10 mg q4h or 15 mg q6-8h; Max. 60mg/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 60mg(24404); Cap: 20mg(24403); Inj:10mg/2mL amp(34000)

ADR:

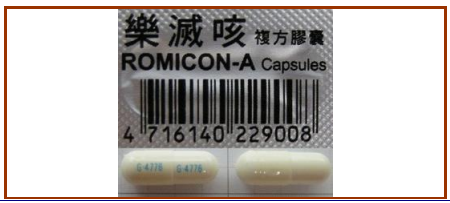
Dizziness, drowsiness, fatigue

NOTE: 室溫儲存

藥名相似: Tab: 60mg(24404); Cap: 20mg(24403); Inj:10

外觀相似: Ulexin* 500mg(20901), Kinxetin*(22928)

外觀描述:



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1038819

22.02B Non-Narcotic Antitussives

24404 a / Infant risk is

DELCOPAN* SR F.C.T. 60MG 抑咳平持續性膜衣錠60公絲

Dextromethorphan HBr 60mg SR tab

Dosage: 1常備品 24404

Adult

·Cough: PO, 60mg bid

Pediatric
·Cough PO:
2-6yrs: 15 mg bid daily
7-12yrs: 30 mg bid daily

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 60mg(24404); Cap: 20mg(24403); Inj:10mg/2mL amp(34000)

ADR:

Dizziness, drowsiness, fatigue

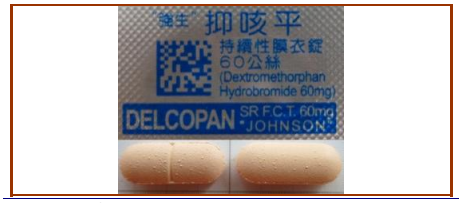
NOTE: 室溫儲存

Swallow whole; do not crush or chew

藥名相似: Tab: 60mg(24404); Cap: 20mg(24403); Inj:10

外觀相似:

外觀描述: 粉紅色長橢圓扁錠，一面中間有刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044829

22.02B Non-Narcotic Antitussives

24405 C /

Zcough Soft Capsules 100mg 咳治得軟膠囊100毫克

Benzonatate 100mg cap

Dosage: 1常備品 24405

Adult
·Cough: PO, 100-200mg tid; Max. 600mg/day

Pediatric (>10 yr)
Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: 100mg(24405)

ADR:

Dizziness, drowsiness, sedation, headache, nausea; numbness of the mouth, tongue, and throat (if capsules are broken or chewed)

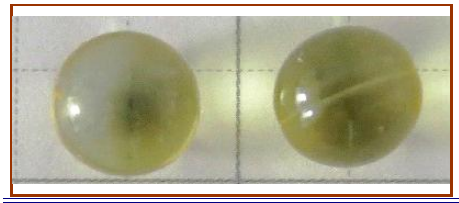
NOTE: 室溫儲存

Swallow whole, do not chew or suck

藥名相似:

外觀相似:

外觀描述: 黃色圓形軟膠囊



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=51058202

22.02B Non-Narcotic Antitussives

28598 B / Caution

SUTUSSI LIQUID 0.8 MG/ML (BUTAMIRATE CITRATE) "瑞德" 停咳喜液0.8毫克/毫升（布他米雷特）

Butamirate citrate 0.8mg/mL soln, 120mL/bot

Dosage: 1常備品 28598

Adult
·Cough: PO, 7.5mL tid-qid

Pediatric
·Cough: PO, 5mL tid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Soln: 120mL/bot(28598)

ADR:

NOTE: 室溫儲存

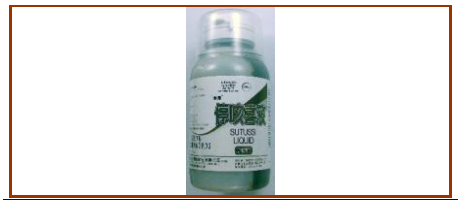
·《仿單禁忌》：對主成分Butamirate citrate過敏者禁用。

·含阿斯巴甜，苯酮尿症者不宜使用。

藥名相似:

外觀相似:

外觀描述: 120mL半透明塑膠瓶，暗褐色液體



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043362

22.02B Non-Narcotic Antitussives

34000 C / Safe

ANTICO INJECTION 5MG/ML (DEXTROMETHORPHAN) "T.F." "大豐" 安止咳注射液 5公絲/公撮（右旋美蘇仿）

Dextromethorphan HBr inj 10mg/2mL amp

Dosage: 1常備品 34000

Adult
·Cough: IM/SC, 10-15mg qd-bid

Pediatric
·Cough: IM/SC, 5-10mg qd-bid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 60mg(24404); Cap: 20mg(24403); Inj:10mg/2mL amp(34000)

ADR:

Dizziness, drowsiness, fatigue

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 2mL透明注射液『棕』色安瓿頸部有白點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1033563

22.04 Expectorants

28600 C / Unknown(有

GUAPHEN SYRUP 20MG/ML (GUAIFENESIN) "CENTER" 〝晟德〞咳酚糖漿20 毫克/毫升（呱芬那辛）

Guaifenesin 20mg/mL Syrup, 120mL/bot

Dosage: 1常備品 28600

Adult
·Expectoration: PO, 10mL-20mL q4h; Max. 120mL/day

Pediatric
·Expectorationt: PO
2-6 yr: 2.5-5mL q4h; Max. 30mL/day
6-12 yr: 5-10mL q4h; Max. 60mL/day
>12 yr: same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Soln: 120mL/bot(28600)

ADR:

Dizziness, headache, N/V, rash

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to guaifenesin products；
·含阿斯巴甜，苯酮尿症者不宜使用。(3.875mg/mL)

藥名相似:

外觀相似:

外觀描述: 120mL塑膠瓶，深紫色液體

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1036094

22.06 Mucolytic Agents

24408 ɔt be ruled out / Infant risk can

AMBROXOL TABLETS 30MG "SINPHAR" "杏輝"安嗽錠30毫克（安布索）

Ambroxol HCl 30mg tab

Dosage: 1常備品 24408

Adult
·Mucolysis: PO, 60-180mg/day div into 2-3 doses

Pediatric
·Mucolysis: PO
<2 yr: 15mg/day
2-5 yr: 15-30mg/day
5-12 yr: 30-45mg/day
>12 yr: 60-90mg/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab:75mg SR(24410), 30mg(24408)

ADR:

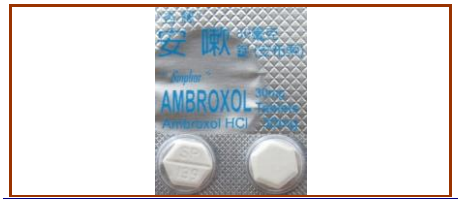
Fatigue, dry mouth, contact dermatitis

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色六角形扁錠，一面中間有一刻痕及"SP 139"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1033415

22.06 Mucolytic Agents

24410 ɔt be ruled out / Infant risk can

LOXOL SR TABLETS 75MG 樂咳痰舒長效錠 75公絲

Ambroxol HCl 75mg SR tab

Dosage: 1常備品 24410

Adult
·Mucolysis: PO, 75mg qd

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Dose adjustment needed

P: Tab:75mg SR(24410), 30mg(24408)

ADR:

nausea, vomiting, dry mouth, dermatitis

NOTE: 室溫儲存

Swallow whole, do not crush or chew

藥名相似: Tab:75mg SR(24410), 30mg(24408)

外觀相似:

外觀描述: 淺黃色圓扁錠

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046386

22.06 Mucolytic Agents

28592 a / Unknown(有

Bisolvon (R) Solution 2mg/ml 氣舒痰(R)液2毫克/毫升(印尼廠)

Bromhexine HCl soln 2mg/mL, 50mL/bot

Dosage: 1常備品 28592

Adult
·Mucolysis: PO, 8-16mg(4-8mL) tid

Pediatric
·Mucolysis: PO
<6 yr: 4mg(2mL) tid
6-14 yr: 8mg(4mL) tid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Soln: 50mL/bot(28592)

ADR:

Dizziness, headache, rash

NOTE: 室溫儲存30℃以下

·《仿單禁忌》：hypersensitivity to brohexine or other components of formulation。
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 50mL玻璃瓶裝透明液劑

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025729

22.08 Leukotriene Modifers

22070 ɔt be ruled out / Infant risk has

SINGULAIR* FILM COATED TABLET 10MG 欣流膜衣錠10毫克

Montelukast sodium 10mg FC tab

Dosage: 1常備品 22070

Adult
·Asthma, seasonal allergic rhinitis: PO, 10 mg hs

Pediatric
·Asthma, seasonal allergic rhinitis: PO
6-24 mons: 4mg (granules) hs
2-5 yrs: 4mg (chewable tab or granules) hs
6-14 yrs: 5mg hs
≧15 yrs: 10mg hs

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 10mg(22070), Chewable tab: 5mg(22071), 4mg(22702), Granules: 4mg(22072)

ADR:

COMMON
Abdominal pain, Diarrhea, Headache, Otitis, Otitis media, Cough, Nasal discharge, Pharyngitis, Sinusitis, Upper respiratory infection, Fever, Influenza.
SERIOUS
Eosinophilic granulomatosis with polyangiitis, Aggressive behavior, Obsessive-compulsive disorder, Suicidal behavior, Suicidal thoughts.
·仿單上市使用後曾發生下列不良反應-精神病學異常：躁動包括侵略性行為或敵意、焦慮、沮喪、定向障礙、注意障礙、夢境異常、言語困難(口吃)、幻覺、失眠、記憶損害、強迫症、精神運動性過度活躍(包括易怒、坐立不安、顫抖)、夢遊、自殺的想法和行為(Suicidality)、抽搐(tic)。

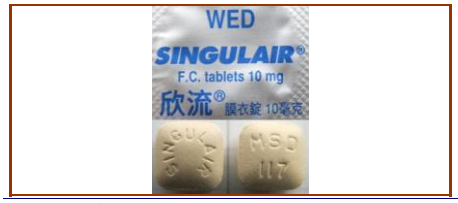
NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to any component of the product；

藥名相似:

外觀相似:

外觀描述: 淺橙色四角形扁錠，有MSD 117及SINGULAIR字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022778

22.08 Leukotriene Modifers

22071 ɔt be ruled out / Infant risk can

SINGULAIR* CHEWABLE TABLET 5MG 欣流咀嚼錠5毫克

Montelukast sodium 5mg chewable tab

Dosage: 1常備品 22071

Adult
·Asthma, seasonal allergic rhinitis: PO, 10mg hs

Pediatric
·Asthma, seasonal allergic rhinitis: PO
6-24 mons: 4mg (granules) hs
2-5 yrs: 4mg (chewable tab or granules) hs
6-14 yrs: 5mg hs
≧15 yrs: 10mg hs

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 10mg(22070), Chewable tab: 5mg(22071), 4mg(22702), Granules: 4mg(22072)

ADR:

COMMON
Abdominal pain, Diarrhea, Headache, Otitis, Otitis media, Cough, Nasal discharge, Pharyngitis, Sinusitis, Upper respiratory infection, Fever, Influenza.
SERIOUS
Eosinophilic granulomatosis with polyangiitis, Aggressive behavior, Obsessive-compulsive disorder, Suicidal behavior, Suicidal thoughts.
·仿單上市使用後曾發生下列不良反應-精神病學異常：躁動包括侵略性行為或敵意、焦慮、沮喪、定向障礙、注意障礙、夢境異常、言語困難(口吃)、幻覺、失眠、記憶損害、強迫症、精神運動性過度活躍(包括易怒、坐

立不安、顫抖)、夢遊、自殺的想法和行為(Suicidality)、抽搐(tic)。

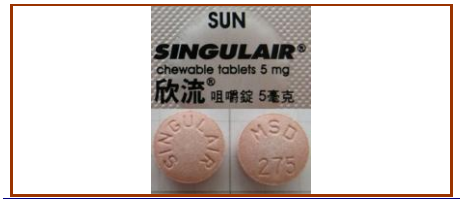
NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to any component of the product；
·含阿斯巴甜，苯酮尿症者不宜使用。(Each 5mg chewable tablets contain phenylalanine(a component of aspartame) 0.842mg)

藥名相似:

外觀相似:

外觀描述: 淺膚色圓扁錠，有MSD 275及SINGULAIR字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022779

22.08 Leukotriene Modifers

22072 **ɔt be ruled out / Infant risk can**

SINGULAIR ORAL GRANULES 4MG 欣流顆粒劑4公絲

Montelukast granules 4mg/pk

Dosage: 1常備品 22072

Adult
·Asthma, seasonal allergic rhinitis: PO, 10mg hs

Pediatric
·Asthma, seasonal allergic rhinitis: PO
6-24 mons: 4mg (granules) hs
2-5 yrs: 4mg (chewable tab or granules) hs
6-14 yrs: 5mg hs
≧15 yrs: 10mg hs

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 10mg(22070), Chewable tab: 5mg(22071), Granules: 4mg(22072)

ADR:

COMMON
Abdominal pain, Diarrhea, Headache, Otitis, Otitis media, Cough, Nasal discharge, Pharyngitis, Sinusitis, Upper respiratory infection, Fever, Influenza.
SERIOUS
Eosinophilic granulomatosis with polyangiitis, Aggressive behavior, Obsessive-compulsive disorder, Suicidal behavior, Suicidal thoughts.
·仿單上市使用後曾發生下列不良反應-精神病學異常：躁動包括侵略性行為或敵意、焦慮、沮喪、定向障礙、注意障礙、夢境異常、言語困難(口吃)、幻覺、失眠、記憶損害、強迫症、精神運動性過度活躍(包括易怒、坐立不安、顫抖)、夢遊、自殺的想法和行為(Suicidality)、抽搐(tic)。

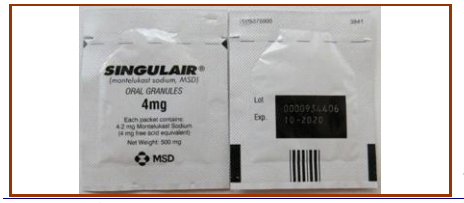
NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to any component of the product；
·The 4-mg oral granule formulation is bioequivalent to the 4-mg chewable tablet.
·Granules may be administered directly in the mouth or mixed with cold or room temperature applesauce, carrots, rice, ice cream, baby formula or breast milk. Do not add to any other liquids.
·Administer within 15 minutes of opening packet, discard unused portion.
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 白色鋁箔包裝，黑色字體



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024134

22.10 Mast-cell Stabilizers

29065 **B /**

ALLERGOCROM NASAL SPRAY SOLUTION 2.8MG/SPRAY 艾麗鼻用噴液劑

Sodium cromoglycate 2% nasal solution, 15mL/bot

Dosage: 1常備品 29065

Adult
·Allergic rhinitis: nasal, 1 puff in each nostril, 3-6 times/day

Pediatric(≧2 years)
·Allergic rhinitis: nasal, 1 puff in each nostril, 3-6 times/day

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Dosage adjustment needed

P: Nasal soln: 2%, 15mL/bot(29065); Oph soln: 2%, 10mL/bot(29286)

ADR:

COMMON
bad taste, cough, throat irritation
SERIOUS
anaphylaxis, bronchospasm

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 15mL藥液，噴鼻瓶裝，白底黑字標籤有黃色圖像與區塊，紙盒裝白底黑字有黃色圖像與區塊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021824

22.12 Interleukin Antagonists

37637 ɔt be ruled out / Infant risk can

Nucala Powder for Solution for Injection 舒肺樂凍晶注射劑

Mepolizumab inj 100mg vial

Dosage: 1常備品 37637

Adult
·Severe asthma, Add-on maintenance in patients with eosinophilic phenotype: 100 mg subQ once every 4 weeks injected into the upper arm, thigh or abdomen.

Pediatric(≧12yrs)
·Severe asthma, Add-on maintenance in patients with eosinophilic phenotype: Same as adult.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 100mg(37637)

ADR:

COMMON
Injection site reaction, Backache, Headache, Fatigue.

SERIOUS
Herpes zoster, Hypersensitivity reaction.

NOTE: 冰箱冷藏，不可冷凍。

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『紅』蓋透明玻璃小瓶

22.14 Inhalation

29052 C / Unknown(有

VENTOLIN INHALER 泛得林定量噴霧劑

Salbutamol (Albuterol) inhalation 100mcg/dose, 200dose/bot

Dosage: 1常備品 29052

Adult
·Asthma: Inhalation, 1-2 dose bid-qid as needed. Max. 200mcg qid

Pediatric(≧4 years)
· Asthma: Inhalation, 2 dose every 4-6hrs or 1 dose every 4hrs as needed

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 2mg(22064); Ventolin* Inhaler: 100mcg/dose, 200dose/B (29052); Combivent* MDI: 200puff/B (29100); Nebuliser soln: 5mg/2.5mL (29086), Combivent* UDV 2.5mL/amp (29114)

ADR:

tachycardia, palpitations, tremor, agitation, premature ventricular contractions, nervousness, headache, dizziness, insomnia, hyperglycemia, nausea, vomiting

NOTE: 室溫儲存

· 《Contraindications》Hypersensitivity to albuterol or any of its components, including milk proteins, or levalbuterol ;

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2017528

22.14 Inhalation

29070 B / Unknown(有

SIRUTA INHALATION SOLUTION 200MG/ML (MESNA) "S.T." 息汝痰吸入液〝信東〞

Mesna soln for inhalation 600mg/3mL amp

Dosage: 1常備品 29070

Adult
·Mucolytic: Nebulization, 3-6mL (undiluted or diluted with an equal quantity of NS or distilled water) 1-4 times a day; Instillation, 1-2mL (diluted with an equal quantity of NS or distilled water) q1h until liquification of the bronchial secretions was observed

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Nebulizer Soln: 600mg/3mL Amp(29070); Inj: 400mg/4mL Amp(30007)

ADR:

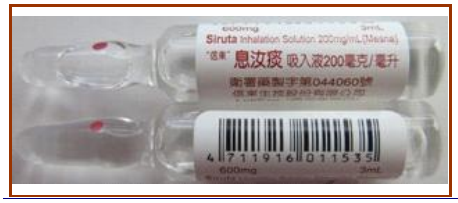
Irritative cough, bronchospasm, heart burn

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 3mL透明液，透明玻璃安瓿，頸部有藍點



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044060

22.14 Inhalation

29077 B / Unknown(有

ATROVENT NEBULISER SOLUTION 0.5MG/2ML IN UNIT-DOSE VIALS 定喘樂單一劑量吸入液 0 · 5 毫克/ 2 毫升

Ipratropium bromide nebuliser soln 0.5mg/2mL amp

Dosage: 1常備品 29077

Adult
·Bronchospasm, associated with COPD or asthma: nebulized, 500mcg tid-qid, Max. 2 mg/day

Pediatric
·Bronchospasm, associated with COPD or asthma: nebulized, 125-250 mcg tid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Combivent MDI: 200puff/B(29100); Nebuliser soln: 0.5mg/2mL(29077), Combivent* UDV 2.5mL/amp (29114)

ADR:

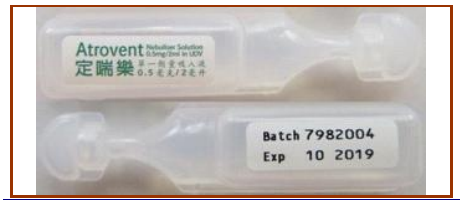
COMMON
bitter taste, dry mouth, nasal congestion, nasal dryness
SERIOUS
hypersensitivity reactions (angioedema, bronchospasm, urticaria, anaphylaxis, oropharyngeal edema), paralytic ileus

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 2mL透明澄清單一劑量吸入液



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2018863

22.14 Inhalation

29080 C / Unknown(有

SYMBICORT TURBUHALER 160/4.5MCG/DOSE 都保定量粉狀吸入劑160 / 4.5MCG / DOSE"吸必擴"

Budesonide 160mcg & Formoterol fumarate 4.5mcg /dose 120dose/bot Inhalation powder

Dosage: 1常備品 29080

Adult (12 yr and older): Oral inhalation
·Asthma: 1-2 dose bid
·COPD: 2 dose bid

Pediatric (6 yr and older)
·Asthma: Oral inhalation, 1 dose bid, Max. 2 dose/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Symbicort* Rapihaler:120 dose/B (29171);Symbicort Turbuhaler:120 dose/B (29080); Duasma Inhaler:200 puff/B(29099)

ADR:

Common
Oral candidiasis, Stomach ache, Vomiting, Backache, Headache, Nasal congestion, Nasopharyngitis, Sinusitis, Upper respiratory infection.
Serious
Hypokalemia, Glaucoma, Raised intraocular pressure.

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023265

22.14 Inhalation

29086 C / Unknown(有

VENTOLIN NEBULES 5MG PER 2.5ML INHALATION SOLUTION 泛得林呼吸溶液劑

Albuterol nebuliser soln 5mg/2.5mL amp

Dosage: 1常備品 29086

Adult
·Asthma: nebulization, 2.5 mg 3-4 times daily

Pediatric (2-12ys)
·Asthma: nebulization,
<15kg: 0.63mg or 1.25mg 3-4 times daily
>15kg: same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 2mg (22064); Ventolin* Inhaler: 100mcg/dose, 200dose/B (29052); Combivent* MDI: 200puff/B (29100); Nebuliser soln: 5mg/2.5mL (29086), Combivent* UDV 2.5mL/amp (29114)

ADR:

COMMON
hypokalemia, nausea, nervousness, palpitations, tachycardia, tremor
SERIOUS
erythema multiforme (in children), Stevens-Johnson syndrome

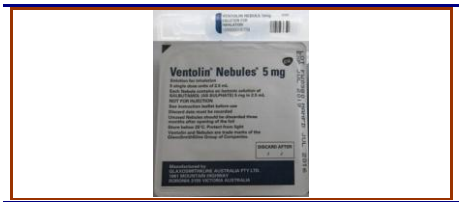
NOTE: 室溫儲存

Nebulizer soln dilute with NS deliver over 5-15 min

藥名相似:

外觀相似:

外觀描述:



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2019536

22.14 Inhalation

29091 C / Infant risk can

SERETIDE 250 EVOHALER 使肺泰250優氟吸入劑

Salmeterol 25mcg & Fluticasone Propionate 250mcg/PF 120PF/bot (inhalation aerosol)

Dosage: 1常備品 29091

Adult
·Asthma, COPD: 2 puffs bid

Pediatric
·Safety and efficacy have not been established in patients less than 12 years old

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P:

ADR:

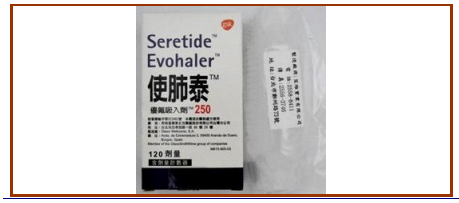
COMMON
Tachyarrhythmia, cushing's syndrome, oral candidiasis, headache, hoarse, throat irritation
SERIOUS
Asthma-related death, exacerbation of asthma (severe)(with salmeterol)

NOTE: 室溫儲藏

藥名相似:

外觀相似:

外觀描述: 紙盒白底深紫色"Seretide Evohaler",黑色"使肺泰",紅色"250"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023481

22.14 Inhalation

29097 C / Infant risk can

SERETIDE 125 EVOHALER 使肺泰125優氟吸入劑

Salmeterol 25mcg & Fluticasone Propionate 125mcg/PF 120PF/bot (inhalation aerosol)

Dosage: 1常備品 29097

Adult
·Asthma: 2 puffs bid

Pediatric(≧12 years)
·Asthma: 2 puffs bid

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

NDA

P: Inhalation Aerosol: Seretide 250 Evohaler 120puff/B(29091); Seretide 125 Evohaler 120puff/B(29097); Seretide 50 Evohaler 120puff/B(29113); Flixotide Evohaler: 120puff/B(29111); Nasal spray: Flixonase 120puffs/set(29059); Cream: Cutivate 0.05% 5g(29428)

ADR:

COMMON
Cushing's syndrome, headache, hoarseness, oral candidiasis, tachycardia, throat irritation
SERIOUS
asthma patients: asthma-related death, worsening of asthma-related events in African Americans (with salmeterol)

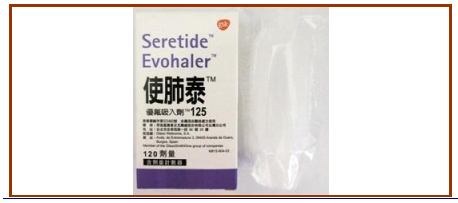
NOTE: 室溫儲藏

Contraindications: acute bronchospasm, immediate prevention of exercise-induced bronchospasm, status asthmaticus, IgE-mediated allergic reactions to lactose or milk products

藥名相似:

外觀相似:

外觀描述: 紙盒白底紫色"Seretide Evohaler"字樣,黑色"使肺泰"及"125"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023482

22.14 Inhalation

29099 B / Caution

Duasma HFA 200 (Budesonide 200mcg) Inhaler 帝舒滿定量噴霧劑

Budesonide 200mcg/puff, 200puff/bot

Dosage: 1常備品 29099

Adult
·Asthma: initial, 200-800mcq(1-4 puffs) bid, Max 1.6mg/day

Pediatric (≧6yrs)
·Asthma: initial, 200-400mcq(1-2 puffs) bid, Max 400mcg bid

Dosing adjustments in hepatic impairment:

Dosage adiustment required

Dosing adjustments in renal impairment:

NDA

P: HFA: Duasma 200puff/set(29099); Symbicort* Rapihaler: 120dose/B(29171); Turbuhaler: Symbicort 120dose/B(29080)

ADR:

COMMON
Cushing's syndrome, epistaxis, headache, nasal dryness, nasal stinging, throat irritation
SERIOUS
Cataract, adrenal suppression, glaucoma

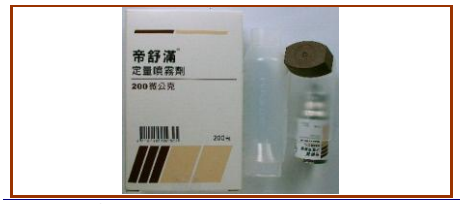
NOTE: 室溫儲存

Contraindications: status asthmaticus or other acute episodes of asthma

藥名相似:

外觀相似:

外觀描述:



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1057770

22.14 Inhalation

29111 **C / Unknown(有**

FLIXOTIDE EVOHALER 50MCG 輔舒酮 優氟 吸入劑 5 0 微公克 / 劑量

Fluticasone propionate 50mcg/puff, 120puff/B

Dosage: 1常備品 29111

Adult
·Asthma, prophylaxis: inhalation, 100mcg-1000mcg bid

Pediatric (>4 yrs)
·Asthma, prophylaxis: inhalation, 50mcg-200mcg bid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inhalation Aerosol: Seretide 250 Evohaler 120puff/B(29091); Seretide 125 Evohaler 120puff/B(29097); Seretide 50 Evohaler 120puff/B(29113); Flixotide Evohaler: 120puff/B(29111); Nasal spray: Fluticasone 120puffs/set(29134); Cream: Cutivate 0.05% 5g(29428),

ADR:

COMMON
pharyngeal candidiasis, epistaxis, pharyngitis
SERIOUS
secondary hypocortisolism, anaphylaxis (rare), hypersensitivity reaction (rare), glaucoma (rare)

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 紙盒白底 粉橘色"Flixotide Evohaler","50"及 黑色"輔舒酮 優氟"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023755

22.14 Inhalation

29113 **C / Infant risk can**

SERETIDE 50 EVOHALER 使肺泰50優氟吸入劑

Salmeterol 25mcg & Fluticasone Propionate 50mcg/PF 120PF/bot (inhalation aerosol)

Dosage: 1常備品 29113

Adult
·Asthma: 2 puffs bid

Pediatric(≧4yrs)
·Asthma: 2 puffs bid

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Inhalation Aerosol: Seretide 250 Evohaler 120puff/B(29091); Seretide 125 Evohaler 120puff/B(29097); Seretide 50 Evohaler 120puff/B(29113); Flixotide Evohaler: 120puff/B(29111); Nasal spray: Flixonase 120puffs/set(29059); Cream: Cutivate 0.05% 5g(29428)

ADR:

COMMON
Tachyarrhythmia, hypercortisolism, oral candidiasis, headache, hoarse, throat irritation
SERIOUS
Asthma-related death, exacerbation of asthma (Severe), nonfatal (with salmeterol)

NOTE: 室溫儲藏

· 《Contraindications》Hypersensitivity to any component of the product; Severe hypersensitivity to milk proteins (inhalation powder); Primary treatment of status asthmaticus or acute episodes of asthma or COPD ;

藥名相似:

外觀相似:

外觀描述: 紙盒白底淺紫色"Seretide Evohaler",黑色"使肺泰",綠色"50"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023480

22.14 Inhalation

29114 /

COMBIVENT* UDV INHALATION SOLUTION 冠喘衛單一劑量吸入液

Ipratropium bromide 0.5mg [B] & Salbutamol 2.5mg [C] 2.5mL/amp

Dosage: 1常備品 29114

Adult
·COPD: Nebulization, 1 amp st, MD 1 amp tid-qid, Max. 6 doses/ 24 hr

Pediatric
·Safety and efficacy have not been established in patients less than 12 years old

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 2mg(22064); Ventolin* Inhaler: 100mcg/dose, 200dose/B (29052); Combivent* MDI: 200puff/B (29100); Ipratropium nebuliser soln: 0.5mg/2mL (29077); Ventolin* nebuliser soln: 5mg/2.5mL (29086), Combivent* UDV 2.5mL/amp (29114)

ADR:

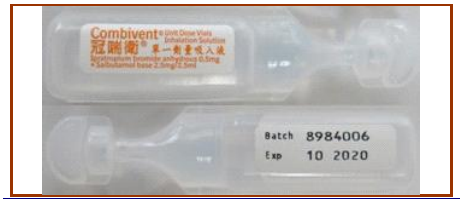
COMMON
hypertension, tachyarrhythmia, diarrhea, dyspepsia, nausea, vomiting, xerostomia, headache, bronchitis, cough, dyspnea, pharyngitis, sinusitis, upper respiratory infection, change in voice
SERIOUS
cardiac dysrhythmia

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 2.5mL透明澄清單一劑量吸入液



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023357

22.14 Inhalation

29117 a /

BEROTEC N 100MCG/PUFF METERED AEROSOL 備勞喘１００微公克定量噴霧液

Fenoterol Inhaler 100mcg/puff, 200puff/bot

Dosage: 1常備品 29117

Adult
·Bronchospasm: Inhalation, 1-2 puff repeated in 5 min when necessary, Max. 8 puffs/day

Pediatric
·Bronchospasm: Inhalation, 1 puff repeated in 5 min when necessary

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 2.5mg(22062); Inhalation Aerosol: 100mcg/puff, 200puff/B(29117)

ADR:

Tachycardia, nervousness, palpitations, muscle tremor, headache, dizziness

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to fenoterol, other product components, or other sympathomimetic amines; Hyperthyroidism; Hypertrophic obstructive cardiomyopathy; Tachyarrhythmia ;
·It is a HFA-containing formulation
·Berotec HFA formulations and Berotec CFC formulations are interchangeable for all practical purposes and the difference in taste has no consequences of safety or efficacy

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023074

22.14 Inhalation

29118 C / Infant risk can

SPIRIVA* respimat 2.5mcg soln for inhalation 適喘樂舒沛噴吸入劑 2.5 微公克

Tiotropium soln for inhalation 2.5mcg/puff 60puffs/bot

Dosage: 1常備品 29118

·COPD: Inhalation, 2 puffs (5mcg) qd at the same time of day
·Asthma: Inhalation, 2 puffs (5mcg) qd at the same time of day

·Asthma(≧6yrs): Inhalation, 2 puffs (5mcg) qd at the same time of day
·< 6yrs: Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Use with caution

P: Soln for Inhalation(Respimat):Tiotropium 2.5mcg/puff, 60puffs/bot (29118) ; Tiotropium 2.5mcg/Olodaterol 2.5mcg/puff, 60puffs/bot (29158).

ADR:

COMMON
Constipation, xerostomia, pharyngitis, sinusitis, upper respiratory infection
SERIOUS
Bowel obstruction, cerebrovascular accident

NOTE: 室溫儲存

1. It is contraindicated in patietns with a history of hypersensitivity to atropine or its derivatives.
2. It is not indicated for the initial treatment of acute episodes of bronchospasm
3. It should not be used more frequently than once daily.

藥名相似:

外觀相似:

外觀描述: 紙盒白底黑字"Spiriva Respimat",有"淺綠色"區塊"及藥物外觀圖形

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025033

22.14 Inhalation

29135 B / Caution

BERODUAL N METERED AEROSOL 備喘全定量噴霧液 "德國廠"

Ipratropium bromide 20mcg/puff [B], Fenoterol hydrobromide 50mcg/puff [a] 200puff/bot

Dosage: 1常備品 29135

Adult
·Bronchospasm: Inhalation, 2 puffs for symptom relief, may be repeated in 5 mins if needed. MD 1-2 puffs tid, Max. 8 puffs/day

Pediatric(>6yrs)
·Bronchospasm: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 2.5mg(22062); Liq: 0.5mg/mL, 60mL/B(28681); Inh: BEROTEC* N MDI: 100mcg/puff, 200puff/B (29117), BERODUAL N* MDI: 200puff/B (29135); Ipratropium nebuliser soln: 0.5mg/2mL (29077)

ADR:

Nervousness, dryness of the mouth, headache, dizziness, tremor of skeletal muscles, tachycardia, gastro-intestinal motility disturbances, urinary retention, accommodation disturbances of eyes, glaucoma, skin rash, allergic reactions, hypokalemia, psychological alterations, cough, local irritation

NOTE: 室溫儲存

·It is a HFA-containing formulation

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023473

22.14 Inhalation

29136 C / Caution

Alvesco 160 Inhaler ” 保衛康” 治喘樂吸入劑 160 微公克

Ciclesonide 160mcg/dose, 60dose/bot

Dosage: 1常備品 29136

Adult & >11yrs child
·Asthma: inhalation, 160mcg qd - 640mcg bid

Pediatric (4-11 yrs)
·Asthma: inhalation, 160mcg qd

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inhalation Aerosol: ALVESCO* 160 inhaler 60puff/B(29136)

ADR:

COMMON
Arthralgia, backache, headache, nasal congestion, nasopharyngitis, pain in throat , sinusitis, upper respiratory infection, pain in extremity
SERIOUS
Adrenal insufficiency, hypersensitivity disorder (rare), cataract, glaucoma, raised intraocular pressure, bronchospasm, exacerbation of asthma

NOTE: 室溫儲存

· 《Contraindications》Hypersensitivity to ciclesonide or any component of the product; Primary treatment of status asthmaticus or other acute episodes of asthma requiring intensive intervention ;

藥名相似:

外觀相似:

外觀描述: 紅色握管內有一充填藥品之壓力小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024786

22.14 Inhalation

29140 C / No report(毫

Anoro Ellipta 55/22 mcg inhalation Powder 安肺樂易利達 55/22 mcg 乾粉吸入劑

Umeclidinium 55mcg /PF[C], Vilanterol trifenatate 22mcg /PF[C], 30PF/bot

Dosage: 1常備品 29140

Adult
·COPD: Inhalation,1 puff once daily

Pediatric
·efficacy and safety not established

Dosing adjustments in hepatic impairment:

no dose adjustment required

Dosing adjustments in renal impairment:

no dose adjustment required

P: Inhalation aerosol:Umeclidinium 55mcg / Vilanterol trifenatate 22mcg, 30dose/bot (29140)

ADR:

COMMON
Chest pain, Constipation, Diarrhea, Lower respiratory tract infection, Pharyngitis, Sinusitis.
SERIOUS
Atrial fibrillation, Myocardial infarction, Paradoxical bronchospasm

NOTE: 室溫儲藏

1.開封後可存放6週
2.本品含lactose,對牛奶嚴重過敏者不建議使用.

藥名相似:

外觀相似:

外觀描述: 灰色吸入器內含乾粉藥劑，外觀有紅色區塊，白底黑字紙盒並有紅色字藥名

22.14 Inhalation

29141 C / No report(毫

Ultibro Breezhaler 110/50 microgram, inhalation powder hard capsules 昂帝博吸入膠囊110/50微克

Indacaterol 110mcg, glycopyrronium 50mcg/cap, 30cap/bot

Dosage: 1常備品 29141

Adult
·COPD: Inhalation, one capsule qd using the Ultibro breezhaler at the same time of day.

Pediatric
·Safety and efficacy have not been established in patients less than 18 years old.

Dosing adjustments in hepatic impairment:

Severe impairment: use with caution.

Dosing adjustments in renal impairment:

Severe impairment (GFR <30 mL/minute/1.73 m2): use with caution.

P: Inhalation cap: Indacaterol 150mcg (29138)；Indacaterol & glycopyrronium 110mcg/50mcg(29141)；glycopyrronium 50mcg/cap (29153)

ADR:

COMMON
Upper RTI, nasopharyngitis, sinusitis, rhinitis, headache, dizziness, cough, oropharyngeal pain, dyspepsia, musculoskeletal pain, pyrexia, chest pain.
SERIOUS
Atrial fibrillation, bladder outflow obstruction, cystitis, glaucoma, hypersensitivity reaction, ischemic heart disease, paradoxical bronchospasm, tachycardia

NOTE: 室溫儲藏

藥名相似:

外觀相似:

外觀描述: 吸入膠囊30顆及吸入器乙個，白底黑字紙盒，有灰/藍/黃色區塊

22.14 Inhalation

29154 C / Infant risk can

Relvar Ellipta 92/22 mcg Inhalation Powder 潤娃易利達 92/22 mcg乾粉吸入劑

Fluticasone furoate 92mcg, Vilanterol 22mcg inh pow 30dose/bot

Dosage: 1常備品 29154

ADULT
·Asthma: Oral inhalation, 1 dose qd
·COPD: Oral inhalation, 1 dose qd

PEDIATRIC(<17 yrs)
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment is needed.

Dosing adjustments in renal impairment:

No dosage adjustment is needed.

P:

ADR:

Tremor, insomnia, restlessness, headache, hypokalemia, nausea, dry mouth, dyspepsia, abdominal pain, oral candidiasis, dysphonia, respiratory infection,Bronchospasm

NOTE: 儲存30℃以下

(1)氣喘的臨床試驗使用經驗：加註雖然試驗中包括12到17歲的受試者，本藥並未核准用於此年齡患者。(2)本藥不適用於青少年。用於兒童疾患(更新年齡為17歲及以下)的安全性與療效尚未確立。

藥名相似:

外觀相似:

外觀描述: 紙盒白底 藍色"RELVAR"及黑色"ELLIPTA"字樣與藥品外觀圖形

22.14 Inhalation

29156 C / Infant risk can

Incruse Ellipta 55 mcg Inhalation Powder 英克賜易利達 55 mcg乾粉吸入劑

Umeclidinium 55mcg /PF, 30PF/bot

Dosage: 1常備品 29156

Adult
·COPD: Inhalation,1 puff once daily

Pediatric(≦18yrs)
·safety and efficacy not established

Dosing adjustments in hepatic impairment:

no dose adjustment required

Dosing adjustments in renal impairment:

no dose adjustment required

P: Inhalation power: Umeclidinium 55mcg/PF, 30PF/bot(29156)；Umeclidinium 55mcg/Vilanterol trifenatate 22mcg, 30dose/bot (29140)

ADR:

COMMON
Nasopharyngitis, Upper respiratory infection
SERIOUS
Anaphylaxis, Angle-closure glaucoma, Urinary retention, Paradoxical bronchospasm, Angioedema

NOTE: 室溫儲藏

1.開封後可存放6週
2.有嚴重乳蛋白過敏問題的患者不可使用

藥名相似:

外觀相似:

外觀描述: 灰色吸入器內含乾粉藥劑，外觀有淺綠色區塊，白底黑字紙盒並有綠色字藥名

22.14 Inhalation

29158 C / Infant risk can

Spiolto Respimat, Solution for Inhalation 適倍樂 舒沛噴吸入劑

Tiotropium 2.5mcg/puff & Olodaterol 2.5mcg/puff, 60puffs/bot

Dosage: 1常備品 29158

Adult
·COPD: Inhalation, 2 puff once daily

Pediatric
·efficacy and safety not established

Dosing adjustments in hepatic impairment:

Mild to moderate hepatic impairment: No dose adjustment needed
Severe hepatic impairment: NDA

Dosing adjustments in renal impairment:

No dose adjustment is required.
Monitor for anticholinergic effects when CrCl 60 mL/min or less.

P: Soln for Inhalation(Respimat):Tiotropium 2.5mcg/olodaterol 2.5mcg/puff, 60puffs/bot (29158)；Tiotropium 2.5mcg/puff, 60puffs/bot (29118)；Olodaterol 2.5mcg/puff, 60puffs/bot (29151).

ADR:

COMMON
Backache, Nasopharyngitis
SERIOUS
Disorder of cardiovascular system, Hypersensitivity reaction, Angle-closure glaucoma, Urinary retention, Bronchospasm, Pneumonia

NOTE: 室溫儲存30°C 以下

1. It is contraindicated in patietns with a history of hypersensitivity to atropine or its derivatives.
2. It is not indicated for the initial treatment of acute episodes of bronchospasm
3. It should not be used more frequently than once daily.

藥名相似:

外觀相似:

外觀描述: 紙盒白底黑字"Spiolto Respimat",有"綠色"區塊"及藥物外觀圖形

22.14 Inhalation

29171 C / Unknown(有

SYMBICORT* Rapihaler 160/4.5ug/dose "吸必擴"氣化噴霧劑 160/4.5 微克/劑量

Budesonide 160mcg & Formoterol fumarate 4.5mcg /dose, 120dose/bot

Dosage: 1常備品 29171

Adult : Oral inhalation
·Asthma: 1-2 dose bid
·COPD: 2 dose bid

Pediatric (≧12 years)
·Asthma: Oral inhalation, 1-2 dose bid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Symbicort* Rapihaler:120 dose/B (29171);Symbicort Turbuhaler:120 dose/B (29080); Duasma Inhaler:200 puff/B(29099)

ADR:

Common
Oral candidiasis, Stomach ache, Vomiting, Backache, Headache, Nasal congestion, Nasopharyngitis, Sinusitis, Upper respiratory infection.
Serious
Hypokalemia, Glaucoma, Raised intraocular pressure.

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 紙盒白底淡藍色

22.14 Inhalation

29172 ɔt be ruled out / Infant risk can

Trelegy Ellipta 92/55/22 mcg Inhalation Powder 肺樂喜易利達92/55/22 mcg乾粉吸入劑

Fluticasone furoate 92mcg, Umeclidinium 55mcg, Vilanterol 22mcg inh pow 30dose/bot

Dosage: 1常備品 29172

ADULT
·Chronic obstructive pulmonary disease, maintenance therapy: Oral inhalation, 1 dose QD, do not use more than once every 24 hours

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

·No dosage adjustment needed

Dosing adjustments in renal impairment:

·No dosage adjustment needed

P: P Inhalation powder:
Fluticasone/Umeclidinium/Vilanterol(29172), Fluticasone/Vilanterol(29154), Umeclidinium(29156)

ADR:

COMMON
Diarrhea, gastroenteritis, taste sense altered, backache, headache, cough, pain in throat
SERIOUS
Cardiac dysrhythmia, disorder of cardiovascular system, electrocardiogram abnormal, increased diastolic arterial pressure, increased heart rate, increased systolic arterial pressure, prolonged QT interval, adrenal insufficiency, Cushing's syndrome, hyperglycemia, hypocortisolism secondary to another disorder, hypokalemia, hypersensitivity reaction, infection by Candida albicans, decreased bone mineral density, cataract, glaucoma, paradoxical bronchospasm

NOTE: 室溫儲存

·Contraindications: severe hypersensitivity to milk proteins

藥名相似:

外觀相似:

外觀描述: 灰色吸入器內含乾粉藥劑，外觀有綠色及土色區塊

22.16 Antifibrotic Agents

27380 ɔt be ruled out / Infant risk can

OFEV Soft Capsules 150mg 抑肺纖軟膠囊150毫克

Nintedanib ethanesulfonate 150mg soft cap

Dosage: 1常備品 27380

Adult
· Idiopathic pulmonary fibrosis, Lung disease with systemic sclerosis, PF-ILD-progressive fibrosing interstitial lung disease: PO 150 mg bid (approximately 12 hours apart), take with food and swallow capsule whole with liquid. MAX 300 mg/day.
· Adverse effects (eg, diarrhea, nausea, vomiting): Manage symptomatically and consider treatment interruption if adverse effect persists; resume at full dosage or at reduced dosage (100 mg twice daily) and may subsequently increase to full dosage; discontinue treatment for reactions that continue to be severe despite symptomatic management or if patient is unable to tolerate the 100 mg twice daily dosage.

Pediatric
· Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Mild (Child-Pugh score A): 100 mg bid consider interruption or discontinuation for adverse reactions
Moderate or severe (Child-Pugh score B or C): Use not recommended
Hepatic toxicity:
(1) AST or ALT levels 3-5 times ULN without signs of severe liver damage: Interrupt treatment or 100 mg bid; when levels return to baseline, reintroduce at 100 mg bid; may subsequently increase to 150 mg bid.
(2) AST or ALT levels >5 times ULN or > 3 times ULN with signs or symptoms of severe liver damage: Discontinue treatment

Dosing adjustments in renal impairment:

Mild to moderate: No dose adjustment to the starting dose is required
Severe (Clcr < 30 mL/min) and ESRD: Safety and efficacy not established

P: P Cap: 150mg (27380)

ADR:

COMMON
Weight decreased, Abdominal pain, Decrease in appetite, Diarrhea, Nausea, Vomiting, Headache.
SERIOUS
Arterial thromboembolism, Myocardial infarction, Gastrointestinal perforation, Hemorrhage, Drug-induced liver disease, Increased liver enzymes, Bronchitis, Interstitial lung disease, Neoplasm of lung, Pneumonia.

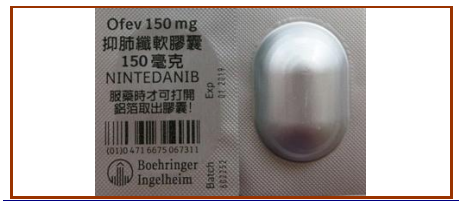
NOTE: 室溫儲存

·《Contraindications》Specific contraindications have not been determined；
1.Do not smoke while being treated with this medicine, because this will cause the medicine to not work as well.
2.體重較輕(<65kg)、亞洲人和女性肝臟酵素升高的風險較高。Nintedanib暴露量隨著病人年齡而增加，可能導致肝臟酵素升高的風險。治療期間發生具有臨床症狀和/或高膽紅素血症或黃疸的嚴重肝臟受損，請立即停止治療。
3.腎功能不全/衰竭之風險：
·腹瀉、嘔吐或嘔吐可能導致脫水，伴隨或未伴隨電解質紊亂，如無適當處置也可能發展成腎功能不全。
·在用藥期間應監測腎功能，尤其有腎功能不全/衰竭風險者宜小心監測。如果發生腎功能不全/衰竭，應考慮調整劑量為 100mg BID，之後可增加至完整的劑量。如果病人無法耐受 100mg BID，應停止接受治療。

藥名相似:

外觀相似:

外觀描述: 棕色橢圓形軟膠囊，印有藥廠商標及150字樣



22.16 Antifibrotic Agents

27382 ɔt be ruled out / Infant risk can

Pirespa Tablets 200 mg 比樂舒活錠200毫克

Pirfenidone 200mg tab

Dosage: 1常備品 27382

Adult

· Idiopathic pulmonary fibrosis:

a)Initial dosage and titration: 200 mg orally 3 times day for 14 days, then 400 mg 3 times a day on weeks 3 through 4.

b) Maintenance dosage: 600 mg orally 3 times a day from weeks 5 onward.

Pediatric

· Safety and efficacy have not been established in pediatric patients

Dosing adjustments in hepatic impairment:

Dosing adjustments in hepatic impairment:
Mild to moderate impairment (Child-Pugh class A and B): Use with caution; consider dose modification or discontinuation as needed.
Severe impairment (Child-Pugh class C): Use is not recommended.
Hepatic toxicity:
(1)ALT/AST >3 to ?5 x ULN (without hyperbilirubinemia): Rule out alternative causes and discontinue potentially confounding medications. As clinically appropriate, may continue current dose, may reduce dose or may temporarily discontinue therapy. Once aminotransferase elevations have resolved, may be re-titrated to the recommended daily dose. Monitor LFTs closely thereafter.
(2)ALT/AST >3 to ?5 x ULN with hyperbilirubinemia or symptoms: Discontinue therapy promptly and do not reinitiate.
(3)ALT/AST >5 x ULN (regardless of serum bilirubin concentrations): Discontinue therapy promptly and do not reinitiate.

Dosing adjustments in renal impairment:

Dosing adjustments in renal impairment:
Mild to severe impairment: Use with caution; consider dose modification or discontinuation as needed.
ESRD requiring dialysis: Use is not recommended.

P: P Tab: 200mg (27382)

ADR:

COMMON
Rash, Abdominal pain, Diarrhea, Gastroesophageal reflux disease, Indigestion, Loss of appetite, Nausea, Vomiting, Weight decreased, Arthralgia, Dizziness, Headache, Insomnia, Sinusitis, Upper respiratory infection, Fatigue..
SERIOUS
Photosensitivity, Drug-induced disorder of liver, Increased liver enzymes.

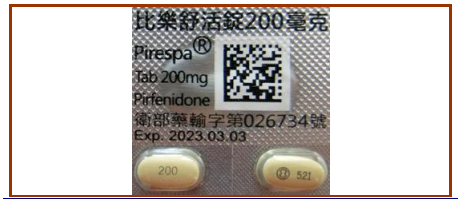
NOTE: 室溫儲存30℃以下

·《Contraindications》Specific contraindications have not been determined；
·Do not smoke while being treated with this medicine, because this will cause the medicine to not work as well.

藥名相似:

外觀相似:

外觀描述: 淡黃色橢圓形膜衣錠，一面有商標與"521"字樣，另一面有"200"字樣



22.18 Miscellaneous

37838 B /

Xolair 150 mg powder and solvent for solution for injection 喜瑞樂凍晶注射劑150毫克

Omalizumab inj 150mg vial

Dosage: 1常備品 37838

Adult

·Allergic asthma: SC, 225 to 600 mg every 2 wks or 75 to 600 mg every 4 wks(UK regimens及仿單), 225 to 375 mg every 2 wks or 150 to 300 mg every 4 wks(USA regimens); dosage determined by IgE level before first treatment and body weight.
·Chronic idiopathic urticaria: SC, 150 or 300 mg every 4 wks.

Pediatric

·Allergic asthma: ≧6yrs, Same as adult
·Chronic idiopathic urticaria: ≧12yrs, Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 150mg(37838)

ADR:

COMMON
Injection site reaction, headache, pharyngitis, sinusitis, upper respiratory infection, viral disease
SERIOUS
Thrombocytopenia, allergic reaction to drug, anaphylaxis, cancer

NOTE: 冰箱儲存

·Dosage more than 150mg should divided over more than one site
·Patients should be observed for a minimum of 2 hours following administration; appropriate medications for the treatment of anaphylactic reactions should be available

22.00 呼吸道藥物 RESPIRATORY DRUGS

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『藍』蓋透明玻璃小瓶附1支稀釋液

24.02 Antacids

172001 D / Infant risk is

LEDERSCON TABLETS 立達腸康口嚼錠

Al hydroxide 334mg, MgO 166mg, Antifoam AF(Simethicone) Emulsion36.7mg /tab 10tab/pc

Dosage: 31醫學保健品-指示藥 172001

Adult

· Antacids: PO, 1 tab tid-qid or as needed.

Pediatric

· Antacids(>=12 yrs): same as adult. 6-11yrs 1/2 tab tid-qid, 3-5yrs 1/4 tab tid-qid; <3yrs as order.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: Lederscon* tab (172001)

ADR:

NOTE: 室溫儲存

20粒/盒(整盒發放)

藥名相似:

外觀相似:

外觀描述: 黃色圓扁錠

24.02 Antacids

24804 D / Infant risk can

A.M.D. TABLETS 愛姆得錠

Aluminum hydroxide dried gel 334 mg, Magnesium hydroxide 166 mg, Dimethylpolysiloxane 36.7 mg

Dosage: 1常備品 24804

Adult

· Antacids: PO, 1-2 tab tid-qid

Pediatric

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: A.M.D.* (24804)

ADR:

Constipation, diarrhea

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色/淺綠色雙層圓扁錠，有310 winston字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1003739

24.02 Antacids

24805 B /

Algitab Chewable Tablets 艾胃逆服咀嚼錠

Alginic acid 0.2 g, magnesium carbonate 0.04 g, aluminum hydroxide gel 0.03 g

Dosage: 1常備品 24805

Adult

·Gastroesophageal reflux disease, pyrosis, peptic ulcer, antacids: PO, 2 tabs tid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: ALGITAB* (24805)

ADR:

Abdominal flatulence, hiccups, diarrhea, constipation

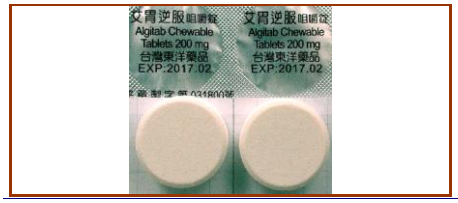
NOTE: 儲存25℃以下

·本品賦形劑不含阿斯巴甜。

藥名相似: Tab: ALGITAB* (24805)

外觀相似:

外觀描述: 白色圓扁錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1031800

24.02 Antacids

24806 ɔt be ruled out / Infant risk is

MAGNESIUM OXIDE TABLETS "SYNMOSA" "健喬"氧化鎂錠

Magnesium oxide 250mg tab

Dosage: 1常備品 24806

Adult

· Antacid : PO, 250-500 mg daily

· Laxative : PO, 2-4 g daily

Pediatric

·

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 250 mg(24806)

ADR:

NOTE: 室溫儲存

Mg=12.4mEq

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面中央有刻痕，及SK與MGO字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1023521

24.02 Antacids

24807 C /

SWEI TABLETS "YU SHENG" 舒胃錠

Aluminum hydroxide 233 mg [C], homatropine methylbromide 1 mg [C]

Dosage: 1常備品 24807

Adult

· Peptic ulcer and acute or chronic gastritis: PO, 2-4 tab q3-4h

· Gastric hyperacidity: PO, 1-2 tab, 1/2 or 1hr after meals or as necessary

· Pregancy heartburn: PO, 1-2 tab before breakfast and 1/2 hr after meal

· Steroid and ACTH treatment: PO, 2 tab with each oral dose of hormone, 2 tab tid with parenteral hormonal administration; Max. 20 tab/day

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: Swei* (24807)

ADR:

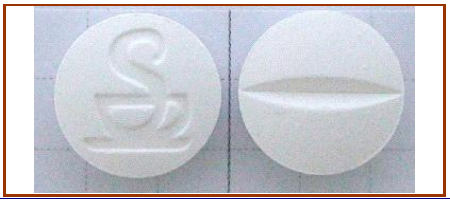
Constipation

NOTE: 室溫儲存

藥名相似: Tab: Swei* (24807)

外觀相似:

外觀描述: 白色圓形錠一面有商標圖案



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1023833

24.02 Antacids

24809 B /

IWELL TABLETS "EVEREST" "永勝" 宜胃錠

Dihydroxyaluminum allantoninate 50mg, Metamagnesium alumino silicate 450mg

Dosage: 1常備品 24809

Adult

· Antacids: PO, 1-2 tab tid

Pediatric

·

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: Iwell* (24809)

ADR:

NOTE: 室溫儲存

藥名相似: Tab: Iwell* (24809)

外觀相似:

外觀描述: 粉紅色/白色 雙層圓扁錠，粉紅面有IWELL字樣及商標圖樣，白色面刻有"EEP 187"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045031

24.02 Antacids

25008 B /

STROCAIN TABLETS 息痛佳音錠

Oxethazaine 5mg, Polymigel (Aluminium hydroxide, calcium carbonate and magnesium carbonate) 244mg tab

Dosage: 1常備品 25008

Adult

Antacids: PO, ac, 1-2 tab qid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: Strocain*(25008); Susp: Ulstal* 200 mL/Bot (28660)

ADR:

Constipation, diarrhea.

NOTE: 室溫儲存

Swallow whole; do note crush or chew

藥名相似:

外觀相似: Zolpi* 10mg(23069)

外觀描述: 白色圓扁錠,有EISAI及SR005字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1005811

24.02 Antacids

28660 B /

ULSTAL SUSPENSION "SINPHAR" "杏輝" 胃立舒泰懸濁液

Aluminum hydroxide gel 0.95mL/mL, magnesium hydroxide 20 mg/mL, oxethazaine 2 mg/mL, 200mL/bot

Dosage: 1常備品 28660

Adult

· Antacids: PO, ac, 5-10 mL qid

NDA

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: Strocain* (25008); Susp: Ulstal* 200 mL/Bot (28660)

ADR:

Constipation, diarrhea

NOTE: 室溫儲存15-30℃

· 《仿單禁忌》：曾因本藥成分過敏者。
· 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 200mL白色塑膠瓶，貼有綠色圖樣標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1031350

24.04B Non-narcotic Antidiarrhea Agnents

24834 C / Infant risk can

IMOLEX CAPSULES (LOPERAMIDE) "SINPHAR" 依莫瀉膠囊（樂必寧）

Loperamide HCl 2mg cap

Dosage: 1常備品 24834

Adult

· Diarrhea: PO, initial 4 mg followed by 2 mg after each loose stool up to a maximum of 16 mg/day

Pediatric

· Acute diarrhea: PO, initial (in first 24 hrs) 2-5 yrs: 1 mg tid; 6-8 yrs: 2 mg bid; 8-12 yrs: 2 mg tid After initial dosing, 0.1 mg/kg after each loose stool but do not exceed initial dosage
· Chronic diarrhea: 0.08-0.24 mg/kg/day div into 2-3 doses

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 2mg(24834)

ADR:

Abdominal pain, distention or discomfort, constipation, dry mouth, nausea, vomiting, tiredness, drowsiness or dizziness, hypersensitivity reactions (including skin rash)

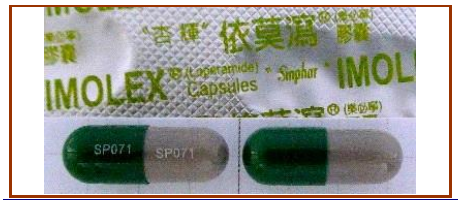
NOTE: 室溫儲存

Do not use loperamide in acute diarrhea associated with organisms that penetrate the intestinal mucosa (Escherichia coli, Salmonella and Shigella) or in pseudomembranous colitis associated with broad-spectrum antibiotics.

藥名相似:

外觀相似:

外觀描述: 灰色/綠色膠囊，SP071字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1022123

24.04B Non-narcotic Antidiarrhea Agnents

24837 ɔt be ruled out / Infant risk can

HIDRASEC* INFANTS 10mg Granules for oral suspension 瀉必寧10毫克懸浮液用顆粒劑

Racecadotril granules 10mg/1g sachet

Dosage: 1常備品 24837

NDA

Pediatric (≧ 3 mons)

· Acute diarrhea: PO, 1.5mg/kg tid until recovery (two normal stools are recorded) or for up to 5 days; Max. 60mg/dose

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P: Granules: 10mg/1g sachet (24837)

ADR:

Tonsillitis, rash, erythema, erythema multiforme, tongue edema, face edema, lip edema, eyelid edema, angioedema, urticaria, erythema nodosum, rash papular, prurigo, pruritus

NOTE: 室溫儲存25℃以下

· 《Contraindications》Prior hypersensitivity to racecadotril or ecadotril (sinorphan)；
· The granules can be added to food or dispersed in a small amount of water (e.g. a teaspoon), mixed well and should be administered immediately.
· Each sachet contains 0.966g of sucrose.
· 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 白色藥品，白底綠字紙包裝，上有綠色線條

24.04B Non-narcotic Antidiarrhea Agnents

24936 **ɔt be ruled out / Infant risk can**

SMECTA, POWDER FOR ORAL SUSPENSION 舒腹達口服懸液用粉劑

Dioctahedral smectite powder 3g(diosmectite) /pk

Dosage: 1常備品 24936

Adult
· Diarrhea: PO, 3 sachet/day in 3 div doses; administer bewteen meals

Pediatric
· Diarrhea: PO, ≧ 2 yrs: 2-3 sachet/day in 3 div doses; administer between meals

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Pow: 3 g/sachet (24936)

ADR:
Constipation, vomiting, eruption, urticaria, angioedema, pruritus, hypersensitivity

NOTE: 室溫儲存

· 《仿單禁忌》：對diosmectite任何賦形劑過敏者，有嚴重慢性便秘病史之病患，嬰兒及2歲以下的兒童。
· Smectite is a natural mineral of the family of clay-earth.
· Each sachet is mixed with 50 mL of water.
· As the adsorbent properties of this product may interfere with the rates and/or levels of absorption of other substances, it is recommended to administer any other medication at a distance from SMECTA (more than 2 hours, if possible)..
· 本品賦形劑不含阿斯巴甜。
· 嬰兒及2歲以下的兒童，應避免使用本藥。急性腹瀉的參考治療為口服脫水補充液。
· 2歲以上兒童之急性腹瀉應在治療初期併用口服脫水補充液以避免脫水。應避免長期使用本藥。
· 懷孕及哺乳婦女不建議使用。

藥名相似:

外觀相似:

外觀描述: 白色紙包裝上有藍色"舒腹達口服懸液用粉劑"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023349

24.04B Non-narcotic Antidiarrhea Agnents

28635 **C / Safe**

PECOLIN SUSPENSION "STANDARD" "生達"高克痢懸乳液

Kaolin 3g/15mL, Pectin 150 mg/15 mL, 120 mL/bot

Dosage: 1常備品 28635

ADULT
· Diarrhea: PO, 30 mL/dose, should be taken at intervals of more than 4 hours, Max: 4 times/day

PEDIATRIC
· Diarrhea: PO, ≧6 yrs and <12 yrs: 15 mL/dose; ≧3 yrs and <6 yrs: 7.5 mL/dose, should be taken at intervals of more than 4 hours, Max: 4 times/day

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: P Susp: 120 mL/Bot (28635)

ADR:
Constipation

NOTE: 室溫儲存

· 《仿單禁忌》：血便或黑便之病患。
· 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 120mL白色塑膠瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12008873

24.06A Antiemetics, Antihistamines

20405 **/**

DIPHENIDOL S.C. TABLETS "生達" 敵芬尼朵糖衣錠

Diphenidol HCl 25mg tab

Dosage: 1常備品 20405

Adult
·Vertigo/Nausea and Vomiting: PO, 25-50 mg q4h; Max. 300 mg/day

Pediatric
·Vertigo/Nausea and Vomiting: PO, 0.88mg/kg q4h as necessary; Max. 5.5mg/kg/day

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
Diphenidol should not be used in patients with anuria.

P: Tab:25mg(20405)

ADR:
Hallucination, confusion, disorientation

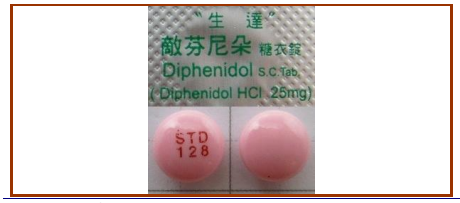
NOTE: 室溫儲存

Diphenidol should not be used in children weighing less than 22.7 kg.

藥名相似:

外觀相似:

外觀描述: 粉紅色圓扁糖衣錠，有STD 128字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1015078

24.06D Antiemetics, Prokinetic Drugs

22043 UK /

MOSAPULIN* FILM COATED TABLETS 5MG 腸安寧 膜衣錠 5 毫克

Mosapride citrate 5mg tab

Dosage: 1常備品 22043

Adult

·GI motility disturbance: PO, 5mg tid before or after meals

Pediatric

· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 5mg (22043)

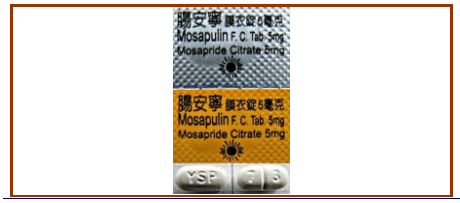
ADR:

NOTE: 室溫儲存

藥名相似: Tab: 5mg (22043)

外觀相似: Catilon* 40mg Tab (22044)

外觀描述: 白色橢圓形錠，一面有YSP，一面中央有刻痕及7 3字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1055566

24.06D Antiemetics, Prokinetic Drugs

25004 B / Infant risk can

PROMERAN F.C. TABLETS 3.84mg "生達"胃明朗膜衣錠 3.84公絲

Metoclopramide HCl 5mg tab

Dosage: 1常備品 25004

Adult

· Chemotherapy induced nausea and vomiting: PO, ac,2 mg/kg/dose every 2-4 hrs for 2 to 5 doses

· Gastroesophageal reflux disease: PO,ac,10-15 mg up to 4 times daily; 30 min before meals and at bedtime

· Diabetic gastroparesis: PO,ac,10 mg before meals and at bedtime for 2-8 wks

Pediatric

· Gastroesophageal hypomotility: PO, initial 1 mg before meals and at bedtime

· Gastroesophageal reflux disease: PO; Max. 0.3-0.75 mg/kg/day for 2 wks to 6 mon

Neonates: 0.15 mg/kg q6h

Infants: 0.1 mg/kg tid-qid, 10-30 min before each meal and at bedtime

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

· Clcr≧ 51 mL/min : 100% of dose

· Clcr 10-50 mL/min: 75% of dose

· Clcr < 10 mL/min: 50% of dose

P: Tab: 5mg (25004); Soln: 1mg/1mL, 60 mL/bot (28641); Inj: 9.08mg/2mL Amp (34435)

ADR:

COMMON

Body fluid retention, nausea, vomiting, asthenia, headache, somnolence, fatigue

SERIOUS

Neuroleptic malignant syndrome, tardive dyskinesia

NOTE: 室溫儲存

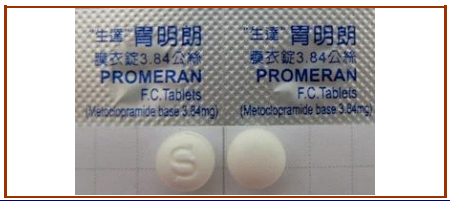
Contraindications:

1. Concomitant therapy with drugs which are likely to cause EPS
2. Seizure disorders
3. Gastrointestinal hemorrhage, obstruction (mechanical), or perforation
4. Pheochromocytoma (except if used for provocation and diagnostic tests)

藥名相似: Tab: 5mg (25004); Soln: 1mg/1mL, 60 mL/bot

外觀相似: Domtoo* 10mg Tab (25013)

外觀描述: 白色圓扁錠，有S字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1003318

24.06D Antiemetics, Prokinetic Drugs

25013 b2 /

EMETROL TABLET 10MG (DOMPERIDONE) "PURZER" "瑞安"癒吐寧錠１０毫克（多普利杜）

Domperidone 10mg tab

Dosage: 1常備品 25013

Adult

· Nausea and vomiting: PO,ac, 20 to 30 mg tid-qid

· Postprandial dyspepsia: PO, 10 mg tid (15 to 30 min ac)

· 衛福部(2014-11-12)公告，修訂用法用量：口服劑型藥品之「用法用量」修訂為：「成人」及「12歲以上體重大於35kg之青少年」：1次10mg，每日最多3次。

Pediatric

· Postprandial dyspepsia: PO, 0.2-0.4 mg/kg q4-8h

· Chemotherapy induced nausea/vomiting: PO, 0.2-0.4 mg/kg q4-8h

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab:10mg(25013); Susp: 60mg/60mL (28642)

ADR:

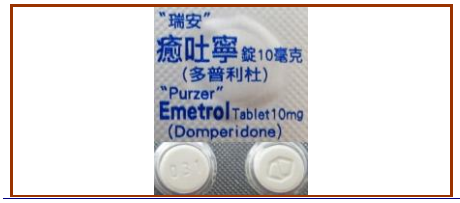
Dystonic reactions, arrhythmias, galactorrhea

NOTE: 室溫儲存

藥名相似: Tab:10mg(25013); Susp: 60mg/60mL (28642)

外觀相似: Promeran* 5mg (25004), Mequitazine 5mg T

外觀描述: 白色圓扁錠，一面有"031"字樣，另一面中間有商標圖樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1033947

24.06D Antiemetics, Prokinetic Drugs

28641 **B / Unknown(有**

ASWELL SOLUTION 1MG/ML 安適胃寧液 1 毫克/毫升

Metoclopramide HCl soln 1mg/mL 60mL/bot(= base 0.767mg/mL)

Dosage: 1常備品 28641

ADULT

·

Pediatric

· Gastroesophageal hypomotility: PO, initial 1 mg before meals and at bedtime

· Gastroesophageal reflux disease: PO; Max. 0.3-0.75 mg/kg/day for 2 wks to 6 mon

Neonates: 0.15 mg/kg q6h

Infants: 0.1 mg/kg tid-qid, 10-30 min before each meal and at bedtime

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

CrCl less than 10 mL/min: 50% of dose

CrCl 10-50 mL/min: 75% of dose

CrCl 51 mL/min or greater: 100% of dose

P: Tab: 5mg (25004); Soln: 1mg/1mL, 60 mL/bot (28641); Inj: 9.08mg/2mL Amp (34435)

ADR:

COMMON

Body fluid retention, nausea, vomiting, asthenia, headache, somnolence, fatigue

SERIOUS

Neuroleptic malignant syndrome, tardive dyskinesia

NOTE: 室溫儲存

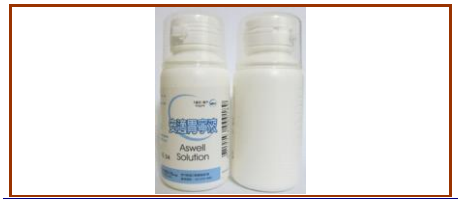
· 《Contraindications》Concomitant use with drugs likely to cause extrapyramidal reactions; Dystonic reaction to metoclopramide; Epilepsy; increased risk of severity and/or frequency of seizure; Gastrointestinal hemorrhage, mechanical obstruction, or perforation or any other use where stimulation of gastrointestinal motility might be dangerous; History of tardive dyskinesia; Pheochromocytoma or other catecholamine-releasing paragangliomas, preexisting; increased risk of hypertensive crisis; Sensitivity or intolerance to metoclopramide products ;

· 含阿斯巴甜，苯酮尿症者不宜使用。

藥名相似:

外觀相似:

外觀描述: 60mL白色塑膠瓶，內有黃色檸檬味藥水



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043730

24.06D Antiemetics, Prokinetic Drugs

28642 **b2 / Unknown(有**

WEMPTY SUSPENSION "CENTER" 1MG/ML "晟德" 胃利空懸液劑1毫克/毫升

Domperidone susp 1mg/mL 60mL/bot

Dosage: 1常備品 28642

Adult

· Nausea and vomiting: PO, ac, 20 mg tid-qid

· Postprandial dyspepsia: PO, ac, 10 mg tid

Pediatric

· Postprandial dyspepsia,nausea/vomiting: PO, ac, 0.2-0.4 mg/kg q4-8h

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Susp: 60mg/60mL (28642); Tab:10mg (25013)

ADR:

Common

·Gastrointestinal: Xerostomia (1% to less than 10%)

Serious

·Cardiovascular: Prolonged QT interval, Sudden cardiac death, Ventricular arrhythmia

·Immunologic: Allergic reaction (less than 0.01%)

NOTE: 室溫儲存

·《Contraindications》Circumstances in which gastric motility stimulation may cause harm (ie, gastrointestinal hemorrhage, mechanical obstruction, or perforation); Concomitant use of potent CYP3A4 inhibitors; Concomitant use of QT prolonging drugs; Conditions where cardiac conduction is known to be or may be impaired; Electrolyte disturbances, significan; Hepatic impairment, moderate or severe; Hypersensitivity to domperidone or any excipients of the product; Preexisting prolongation of cardiac conduction, particularly QT interval prolongation; Prolactin-releasing pituitary tumor (prolactinoma); Renal impairment; Underlying cardiac disease (ie, congestive heart failure) ;

·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 60mL塑膠瓶，黃色液體

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046242

24.06D Antiemetics, Prokinetic Drugs

34435 ɔt be ruled out / Infant risk can

PROMERAN INJECTION "生達"普克胃注射液

Metoclopramide HCl inj 10mg/2mL amp

Dosage: 1常備品 34435

Adult

· Prevention of chemotherapy induced nausea/vomiting: IV infusion, 1-2 mg/kg, 30 min before antineoplastic agents; may be repeated q2-6h as needed; IV 10 mg q6-8h with dexamethasone after chemotherapy.

· Postoperative nausea/vomiting: IM, 10-20 mg

· Small bowel intubation facilitation: IV (over 1-2 min), 10 mg if tube has not passed pylorus with conventional maneuvers within 10 min.

Pediatric

· Small bowel intubation facilitation: IV(over 1-2 min)

>14 yrs: 10 mg

6-14 yrs: 2.5-5 mg

<6 yrs: 0.1 mg/kg

· Postoperative nausea/vomiting: IV, 0.25 mg/kg

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

· Clcr≧ 51 mL/min : 100% of dose

· Clcr 10-50 mL/min: 75% of dose

· Clcr < 10 mL/min: 50% of dose

P: Tab: 5mg (25004); Soln: 1mg/1mL, 60 mL/bot (28641); Inj: 9.08mg/2mL Amp (34435)

ADR:

COMMON

Body fluid retention, Nausea, Taste sense altered, Vomiting, Asthenia, Headache, Somnolence, Fatigue.

SERIOUS

Neuroleptic malignant syndrome, Tardive dyskinesia.

NOTE: 室溫儲存

·《Contraindications》Dystonic reaction to metoclopramide; Epilepsy; increased risk of severity and/or frequency of seizures; Gastrointestinal hemorrhage, mechanical obstruction, or perforation or any other use where stimulation of gastrointestinal motility might be dangerous; History of tardive dyskinesia; Preexisting pheochromocytoma or other catecholamine-releasing paragangliomas; increased risk of hypertensive crisis; Sensitivity or intolerance to metoclopramide products ;

藥名相似:

外觀相似:

外觀描述: 2mL透明注射液,『棕』色安瓿頸部灰點 ,藍底白字標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1003552

24.06E Antiemetics, Serotonin (5-HT3) receptor Inhibitor

25031 ɔt be ruled out / Infant risk can

ZOFRAN* TABLETS 8MG 卓弗蘭膜衣錠 8 毫克

Ondansetron FC tab 8mg

Dosage: 1常備品 25031

ADULT

·Highly emetogenic C/T induced nausea & vomiting prophylaxis: PO, 24mg 30min prior to C/T

·Moderately emetogenic C/T induced nausea & vomiting prophylaxis: PO, 8mg 30min prior to C/T and repeat in 8hrs, then 8mg q12h for 1-2 days post C/T

·Post-OP nausea & vomiting prophylaxis: PO, 16mg 1hr before anesthesia

·Radiation-induced nausea and vomiting prophylaxis:

- Daily fractionated R/T to abdomen: PO, 8mg 1-2 hrs prior to R/T and q8h after first dose for each day R/T is given

- Single high-dose fraction R/T to abdomen: PO, 8mg 1-2 hrs prior to R/T and q8h after first dose for 1-2 days after R/T completion

- Total body irradiation R/T: PO, 8mg 1-2 hrs prior to R/T

PEDIATRIC

·Moderately emetogenic C/T induced nausea & vomiting prophylaxis:

- 4-11yrs: PO, 4mg 30min prior to C/T, repeated 4 and 8 hours after first dose, then q8h for 1-2 days post C/T

- >12yrs: Same as adult

Dosing adjustments in hepatic impairment:

Severe hepatic impairment (Child-Pugh score 10 or greater): do not exceed 8 mg/day

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 8mg (25031) (27666, 兒癌用藥); Inj: 8mg/4mL Amp (34437) (39968, 兒癌用藥); Inj: 4mg/2mL Amp (39970, 兒癌用藥)

ADR:

COMMON

Constipation, diarrhea, xerostomia, increased liver enzymes, headache, fever, hypoxia, fatigue, malaise

SERIOUS

Atrial fibrillation, electrocardiogram abnormal, prolonged QT interval, Torsades de pointes, oculogyric crisis, serotonin syndrome

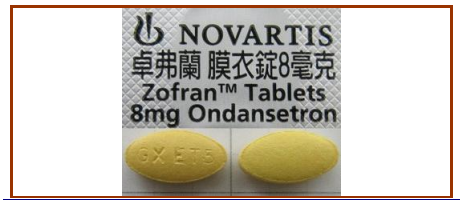
NOTE: 室溫儲存

此藥使用於第一孕期有先天缺陷的風險；育齡婦女使用此藥應考慮避孕。
[Based on human experience of epidemiological studies (Parker et al 2019, Lemon et al 2019 and Huybrechts et al 2018, 2020), ondansetron is suspected to cause orofacial clefts and cardiac malformations when administered during first trimester of pregnancy. Advise women of childbearing potential to use contraception while taking ondansetron and for 2 days after stopping treatment.]

藥名相似:

外觀相似:

外觀描述: 黃色橢圓形膜衣錠，刻印有GX ET5字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2018584

24.06E Antiemetics, Serotonin (5-HT3) receptor Inhibitor

25032 ɔt be ruled out / Infant risk can

KYTRIL* 1MG F.C. TABLETS 康您適強膜衣錠 1 毫克

Granisetron 1mg FC tab

Dosage: 1常備品 25032

Adult
· Emetogenic chemotherapy: PO, 2 mg 1 hr before chemotherapy or 1 mg 1 hr before and second 1 mg 12 hrs after chemotherapy; Max. 9 mg/day
· Radiation induced nausea and vomiting: PO, 2 mg 1 hr before radiation therapy

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 1mg (25032) (27667, 兒癌用藥); Inj: 3mg/3mL Amp (34434) (39947, 兒癌用藥); Inj: 1mg/1mL Amp (34438) (39948, 兒癌用藥)

ADR:

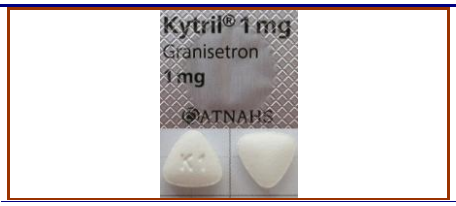
Headache, constipation, asthenia, diarrhea, abdominal pain

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述:



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022016

24.06E Antiemetics, Serotonin (5-HT3) receptor Inhibitor

27666 ɔt be ruled out / Infant risk can

@Zofran* 8 mg 卓弗蘭膜衣錠

@Ondansetron 8mg tab

Dosage: 2兒癌基金用藥 27666

ADULT
·Highly emetogenic C/T induced nausea & vomiting prophylaxis: PO, 24mg 30min prior to C/T
·Moderately emetogenic C/T induced nausea & vomiting prophylaxis: PO, 8mg 30min prior to C/T and repeat in 8hrs, then 8mg q12h for 1-2 days post C/T
·Post-OP nausea & vomiting prophylaxis: PO, 16mg 1hr before anesthesia
·Radiation-induced nausea and vomiting prophylaxis:
- Daily fractionated R/T to abdomen: PO, 8mg 1-2 hrs prior to R/T and q8h after first dose for each day R/T is given
- Single high-dose fraction R/T to abdomen: PO, 8mg 1-2 hrs prior to R/T and q8h after first dose for 1-2 days after R/T completion
- Total body irradiation R/T: PO, 8mg 1-2 hrs prior to R/T

PEDIATRIC
·Moderately emetogenic C/T induced nausea & vomiting prophylaxis:
- 4-11yrs: PO, 4mg 30min prior to C/T, repeated 4 and 8 hours after first dose, then q8h for 1-2 days post C/T
- >12yrs: Same as adult

Dosing adjustments in hepatic impairment:

Severe hepatic impairment (Child-Pugh score 10 or greater): do not exceed 8 mg/day

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 8mg (25031) (27666, 兒癌用藥); Inj: 8mg/4mL Amp (34437) (39968, 兒癌用藥); Inj: 4mg/2mL Amp (39970, 兒癌用藥)

ADR:

COMMON
Constipation, diarrhea, xerostomia, increased liver enzymes, headache, fever, hypoxia, fatigue, malaise
SERIOUS
Atrial fibrillation, electrocardiogram abnormal, prolonged QT interval, Torsades de pointes, oculogyric crisis, serotonin syndrome

NOTE: 室溫儲存

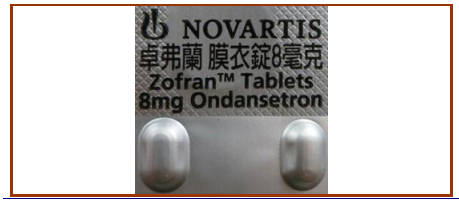
此藥使用於第一孕期有先天缺陷的風險；育齡婦女使用此藥應考慮避孕。
[Based on human experience of epidemiological

studies (Parker et al 2019, Lemon et al 2019 and Huybrechts et al 2018, 2020), ondansetron is suspected to cause orofacial clefts and cardiac malformations when administered during first trimester of pregnancy. Advise women of childbearing potential to use contraception while taking ondansetron and for 2 days after stopping treatment.]

藥名相似:

外觀相似:

外觀描述: 黃色長橢圓扁錠，有8及Glaxo字樣



24.06E Antiemetics, Serotonin (5-HT3) receptor Inhibitor

27667 ɔt be ruled out / Infant risk can

@KYTRIL* 1mg FC tab 康您適強

@Granisetron HCl 1mg FC tab

Dosage: 2兒癌基金用藥 27667

ADULT
· Emetogenic chemotherapy: PO, 2 mg 1 hr before chemotherapy or 1 mg 1 hr before and second 1 mg 12 hrs after chemotherapy; Max. 9 mg/day
· Radiation induced nausea and vomiting: PO, 2 mg 1 hr before radiation therapy

Pediatric
Not recommended

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 1mg (25032) (27667, 兒癌用藥);
Inj: 3mg/3mL Amp (34434) (39947, 兒癌用藥); Inj: 1mg/1mL Amp (34438) (39948, 兒癌用藥)

ADR:

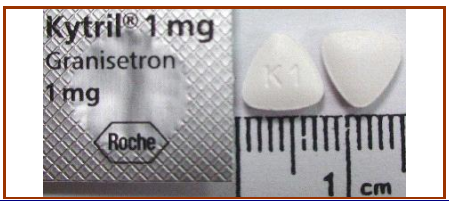
Headache, constipation, asthenia, diarrhea, abdominal pain

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色三角形扁錠



24.06E Antiemetics, Serotonin (5-HT3) receptor Inhibitor

29841 ɔt be ruled out / Infant risk can

Sancuso transdermal patch 3.1mg/24hours 貼固守穿皮貼片劑

Granisetron transdermal patch 3.1mg/24hrs

Dosage: 1常備品 29841

Adult
·Chemotherapy induced nausea and vomiting (CINV): Transdermal, apply 1 patch (34.3 mg; released at 3.1 mg/day for 7 days) a minimum of 24 hours before chemotherapy; may be applied up to a MAX of 48 hours before chemotherapy; remove a minimum of 24 hours after completion of chemotherapy; MAX duration of wearing the patch is 7 days

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

COMMON
Constipation, headache, fatigue
SERIOUS
Atrial fibrillation, prolonged QT interval, hypersensitivity reaction, serotonin syndrome

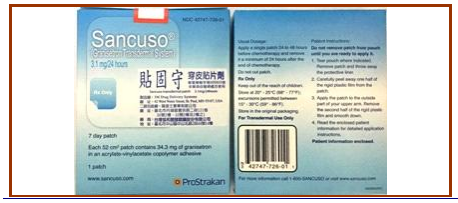
NOTE: 室溫儲存30℃以下

·《Contraindications》Hypersensitivity to granisetron, any other component of the product, or any other 5-hydroxytryptamine-3 (5-HT3) receptor antagonists ;
·Do not cut patch.
·Cover the patch application site (eg, with clothing) throughout the period of wear and for 10 days after removal when exposed to sunlight due to potential skin reaction.
·Each patch contains 34.3mg of granisetron with a 3.1mg/24 hours release rate for up to 7 days.

藥名相似:

外觀相似:

外觀描述: 52cm2貼片,一面有"Granisetron 3.1mg/24 hours"字樣，單片包裝於白底藍字小袋，有淺藍色"Sancuso"字樣



24.06E Antiemetics, Serotonin (5-HT3) receptor Inhibitor

34434 ɔt be ruled out / Infant risk can

GRANTRON I.V. INJECTION 1 MG/ML 康斯吐靜脈注射液 1 毫克/毫升

Granisetron inj 3mg/3mL vial

Dosage: 1常備品 34434

ADULT
· Chemotherapy induced nausea and vomiting (CINV):IV,10-40mcg/kg/dose(1-3mg/dose) 30 min before chemotherapy; further treatment may be administered, if needed, Max. 9mg/24hrs
· Postoperative nausea and vomiting(PONV):IV,1mg (10mcg/kg) before induction of anesthesia or immediately before reversal of anesthesia;Max.3mg/day
· Radiotherapy nausea and vomiting(RINV):IV, 10-40mcg/kg/dose(1-3mg/dose) before radiotherapy

Pediatric
· Chemotherapy induced nausea and vomiting (CINV):IV, 10-40mcg/kg/dose(Max.3mg/dose) 30 min before chemotherapy. One additional doses may be given at 10-min intervals, for a maximum total of 2 doses within a 24-hr period.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 1mg (25032) (27667, 兒癌用藥); Inj: 3mg/3mL Amp (34434) (39947, 兒癌用藥); Inj: 1mg/1mL Amp (34438) (39948, 兒癌用藥)

ADR:

COMMON
Headache, somnolence, fever
SERIOUS
Prolonged QT interval, hypersensitivity reaction

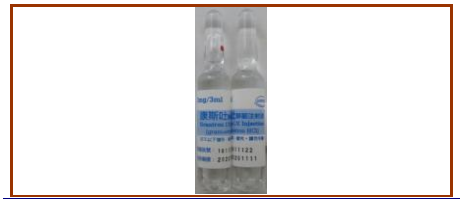
NOTE: 室溫儲存

1. Intravenous granisetron may be administered either undiluted over 30 seconds or diluted with NS or D5W to a total volume of 20 to 50 mL and infused over 5 minutes.
2. After dilution the shelf-life is 24 hrs. Discard unused solution after 24 hrs.

藥名相似:

外觀相似:

外觀描述: 3mL透明注射液，透明安瓿，頸部有紅點，白底藍字標籤，藍色區塊。



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049177

24.06E Antiemetics, Serotonin (5-HT3) receptor Inhibitor

34437 ɔt be ruled out / Infant risk can

SUPREN INJECTION 2MG/ML (ONDANSETRON) "信東" 蘇普瑞注射劑 2 毫克/毫升

Ondansetron inj 8mg/4mL amp

Dosage: 1常備品 34437

ADULT
· Chemotherapy-induced nausea and vomiting prophylaxis: IV, 0.15 mg/kg 30 min prior to C/T, repeated 4 and 8 hours after the first dose, Max: 16 mg/dose
· Postoperative nausea and vomiting: IV, IM, 4 mg immediately prior to anesthesia induction or postoperatively; a second dose does not provide additional benefit

Pediatric
· Chemotherapy-induced nausea and vomiting prophylaxis (>6m): IV, 0.15 mg/kg 30 min prior to C/T, repeated 4 and 8 hours after the first dose, Max: 16 mg/dose
· Postoperative nausea and vomiting prophylaxis:
- 1m-12yrs, <=40kg: IV, 0.1 mg/kg/dose as a single dose
- 1m-12yrs, >40kg: IV, 4 mg/dose as a single dose
- >12yrs: IV, IM, 4 mg/dose as a single dose

Dosing adjustments in hepatic impairment:

Severe hepatic impairment (Child-Pugh score > 10): < 8mg/day

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 8mg (25031) (27666, 兒癌用藥); Inj: 8mg/4mL Amp (34437) (39968, 兒癌用藥)

ADR:

COMMON
Constipation, diarrhea, xerostomia, increased liver enzymes, headache, fever, hypoxia, fatigue, malaise
SERIOUS
Atrial fibrillation, electrocardiogram abnormal, prolonged QT interval, Torsades de pointes, oculogyric crisis, serotonin syndrome

NOTE: 室溫儲存

· The single 32-mg IV dose is no longer an approved dose because of the risk of QT-interval prolongation and torsades de pointes. Max single IV dose is 16 mg
· Monitoring recommended in patients with electrolyte abnormalities (eg, hypokalemia or hypomagnesemia), CHF, bradyarrhythmias, and concomitant use of QT prolonging medications.
· Avoid use in patients with congenital long QT syndrome.
· In patients >= 75 years should limit initial IV doses to <= 8 mg due to the potential for QT prolongation. (Health Canada 2014)
· 此藥使用於第一孕期有先天缺陷的風險；育齡婦女使用此藥應考慮避孕。[Based on human experience of epidemiological studies (Parker et al 2019, Lemon et al 2019 and Huybrechts et al 2018, 2020), ondansetron is suspected to cause orofacial clefts and cardiac malformations when administered during first trimester of pregnancy. Advise women of childbearing potential to use contraception while taking ondansetron and for 2 days after stopping treatment.]

藥名相似:

外觀相似:

外觀描述: 4mL透明注射液，透明玻璃安瓿，頸部有『紅』點外附避光袋

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1039944

24.06E Antiemetics, Serotonin (5-HT3) receptor Inhibitor

34443 B / Infant risk can

Aloxi Solution for Injection 嘔立舒注射劑

Palonosetron 0.25mg/5mL vial

Dosage: 1常備品 34443

Adult
·Prevention of chemotherapy-induced nausea and vomiting: IV over 30 secs, 0.25mg as a single dose 30 mins prior to the start of chemotherapy

Pediatric(>1 mon)
· Prevention of chemotherapy-induced nausea and vomiting: IV over 15 mins, 20 mcg/kg as a single dose 30 mins prior to the start of chemotherapy; MAX. 1.5 mg

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 0.25mg/5mL Vial (34443)

ADR:

COMMON
Bradyarrhythmia, constipation, headache
SERIOUS
Prolonged QT interval, anaphylaxis, hypersensitivity reaction, seizure, serotonin syndrome

NOTE: 室溫儲存

·Repeated dosing within 7 days is not recommended

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液，『藍』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024785

24.06E Antiemetics, Serotonin (5-HT3) receptor Inhibitor

37782 B / Infant risk can

Aloxi Solution for Injection 嘔立舒注射劑

兒癌Palonosetron inj 0.25mg/5mL vial

Dosage: 2兒癌基金用藥 37782

Adult
·Prevention of chemotherapy-induced nausea and vomiting: IV over 30 secs, 0.25mg as a single dose 30 mins prior to the start of chemotherapy

Pediatric(>1 mon)
· Prevention of chemotherapy-induced nausea and vomiting: IV over 15 mins, 20 mcg/kg as a single dose 30 mins prior to the start of chemotherapy; MAX. 1.5 mg

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 0.25mg/5mL Vial (37782)

ADR:

COMMON
Bradyarrhythmia, constipation, headache
SERIOUS
Prolonged QT interval, anaphylaxis, hypersensitivity reaction, seizure, serotonin syndrome

NOTE: 室溫儲存

·《Contraindications》hypersensitivity to palonosetron hydrochloride or any component of the product；
·<基金會原則>
(1)符合健保適應症條件者，請優先使用健保許可藥物。
(2)超出健保適應症條件者，再考慮使用基金會提供的止吐藥。
(3) 每個化療療程，無論連續給幾天，基金會只補助單一次Aloxi的劑量。不足部份請改用其它藥物。
(4)僅IV化學治療適用，口服化療不適用Aloxi
(5)延遲性嘔吐不適用

藥名相似:

外觀相似:

外觀描述:

24.06E Antiemetics, Serotonin (5-HT3) receptor Inhibitor

39947 ɔt be ruled out / Infant risk can

KYTRIL 3MG IN 3ML 康您適強

@Granisetron inj 3mg/3mL vial

Dosage: 2兒癌基金用藥 39947

ADULT
· Emetogenic chemotherapy: IV,10 mcg/kg 30 min before chemotherapy; Max. 9 mg/day
· Postoperative nausea and vomiting: IV ,1 mg before induction of anesthesia or immediately before reversal of anesthesia; Max. 2 mg/day

Pediatric
· Emetogenic chemotherapy: children 2 yrs or older, IV, 10-40 mcg/kg/dose (Max. 3 mg/dose) 30 min before chemotherapy. Two additional doses may be given at 10-minute intervals, for a maximum total of 3 doses within a 24-hr period.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 1mg (25032) (27667, 兒癌用藥); Inj: 3mg/3mL Amp (34434) (39947, 兒癌用藥); Inj: 1mg/1mL Amp (34438) (39948, 兒癌用藥)

ADR:

Headache, constipation, asthenia, diarrhea, abdominal pain

NOTE: 室溫儲存

1. Intravenous granisetron may be administered either undiluted over 30 seconds or diluted with NS or D5W to a total volume of 20 to 50 milliliters and infused over 5 minutes.
2. After dilution the shelf-life is 24 hrs. Discard unused solution after 24 hrs.

藥名相似:

外觀相似:

外觀描述: 3mL透明注射液透明安瓿，頸部有藍點及1條綠色線條

24.06E Antiemetics, Serotonin (5-HT3) receptor Inhibitor

39948 ɔt be ruled out / Infant risk can

KYTRIL 3MG IN 3ML 康您適強

@Granisetron 1mg/1mL amp

Dosage: 2兒癌基金用藥 39948

ADULT

· Emetogenic chemotherapy: IV,10 mcg/kg 30 min before chemotherapy; Max. 9 mg/day

· Postoperative nausea and vomiting: IV ,1 mg before induction of anesthesia or immediately before reversal of anesthesia; Max. 2 mg/day

Pediatric

· Emetogenic chemotherapy: children 2 yrs or older, IV, 10-40 mcg/kg/dose (Max. 3 mg/dose) 30 min before chemotherapy. Two additional doses may be given at 10-minute intervals, for a maximum total of 3 doses within a 24-hr period.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 1mg (25032) (27667, 兒癌用藥); Inj: 3mg/3mL Amp (34434) (39947, 兒癌用藥); Inj: 1mg/1mL Amp (34438) (39948, 兒癌用藥)

ADR:

Headache, constipation, asthenia, diarrhea, abdominal pain

NOTE: 室溫儲存

1. Intravenous granisetron may be administered either undiluted over 30 seconds or diluted with NS or D5W to a total volume of 20 to 50 milliliters and infused over 5 minutes.
2. After dilution the shelf-life is 24 hrs. Discard unused solution after 24 hrs.

藥名相似:

外觀相似:

外觀描述:

24.06E Antiemetics, Serotonin (5-HT3) receptor Inhibitor

39968 ɔt be ruled out / Infant risk can

ZOFRAN INJECTION 2MG/ML 卓弗蘭注射劑 2 公絲 / 公撮

@Ondansetron 8 mg/4 mL amp

Dosage: 2兒癌基金用藥 39968

ADULT

· Chemotherapy-induced nausea and vomiting prophylaxis: IV, 0.15 mg/kg 30 min prior to C/T, repeated 4 and 8 hours after the first dose, Max: 16 mg/dose

· Postoperative nausea and vomiting: IV, IM, 4 mg immediately prior to anesthesia induction or postoperatively; a second dose does not provide additional benefit

Pediatric

· Chemotherapy-induced nausea and vomiting prophylaxis (>6m): IV, 0.15 mg/kg 30 min prior to C/T, repeated 4 and 8 hours after the first dose, Max: 16 mg/dose

· Postoperative nausea and vomiting prophylaxis:
- 1m-12yrs, <=40kg: IV, 0.1 mg/kg/dose as a single dose
- 1m-12yrs, >40kg: IV, 4 mg/dose as a single dose
- >12yrs: IV, IM, 4 mg/dose as a single dose

Dosing adjustments in hepatic impairment:

Severe hepatic impairment (Child-Pugh score > 10): < 8mg/day

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 8mg (25031) (27666, 兒癌用藥); Inj: 8mg/4mL Amp (34437) (39968, 兒癌用藥)

ADR:

COMMON
Constipation, diarrhea, xerostomia, increased liver enzymes, headache, fever, hypoxia, fatigue, malaise
SERIOUS
Atrial fibrillation, electrocardiogram abnormal, prolonged QT interval, Torsades de pointes, oculogyric crisis, serotonin syndrome

NOTE: 室溫儲存

· The single 32-mg IV dose is no longer an approved dose because of the risk of QT-interval prolongation and torsades de pointes. Max single IV dose is 16 mg
· Monitoring recommended in patients with electrolyte abnormalities (eg, hypokalemia or hypomagnesemia), CHF, bradyarrhythmias, and concomitant use of QT prolonging medications.
· Avoid use in patients with congenital long QT syndrome.
· In patients >= 75 years should limit initial IV doses to <= 8 mg due to the potential for QT prolongation. (Health Canada 2014)
· 此藥使用於第一孕期有先天缺陷的風險；育齡婦女使用此藥應考慮避孕。[Based on human experience of epidemiological studies (Parker et al 2019, Lemon et al 2019 and Huybrechts et al 2018, 2020), ondansetron is suspected to cause orofacial clefts and cardiac malformations when administered during first trimester of pregnancy. Advise women of childbearing potential to use contraception while taking ondansetron and for 2 days after stopping treatment.]

藥名相似:

外觀相似:

外觀描述:

24.06G Antiemetics, Miscellaneous

25033 **B /**

EMEND CAPSULES 80MG 止敏吐膠囊80毫克

Aprepitant 80mg cap

Dosage: 1常備品 25033

Adult
· Chemotherapy-induced nausea and vomiting: PO, 125mg 1 hour prior to chemotherapy on day 1; 80mg on day 2 and day 3; should be used in combination with a corticosteroid and 5-HT3 receptor antagonist

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild-to-moderate impairment (Child-Pugh 5-9): No dosage adjustment needed.
Severe hepatic impairment (Child-Pugh > 9): NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Cap: 80mg(25033), 125mg(25034)

ADR:

Somnolence, fatigue, hiccoughs

NOTE: 室溫儲存30℃以下

· In patients on chronic warfarin therapy, the INR should be closely monitored in the 2wks period, particularly at 7-10 days, following initiation of the 3-day regimen of Emend.

藥名相似:

外觀相似:

外觀描述: 白色膠囊,有461及80mg字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023985

24.06G Antiemetics, Miscellaneous

25034 **B /**

EMEND CAPSULES 125MG 止敏吐膠囊125毫克

Aprepitant 125mg cap

Dosage: 1常備品 25034

Adult
· Chemotherapy-induced nausea and vomiting: PO, 125mg 1 hour prior to chemotherapy on day 1; 80mg on day 2 and day 3; should be used in combination with a corticosteroid and 5-HT3 receptor antagonist

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild-to-moderate impairment (Child-Pugh 5-9): No dosage adjustment needed.
Severe hepatic impairment (Child-Pugh > 9): NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Cap:125mg(25034), 80mg(25033)

ADR:

Somnolence, fatigue, hiccoughs

NOTE: 室溫儲存

· In patients on chronic warfarin therapy, the INR should be closely monitored in the 2wks period, particularly at 7-10 days, following initiation of the 3-day regimen of Emend

藥名相似:

外觀相似:

外觀描述: 白/粉紅色膠囊,有462及125字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023986

24.06G Antiemetics, Miscellaneous

25036 **ɔt be ruled out / Infant risk can**

Akynzeo Capsules 嘔可舒膠囊

複方 Netupitant 300mg & Palonosetron 0.5mg cap

Dosage: 1常備品 25036

·Highly emetogenic chemotherapy (including cisplatin-based regimens): PO, 1 cap 1 hr prior to chemotherapy on day 1; coadminister dexamethasone PO 12 mg 30 mins prior to chemotherapy on day 1, and 8 mg on days 2 to 4
·Anthracycline and cyclophosphamide-based regimens and other regimens not highly emetogenic: PO, 1 cap 1 hr prior to chemotherapy on day 1; coadminister dexamethasone PO 12 mg 30 mins before chemotherapy on day 1

·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

·Mild to moderate impairment (Child-Pugh score 5 to 8): No dosage adjustment needed
·Severe impairment (Child-Pugh score > 9): Avoid use

Dosing adjustments in renal impairment:

·Mild to moderate impairment: No dosage adjustment needed
·Severe impairment or ESRD: Avoid use

P: P Cap: AKYNZEO*(25036); Inj: Palonosetron 0.25mg/5mL vial(34443)(37782, 兒癌)

ADR:

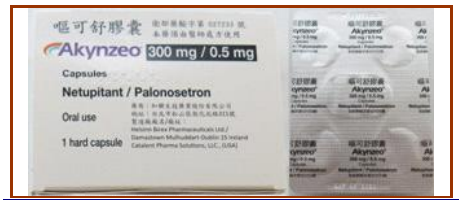
COMMON
Erythema, constipation, indigestion, asthenia, headache, fatigue
SERIOUS
Serotonin syndrome

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白/褐色膠囊，有"HE1"字樣



24.06G Antiemetics, Miscellaneous

34450 ɔt be ruled out / Infant risk can

EMEND IV 150mg Powder for Injection 止敏吐 靜脈注射劑150毫克

Fosaprepitant inj 150mg pow in vial

Dosage: 1常備品 34450

Adult
· Chemotherapy-induced nausea and vomiting (highly-emetogenic chemotherapy): IV infusion over 20-30 mins, 150mg as a single dose, 30 mins prior to chemotherapy on day 1; in combination with a 5-HT3 antagonist on day 1 and a corticosteroid on days 1-4
· Chemotherapy-induced nausea and vomiting (moderate-emetogenic chemotherapy): IV infusion over 20-30 mins, 150mg as a single dose, 30 mins prior to chemotherapy on day 1; in combination with a 5-HT3 antagonist and a corticosteroid on days 1

Pediatric
Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Mild to moderate hepatic impairment (Child-Pugh 5-9): No dosage adjustment needed
Severe hepatic impairment (Child-Pugh > 9): NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P:

ADR:

COMMON
Burping, constipation, diarrhea, indigestion, loss of appetite, ALT/SGPT level raised, AST/SGOT level raised, asthenia, headache, hiccoughs, fatigue
SERIOUS
Stevens-Johnson syndrome, urticaria, duodenal ulcer with perforation, neutropenic colitis, febrile neutropenia, thrombophlebitis after infusion, hypersensitivity reaction, angioedema

NOTE: 冰箱冷藏，不可冷凍。

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『灰』蓋透明玻璃小瓶

24.08 Antiflatulents

24901 B / No report(毫

KASCOAL TABLETS 40MG (DIMETHYLPOLYSILOXANE) 加斯克兒錠40毫克（聚二甲矽烷）

Dimethicone(dimethylpolysiloxane) 40mg tab

Dosage: 1常備品 24901

Adult
· Flatulence: 1-2 tab qid; Max. 500 mg/day

Pediatric(> 3 yrs)
Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 40 mg (24901); Susp:20mg/mL,300mL/B Wilcon (38815)

ADR:

COMMON
diarrhea, mild nausea, regurgitation, vomiting

NOTE: 室溫儲存

Contraindication: intestinal perforation and obstruction

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1029828

24.08 Antiflatulents

28647 **risk is minimal / No report(毫**

WILCON SUSPENSION 20 MG/ML (SIMETHICONE)"UNION" "聯邦"胃爾康懸浮液２０毫克/毫升（喜每暢康）

Simethicone suspension 20mg/mL, 60mL/bot

Dosage: 1常備品 28647

Adult
· Flatulence: PO, 2mL tid-qid

Pediatric(≧ 3 yrs)
· Flatulence: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 40 mg (24901); Susp: 20 mg/mL, 60 mL/B (28647); 20 mg/mL, 300mL/B (38815)

ADR:

COMMON
Mild diarrhea, nausea, regurgitation, vomiting

NOTE: 室溫避光

·《Contraindications》hypersensitivity to simethicone products; known or suspected intestinal perforation and obstruction；
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 60mL懸浮液劑，白色塑膠瓶,白底黑字標籤,有藍色圓形,區塊及條碼

24.10A Antiulcer, H2-Antagonists

25003 **B / Infant risk is**

DEFENSE FILM COATED TABLETS (CIMETIDINE) "YUNG SHIN" "永信" 祛潰膜衣錠（希每得定）

Cimetidine 300mg tab

Dosage: 1常備品 25003

Adult
· Active duodenal/gastric ulcer: PO, 800mg qhs or 300mg qid or 400mg bid
· Maintenance therapy of duodenal/gastric ulcer: PO, 400mg qhs
· Gastroesophageal reflux disease: PO, 400mg qid or 800mg bid
· Hypersecretory conditions: PO, 300mg qid, Max. 2400mg/day

Pediatric (not recommended in children <16yrs)
· Active duodenal ulcer, gastroesophageal reflux disease: PO, 20-40mg/kg/day in divided doses

Dosing adjustments in hepatic impairment:

Severe liver disease: 50% reduction in the dose

Dosing adjustments in renal impairment:

CLcr< 30mL/min: 300mg q8-12h; lowest effective dosage should be used

P: Tab: 300mg(25003); Inj: 300mg//2mL Amp(34440)

ADR:

COMMON
Rash, gynecomastia, diarrhea, dizziness, headache
SERIOUS
Necrotizing enterocolitis in fetus or newborn, agranulocytosis, psychotic disorder

NOTE: 室溫儲存

藥名相似:

外觀相似: DOBECON* 100 mg Tab (26415)

外觀描述: 紅色圓扁錠，有C字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1022836

24.10A Antiulcer, H2-Antagonists

25022 **B / Unsafe**

WELIZEN F.C.TABLETS 20MG "N.K" "南光" 胃利贊膜衣錠２０公絲

Famotidine 20mg FC tab

Dosage: 1常備品 25022

Adult
· Duodenal / gastric ulcer: PO, 40mg hs or 20mg bid for 4-8 wks, MD 20mg hs
· Hypersecretory conditions: PO, initial 20mg q6h; Max. 160mg q6h
· Gastroesophageal reflux disease: PO, 20mg bid for 6 wks
· Esophagitis associated with GERD：PO, 20mg or 40mg bid for 12 wks

Pediatric
· Duodenal / gastric ulcer (1-16 yrs): PO, 0.5mg/kg/day hs or in 2 divided doses; Max. 40mg/day
· Gastroesophageal reflux disease (1-16 yrs): PO, 1mg/kg/day divided twice daily up to 40mg bid

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Adult
CLcr< 50mL/min: 50% of dose or increase dosing interval to 36-48 hrs
Pediatric
CLcr 30-60mL/min/1.48 m(2): 50% of dose
CLcr < 30mL/min/1.48m(2): 25% of dose

P: Tab: 20mg(25022, 膜衣錠)(25028, 口溶錠); Inj: 20mg/2mL Amp(34442)

ADR:

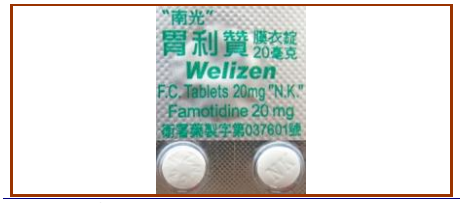
COMMON
Constipation, diarrhea
SERIOUS
Stevens-Johnson syndrome(very rare), toxic epidermal necrolysis(very rare), necrotizing enterocolitis in fetus or newborn, increased liver enzymes(rare), seizure(rare), interstitial pneumonia

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有"NK"，另一面有"WZN 20"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1037601

24.10A Antiulcer, H2-Antagonists

34442 **B / Unsafe**

FAMOSTER INJECTION 10MG/ML "T.F." (FAMOTIDINE) "大豐" 護胃治定注射液10毫克/毫升(發模梯定)

Famotidine inj 20mg/2mL amp

Dosage: 1常備品 34442

Adult
· Duodenal ulcer/gastric ulcer, pathologic hypersecretory conditions, gastroesophageal reflux disease: IV infusion, slow IV, IM, 20mg q12h

Pediatric (1-16 yrs)
· Duodenal ulcer/gastric ulcer, pathologic hypersecretory conditions, gastroesophageal reflux disease: IV infusion, slow IV, IM, 0.25mg/kg q12h; Max. 40mg/day

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr 30-60mL/min: 20mg q24h or 10mg q12h
Clcr < 30mL/min: 5mg q24h or 10mg q48h

P: Tab: 20mg(25022, 膜衣錠)(25028, 口溶錠); Inj: 20mg/2mL Amp(34442)

ADR:

COMMON
Constipation, diarrhea
SERIOUS
Stevens-Johnson syndrome(very rare), toxic epidermal necrolysis(very rare), necrotizing enterocolitis in fetus or newborn, increased liver enzymes(rare), seizure(rare), interstitial pneumonia

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 2mL透明注射液 褐色安瓿，頸部有灰點，白紙『黃』字標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1047442

24.10B Antiulcer, Proton-Pump Inhibitors

25019 **B /**

Gastroloc Gastro-resistant Tablets 40mg 佳樂胃腸溶膜衣錠40毫克

Pantoprazole 40mg tab

Dosage: 1常備品 25019

Adult
· Gastroesophageal reflux disease: PO, 40 mg qd
· Hypersecretory conditions: PO, 40 mg bid; Max. 240 mg/day
· Peptic ulcer: PO, 40-80 mg qd

PEDIATRIC
·

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 40mg (enteric coated) (25019)

ADR:

Diarrhea, headache, hyperglycemia

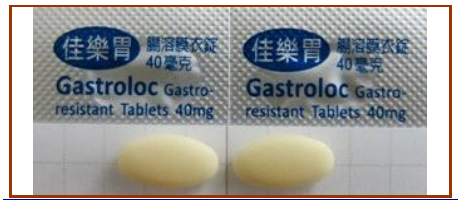
NOTE: 室溫儲存

Swallow whole; do not crush or chew

藥名相似:

外觀相似:

外觀描述: 淺土黃色長橢圓形扁錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048190

24.10B Antiulcer, Proton-Pump Inhibitors

25021 **B / Unsafe**

PARIET ENTERIC-COATED TABLETS 20MG 百抑潰腸溶膜衣錠 2 0毫克

Rabeprazole 20mg FC tab

Dosage: 1常備品 25021

Adult

·Duodenal ulcer: PO, 20 mg qd up to 4-8 wks
·Gastroesophageal reflux disease: PO, 20 mg qd
·H pylori eradication: PO, 20 mg bid for 7 days (in combination with Amoxicillin plus Clarithromycin)
·Hypersecretory conditions: initial, PO 60 mg qd, Max. 120 mg/day

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 20mg(25021)

ADR:

COMMON
abdominal pain, diarrhea, nausea, edema (rare), headache, dizziness (rare), insomnia, rash (rare)

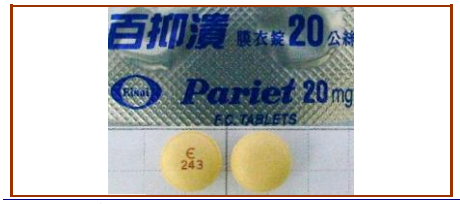
NOTE: 室溫儲存

Swallow whole; do not crush or chew

藥名相似:

外觀相似:

外觀描述: 黃色圓扁錠,有ε及243字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022782

24.10B Antiulcer, Proton-Pump Inhibitors

25027 ɔt be ruled out / Infant risk can

TAKEPRON OD 30MG TABLETS 泰克胃通 口溶錠30毫克

Lansoprazole OD 30mg(口溶錠)

Dosage: 1常備品 25027

Adult
· Erosive esophagitis: PO, 30mg QD for 8-16wks, another 8wks for recurrence may be considered; MD 15mg QD for up to 12mons
· Gastric ulcer, short-term treatment of active ulcer: PO, 30mg QD up to 8wks
· Gastric ulcer - NSAID-associated gastropathy: PO, 15mg QD up to 12wks for prophylaxis; 30mg QD for 8wks for treatment
· GERD: PO, 15mg QD up to 8wks
· H. pylori infection: PO, 30-60mg BID for 10-14 days (in combination with amoxicillin and clarithromycin or other combination therapy)
· Ulcer of duodenum, short-term treatment of active disease and maintenance of healed ulcers: PO, 15mg QD up to 4wks for treatment; MD 15mg QD
· Zollinger-Ellison syndrome: PO, 60mg QD up to 90mg BID; daily doses >120mg should be administered in divided doses

Pediatric
· GERD, erosive esophagitis (1-11yrs): PO, ≦30kg: 15mg QD, >30kg: 30mg QD for up to 12wks, may increase dose up to 30mg BID if symptoms persist after 2 or more wks of treatment
· Erosive esophagitis (≧12yrs): PO, 30mg QD for up to 8wks
· GERD(≧12yrs): PO, 15mg QD for up to 8wks

Dosing adjustments in hepatic impairment:

Severe hepatic impairment (Child-Pugh C): PO, 15mg QD

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: P OD Tab: 30mg (25027); Inj: 30mg Vial (34429)

ADR:

COMMON
Abdominal pain, constipation, diarrhea, nausea, headache
SERIOUS
Cutaneous lupus erythematosus, hypomagnesemia, Clostridium difficile diarrhea, fundic gland polyposis of stomach, pancreatitis, anaphylaxis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, fracture of bone, rhabdomyolysis, acute interstitial nephritis

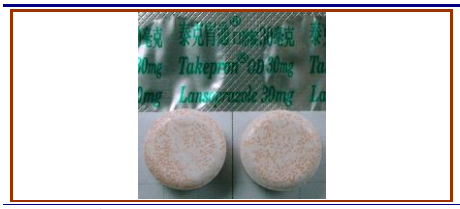
NOTE: 室溫儲存

·OD Tab : Orally-disintegrating tab
·Do not chew. Place on tongue and allow to disintegrate, with or without water, until particles can be swallowed
·NG tube administration: 30mg tab in a syringe and draw up 10mL water. After tablet has dispersed, administer within 15 min. Refill the syringe with 5mL water, shake gently, and then flush the NG tube.
· Vitamin B12 deficiency should be considered when it occurs in patients who use this drug, If the same symptoms of cyanocobalamin deficiency are observed.
· A drug-induced decrease in gastric acid causes an increase in serum chromogranin A (CgA) concentration. Elevated CgA concentrations may lead to false positive results in the diagnosis of neuroendocrine tumors. At least 14 days of lansoprazole treatment should be suspended before checking CgA concentration.
· Each 30 mg tablet contains 3.0 mg of aspartame. Patients with phenylketonuria (PKU) should consider the total daily amount of all sources of aspartame, including Takepron*.
·PPI類藥品高劑量或長時間使用時，可能會增加臀部、脊椎或手腕等部位骨折之風險。使用於具有骨質疏鬆風險之病人時，宜監控病人骨質狀況，並適當補充Vitamin D 與Calcium。
·PPI與胃底腺息肉的風險增加有關，隨長期使用而增加，尤其是使用超過一年。應依照所需狀況選擇最短治療期間。
·1- 17歲兒童不建議使用超過12週。
·含阿斯巴甜，苯酮尿症者不宜使用。(3 mg in 30mg tab)

藥名相似:

外觀相似:

外觀描述: 兩面略凸白色圓扁錠，口溶錠上散佈澄紅色斑點



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024273

24.10B Antiulcer, Proton-Pump Inhibitors

25030 B / Unsafe

Dexilant Delayed Release Capsules 60mg 得喜胃通60毫克緩釋膠囊

Dexlansoprazole 60mg delayed release cap

Dosage: 1常備品 25030

Adult
· Healing of erosive esophagitis: PO, 60mg qd for up to 8 wks
· Maintenance of healed erosive esophagitis and relief of heartburn: PO, 30mg qd for up to 6 mons
· Symptomatic non-erosive GERD: PO, 30mg qd for 4 wks

Pediatric (12 years or older)
· Healing of erosive esophagitis: PO, 60mg qd for up to 8 wks
· Maintenance of healed erosive esophagitis and relief of heartburn: PO, 30mg qd for up to 16 wks
· Symptomatic non-erosive GERD: PO, 30mg qd for 4 wks

Dosing adjustments in hepatic impairment:

Mild liver impairment (Child Pugh class A): No dosage adjustment needed
Moderate liver impairment (Child Pugh class B): Max. 30mg/day
Severe hepatic impairment (Child Pugh class C): Not studied

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: P Cap: 60mg(25030)

ADR:

COMMON
Abdominal pain, diarrhea, flatulence, nausea, vomiting, nasopharyngitis, pain, oropharyngeal, upper respiratory infection
SERIOUS
Cutaneous lupus erythematosus, cobalamin deficiency, hypomagnesemia, clostridium difficile diarrhea, anaphylaxis, hypersensitivity reaction, systemic lupus erythematosus, fracture of bone, acute interstitial nephritis

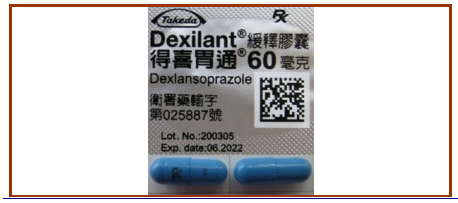
NOTE: 室溫儲存30°C以下

·Swallow whole; do not crush or chew.
·Difficulty swallowing: Open capsule, sprinkle intact granules onto 1 tablespoon of applesauce and swallow immediately; do not chew granules.
·NG tube administration: Open capsule and mix intact granules (not crushed) with 20mL of water. Withdraw mixture into syringe. Swirl syringe and administer mixture immediately. Refill syringe with 10mL water, swirl gently and flush NG tube. Repeat above step again with another 10mL of water.
·仿單加註「以針筒經口注射投藥」及「鼻胃管灌食(≥16 French)」的重要用藥資訊及藥物動力學相關資訊。(版本2013年12月)

藥名相似:

外觀相似:

外觀描述: 藍色膠囊 ，印有60字樣



24.10B Antiulcer, Proton-Pump Inhibitors

34429 ɔt be ruled out / Infant risk can

TAKEPRON* Intravenous 30mg 泰克胃通靜脈注射劑30毫克

Lansoprazole inj 30mg pow in vial

Dosage: 1常備品 34429

Adult
· Gastrointestinal ulcers, acute stress ulcers: IV infusion over 30 mins, 30mg qd-bid for up to 7 days. Once the patient is able to take medications orally, therapy can be switched to an oral formulation.

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

NDA

P: OD Tab: 30mg (25027); Inj: 30mg Vial(34429)

ADR:

Increased ALT, increased AST, increased LDH, increased γ-GTP, diarrhea, fever, decreased WBC, hypomagnesemia, anaphylaxis, pancytopenia, agranulocytosis, hemolytic anemia, thrombocytopenia, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, interstitial pneumonia, interstitial nephritis, collagenous colitis, gynecomastia

NOTE: 室溫儲存

Treatment with lansoprazole for injection should be discontinued as soon as the patient is able to resume treatment with oral formulations.

藥名相似:

外觀相似:

外觀描述: 白色乾粉，『金』色蓋透明玻璃小瓶，白底黑字標籤

24.10C Antiulcer, Prostaglandin Analogues

25017 X / Unsafe

CYTOTEC (MISOPROSTOL) 200MCG 喜克潰錠 2 0 0 微公克

Misoprostol 200 mcg tab

Dosage: 1常備品 25017

Adult
· Abortion (in combination with mifepristone): PO, 400 mcg 2 days after mifepristone dose
· NSAID-induced gastric ulcer prophylaxis: PO, 200 mcg qid with meals
· Duodenal/gastric ulcer: PO, 800 mcg/day in 2 or 4 divided doses for 4 wks

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 200 mcg (25017)

ADR:

COMMON
Abdominal pain, diarrhea.
SERIOUS
Cardiac dysrhythmia, chest pain(infrequent), myocardial infarction, gastrointestinal hemorrhage, anemia(infrequent), thromboembolic disorder(infrequent), anaphylaxis (infrequent), deafness symptom(infrequent), rupture of uterus, toxic shock syndrome, abortion-related Clostridial infection.

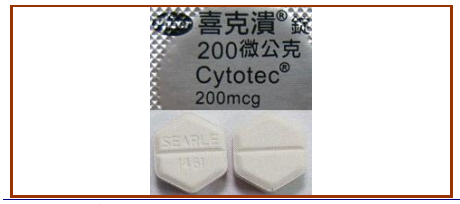
NOTE: 室溫儲存30°C以下

下列病人禁用Misoprostol：
·有生育能力但未使用有效避孕措施的婦女
·孕婦、或未排除懷孕的婦女、或準備懷孕的婦女禁止使用Misoprostol，因服用期間會增強其子宮張力與收縮力，可能會導致部分或全部受孕胎兒的娩出。若在懷孕期間使用Cytotec可能會造成新生兒缺陷。
·已知對Misoprostol、本品賦形劑、或其他前列腺素過敏者。

藥名相似:

外觀相似:

外觀描述: 白色六角形扁錠，兩面中央有刻痕，一面有SEARLE及1461字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2020674

24.10D Antiulcer, Cytoprotective Drugs

25016 B / Caution

Ulban A Gran 胃樂伴 顆粒

Sucralfate granules 900mg/g/pk

Dosage: 1常備品 25016

Adult
· Gastric or duodenal ulcer: PO, ac, 1g qid or 2g bid; MD 1g bid

Pediatric
· Gastric or duodenal ulcer: PO, ac, 40-80mg/kg/day div. q6h or 0.5-1g qid; MD 1g qhs

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Granule: 900mg/g/pk(25016), Susp: 1g/5mL/PK(28615)

ADR:

COMMOM
Constipation
SERIOUS
Bezoar, aluminum toxicity (renal impaired patients)

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to sucralfate or any of its excipients；
·本品賦形劑不含阿斯巴甜。

藥名相似: Granule: 900mg/g/pk(25016), Susp: 1g/5mL/

外觀相似:

外觀描述: 透明塑膠包裝,上有綠色" 胃樂伴顆粒"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024857

24.10D Antiulcer, Cytoprotective Drugs

28616 B / Infant risk can

SCRAT SUSPENSION "STANDARD" 保胃懸乳液 "生達"

Sucralfate 1g/ 10mL/PK Susp

Dosage: 1常備品 28616

Adult
· Duodenal ulcer: PO, ac, 1 PK bid; MD 1 PK qhs

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 500mg (25000); Susp: 1g/10mL/PK (28616), Granule: 900mg/PK(25016)

ADR:

COMMON
constipation
SERIOUS
aluminum accumulation/toxicity (renal impaired patients), bezoar formation

NOTE: 室溫儲存

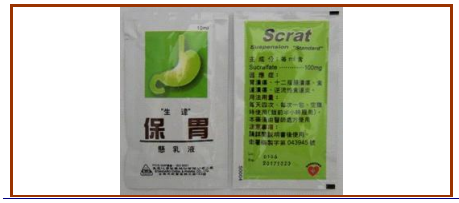
·《Contraindications》Hypersensitivity to sucralfate or any of its excipients；
·本品賦形劑不含阿斯巴甜。
COMMON
constipation
SERIOUS

aluminum accumulation/toxicity (renal impaired patients), bezoar formation

藥名相似:

外觀相似:

外觀描述: 10mL白色懸浮劑，鋁箔包裝



24.10E Antiulcer, Bismuth

25012 **b2 / Infant risk has**

KCB F.C. TABLETS 120MG "SWISS" (DIBISMUTH TRIOXIDE) "瑞士"克潰泌膜衣錠120毫克 (三氧化二鉍)

Dibismuth trioxide 120mg FC tab

Dosage: 1常備品 25012

Adult:
· Gastric and duodenal ulcers: PO, ac, 2 tab bid (30 minutes before breakfast and the evening meal) or 1 tab qid (30 minutes before meals and at bedtime)

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

It should probably be avoided in patients with renal failure, and shorter courses of therapy (4 weeks) would be prudent if administered to those with milder renal insufficiency.

P: Tab: 120mg (25012)

ADR:

Hypotension, rash, fecal discoloration, tongue discoloration, nausea, diarrhea, gastralgia, elevations in hemoglobin levels, elevations in aspartate transaminase levels, headache, dizziness, encephalopathy

NOTE: 室溫儲存25℃以下

1. Concomitant administration of antacids, milk, food, and H2-receptor antagonists may impair the efficacy of Dibismuth trioxide.
2. The concurrent use of a tetracycline and dibismuth trioxide may result in decreased in the absorption of the tetracycline.

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠

24.12A Saline Laxatives

28574 **C /**

Fulisay Oral Solution 富利瀉內服液

Phosphoric acid 226.2mg/mL & disodium phosphate 345.2mg/mL, 45mL/bot

Dosage: 1常備品 28574

Adult
·Constipation: PO, ac, 20-45mL qd or hs
·Bowel cleansing: PO, 45mL q12h for 2 dose

Pediatric
·Constipation:
5-9yrs: PO, ac, 5-10mL qd or hs
10-11yrs: PO, ac,10-20mL qd or hs
>12yrs: same as adult

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P: Soln: 45mL/B (28574)

ADR:

hypernatremia, hypokalemia, hyperphosphatemia, hypocalcemia), dehydration, metabolic acidosis, renal failure, tetany

NOTE: 室溫儲存

1. Dilute recommended dosage with 120-360mL cool water or other clear liquid. Drink, then follow with at least 240mL of water or other clear liquid.
2. 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 白色上蓋，45mL塑膠瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1055294

24.12A Saline Laxatives

28651 **D / Infant risk is**

MAGVAC ORAL SDUTION 鎂福內服液

Magnesium carbonate 4.29g/100 mL, Citric acid anhydrous 7.83 g/100 mL, Potassium bicarbonate 0.714 g/100 mL, 250mL/bot

Dosage: 1常備品 28651

Adult (仿單)
·Consitipation : 20-50 mL hs
·Bowel cleansing: 1 bot (250 mL)

Pediatric (UpToDate)
·Consitipation
<2 yrs: Safety and efficacy not established
2-6 yrs: 60 to 90 mL as a single dose or in divided doses
6-12 yrs: 100 to 150 mL as a single dose or in divided doses
≧12 yrs: 150 to 300 mL as a single dose or in divided doses
·Bowel cleansing
≧6 yrs: 4 to 6 mL/kg/day up to a maximum of 300

mL/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Soln: 250 mL/bot (28651)

ADR:

Diarrhea, asthenia, dizziness, hypermagnesemia, hypoventilation

NOTE: 室溫儲存

·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 250mL白色塑膠瓶，有綠色花紋標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1033998

24.12A Saline Laxatives

29016 C / Unknown(有

FLEET READY TO USE ENEMA "佛利特" 樂利灌腸液

Monobasic sodium phosphate 160.2mg/mL, dibasic sodium phosphate 60mg/mL, 133mL/bot

Dosage: 1常備品 29016

Adult

·Constipation/bowel cleansing: 1 bot

Pediatric

·Constipation/bowel cleansing (2-11yrs): 1/2 bot

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

Hypocalcemia, hyperphosphatemia, hypernatremia, acidemia

NOTE: 室溫儲存

·Each enema unit delivers a dose of 118 mL, which contains monosodium phosphate anhydrous 16.52g (140mg/mL) and disodium phosphate anhydrous 3.71g (31.4mg/mL)

·電解質失衡、結腸造口術的人、使用利尿劑或其他會影響電解質平衡的藥品的人及11歲以下兒童，請醫師診治後使用。

·一旦排便正常，即應停藥。長期使用會造成電解質不平衡與水分缺乏。

藥名相似:

外觀相似:

外觀描述: 塑膠灌注瓶，上有橘色保護外蓋

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023344

24.12A Saline Laxatives

29066 / Unknown(有

EVAC ENEMA 意福灌腸液

Monosodium phosphate anhy.139.1mg/mL, disodium phosphate anhy.31.8mg/mL, 118mL/bot

Dosage: 1常備品 29066

Adult

·Constipation/bowel cleansing: 1 bot

Pediatric

·Constipation/bowel cleansing (2-12yrs): 1/2 bot

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Enema: 118 mL/bot(29066, Evac*); 133mL/bot(29016, Fleet*)

ADR:

Hypocalcemia, hyperphosphatemia, hypernatremia, acidemia

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1034255

24.12B Stimulant Laxatives

24930 B / Caution

BISACODYL* E.C. TABLETS 5MG "VPP" "榮民" 秘克的腸溶糖衣錠 5 毫克

Bisacodyl 5 mg ESC tab

Dosage: 1常備品 24930

Adult

· Constipation: PO, 5-15 mg once daily up to 30 mg/day

· Bowel preparation for surgery or diagnostic tests: PO,10-15 mg once daily up to 30 mg/day

Pediatric

· Constipation (6-11 yrs): PO, 5 mg once daily

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 5mg (enteric sugar coated) (24930); Supp: 10mg (29005)

ADR:

COMMON
abdominal discomfort, colic, diarrhea, proctitis (suppository use)
SERIOUS
colonic atony

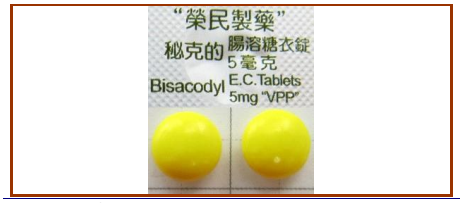
NOTE: 室溫儲存

Contraindications: appendicitis, intestinal obstruction, gastroenteritis

藥名相似: Tab: 5mg (enteric sugar coated) (24930); Sup

外觀相似: Buscopan* 10mg Tab (22041)

外觀描述: 黃色圓形糖衣錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1018949

24.12B Stimulant Laxatives

24932 C /

THROUGH F.C. TABLETS "C.M."(SENNOSIDES) "中美"便通樂膜衣錠(番瀉葉甘)

Sennoside 20 mg (sennoside A & B 12 mg)

Dosage: 1常備品 24932

Adult
· Constipation: PO, 15-17 mg qhs; Max. 34-50 mg bid

Pediatric
· Constipation: PO
2-6 yrs: 4.3 mg qhs; Max. 8.6 mg bid
6-12 yrs: 8.5-15 mg qhs; Max. 17-25 mg bid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab:20mg(24932)

ADR:

Electrolyte abnormalities, abdominal pain, weakness, fatigue, thirst, vomiting, edema, bone pain

NOTE: 室溫儲存

藥名相似: Tab:20mg(24932)

外觀相似:

外觀描述: 土黃色圓扁錠

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1037697

24.12B Stimulant Laxatives

24937 UK / No report(毫

CONSLIFE SUGAR COATED TABLETS 秘福糖衣錠

Dioctyl sodium sulfosuccinate 20mg, Sennosides 10mg & Bisacodyl 2mg tab

Dosage: 1常備品 24937

Adult
· Constipation: PO, 2-3 tabs qhs

Pediatric
There is no information provided in manufacturer's labeling

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: CONSLIFE*(24937), Sennosides 20mg(24932), Bisacodyl 5mg(24930); Supp: Bisacodyl 10mg(29005)

ADR:

(1)Dioctyl sodium sulfosuccinate (Docusate sodium)
COMMON: Abnormal bitter taste in mouth, diarrhea, nausea, cramp
SERIOUS: Hepatotoxicity (rare)
(2)Sennosides
SERIOUS: Electrolytes abnormal, nephritis
(3)Bisacodyl
COMMON: Abdominal colic, abdominal discomfort, diarrhea
SERIOUS: Atony of colon

NOTE: 室溫儲存

· Docusate sodium is a synonym of dioctyl sodium sulfosuccinate.

藥名相似:

外觀相似:

外觀描述: 藍色圓形糖衣錠

24.12B Stimulant Laxatives

28579 ɔt be ruled out / Infant risk can

BOWKLEAN* powder 保可淨散劑

Sodium picosulfate 10mg, magnesium oxide 3.5g & citric acid 12g, 16.2g/pk

Dosage: 1常備品 28579

Adult
· Colonoscopy - Preparation of bowel for procedure
(1) Split-dose regimen (preferred method): PO, 1 pk during evening before colonoscopy (5 PM to 9 PM), followed by 1 pk the next morning ~5 hours before the colonoscopy; follow each dose with additional fluids
(2) Prior-day regimen (alternative method): PO, 1 pk during afternoon or early evening before

colonoscopy (4 PM to 6 PM) followed by 1 pk 6 hours later (10 PM to 12 AM); follow each dose with additional fluids

· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Mild to moderate impairment: Use with caution
Severe impairment (CrCl < 30 mL/min): Use is contraindicated

P: Pow: 16.2g/pk (28579)

ADR:

COMMON
Hypermagnesemia, hypokalemia, hyponatremia, nausea, vomiting, headache
Serious
Ischemic colitis, tonic-clonic seizure

NOTE: 室溫儲存25℃以下

1. Each packet must be dissolved in 150mL of cold water and administered at separate times according to the dosing regimen.
2. Split-dose dosing regimen: Following first dose, administer five 8-ounce (250mL) cups of clear liquid within 5 hrs. Following second dose, administer three 8-ounce (250mL) cups of clear liquid within 5 hrs and at least 2 hrs prior to the procedure.
3. Prior-day regimen: Following first dose, administer five 8-ounce (250mL) cups of clear liquid within 5 hrs and prior to the next dose. Following second dose, administer three 8-ounce (250mL) cups of clear liquid within 5 hrs and prior to bedtime.
4. Oral medications administered ≦ 1 hr prior to this medicine may not be absorbed.
5. Take chlorpromazine, digoxin, penicillamine, iron supplements, tetracycline or fluoroquinolone antibiotics at least 2 hrs before or 6 hrs after you take this medicine to avoid chelation with Mg.
6. Prior or concomitant use of antibiotics may diminish the therapeutic effect of sodium picosulfate as conversion of sodium picosulfate to its active metabolite BHPM is mediated by colonic bacteria.
7. 本品賦形劑不含阿斯巴甜。

藥名相似: GI Klean* Powder (28572)

外觀相似:

外觀描述: 16.2克粉末，鋁箔袋裝 ，白底藍字及綠色 "Bowklean"英文商品名

24.12B Stimulant Laxatives

28650 **ɔt be ruled out / Infant risk can**

OLEUM RICINI* "Y.Y." "應元"蓖麻子油

Castor oil 30mL/bot

Dosage: 1常備品 28650

Adult
· Bowel evacuation, constipation: PO, ac, 15-60 mL/day

Pediatric
· Bowel evacuation, constipation: PO, ac, <2 yrs: 1-2 mL/day, Max. 5 mL/day, 2 -12 yrs: 5-15 mL/day, >12 yrs: same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: 30mL/Bot (28650)

ADR:

COMMON
Abdominal pain, nausea, vomiting
SERIOUS
Electrolytes abnormal

NOTE: 室溫儲存25℃以下

·Do not administer at bedtime because of rapid onset of action.
·Should be administered on an empty stomach with juice or carbonated beverages.
·Use for more than 1 week requires medical supervision.
·Contraindications: intestinal obstruction, symptoms of appendicitis, peritonitis
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 30mL微黃油狀液體，白色塑膠瓶裝

24.12B Stimulant Laxatives

29005 **B / Caution**

BISACODYL SUPPOSITORIES "YUNG SHIN" 無秘栓劑

Bisacodyl 10 mg supp

Dosage: 1常備品 29005

Adult
· Constipation: PR, 10 mg once daily
· Bowel preparation for surgery or diagnostic tests: PR,10 mg, 1-2 hr before special procedure

Pediatric
· Constipation (6-11 yrs): PR, 5 mg once daily

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 5mg (enteric sugar coated) (24930); Supp: 10mg (29005)

ADR:

NOTE: 室溫儲存

·《Contraindications》appendicitis; intestinal obstruction; gastroenteritis ;

藥名相似: Tab: 5mg (enteric sugar coated) (24930); Sup

外觀相似:

外觀描述: 子彈型黃色臘質栓劑，外有白色塑膠膜、印有中英文藥品名稱

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1009250

24.12C Bulk Laxatives

24933 B /

KONSYL --

Psyllium hydrophillic mucilloid 6 g/PK

Dosage: 1常備品 24933

Adult
· Constipation: PO, 0.5-1 pack qd-tid

Pediatric (≧6 yrs)
· Constipation: PO, half adult dose

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Pow: 6g/PK (24933)

ADR:

Allergic reactions, esophageal blockage, intestinal impaction

NOTE: 室溫儲存

1. For constipation : each dose should be administered with at least 250 mL of liquid
2. For watery diarrhea : each dose should be administered with 80 mL of liquid
3. Each pack supply 3 cals of energy
4. 本品賦形劑不含阿斯巴甜

藥名相似: Pow: 6g/PK (24933)

外觀相似:

外觀描述: 粉末，白色紙包，暗紅色"康賜爾散劑"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1009250

24.12C Bulk Laxatives

24935 ɔt be ruled out / Infant risk can

NORMACOL PLUS GRANULES 樂瑪可顆粒

Sterculia BP(梧桐) 62%, Frangula BPC (歐鼠李)8%, 7g/sachet Granule

Dosage: 1常備品 24935

Adult
· Constipation: 1-2 PK qd-bid

Pediatric
· Constipation
6 - 12 yrs: 0.5-1 PK qd-bid
> 12 yrs: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Granule: 7g/sachet (24935)

ADR:

Allergic reactions, esophageal blockage or intestinal impaction

NOTE: 室溫儲存

1. Place dry granules in your mouth, in samll quantities if necessary.
2. Swallow granules immediately with plenty of water or cool drink without chewing.
3. Do not take if pregnant or breast-feeding.
4. 本品賦形劑不含阿斯巴甜。

藥名相似: Granule: 7g/sachet (24935)

外觀相似:

外觀描述: 白色紙包裝上有"Normacol Plus"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2017218

24.12D Lubricant Laxative

28653 C / Unknown(有

"RS" U.S.P. Liquor Paraffin 白蠟油

Liquid paraffin

Dosage: 1常備品 28653

Adult
· Constipation: PO, 15-45 mL qhs; Max. 45 mL

Pediatric
· Constipation: PO
< 6yrs: Not recommended
6-12 yrs: 5-15 mL qhs
≧12 yrs: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Soln: prescribed as mL

ADR:

COMMON
anal incontinence, anal skin irritation, laxative abuse (chronic use), malabsorption of fat-soluble vitamins, pruritus ani, rectal oil leakage
SERIOUS
pneumonia due to aspiration of mineral oil, rectal

bleeding

NOTE: 室溫儲存

· It is a colorless transparent oily and tastless liquid
· Oral mineral oil is not recommended for children up to 6 years of age since patients in this age group are more prone to aspiration of oil droplets, which may produce lipid pneumonia

藥名相似:

外觀相似:

外觀描述: 透明液體，白色半透明塑膠瓶

24.12E Hyperosmolar Laxative

28572 C / Unknown(有

GI Klean Powder 腸見淨 粉劑

Polyethylene glycol 3350 & Electrolytes, 68.6g/PK

Dosage: 1常備品 28572

Adult
· Bowel cleansing: PO, 2-4 sachet or until the rectal effluent is clear

Pediatric
·

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Pow: 68.6g/PK (28572)

ADR:

Nausea, abdominal fullness, bloating

NOTE: 室溫保存

1. One sachet to be dissolved in 1 L of water. Drink 250mL every 10-15 min until all the solution has been consumed.
2. The reconstituted solution should be refrigerated and used within 24 hrs.
3. Each sachet contains : polyethylene glycol (3350) 59g, sodium sulphate anhydrous 5.685g, sodium bicarbonate 1.685g, sodium chloride 1.465g, potassium chloride 0.7425g, aspartame 0.0494g
4. 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 白色紙袋裝，印有藍底白色"GI Klean"字樣

24.12E Hyperosmolar Laxative

28575 UK /

FORLAX 10G 腹樂疏口服懸液用粉劑

Polyethylene glycol (macrogol) 4000, 10g/pk

Dosage: 1常備品 28575

Adult
· Constipation: PO, 1-2 sachet per day

Pediatric (≧ 8 yrs)
· Constipation: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Pow: Fortrans* 64g/sachet(28578), Forlax* 10g/pk(28575)

ADR:

Abdominal pain

NOTE: 室溫儲存

1. Each sachet must be dissolved in a glass of water for oral consumption
2. Take at least 2 hours apart from other products
3. The effect becomes apparent within 24-48 hrs after administration
4. Treatment should not exceed 3 months in children
5. 本品賦形劑不含阿斯巴甜。

藥名相似: Pow: Fortrans* 64g/sachet(28578), Forlax* 10

外觀相似:

外觀描述: 10公克粉劑,白色紙小袋,白底深灰字,有桃紅色漸層區塊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023462

24.12F Miscellaneous

28561 B /

LACTUL SYRUP 666MG/ML (LACTULOSE) "SINPHAR" "杏輝"樂多糖漿666毫克/毫升（拉特樂斯）

Lactulose 666mg/mL, 60mL/bot

Dosage: 1常備品 28561

Adult
· Constipation: PO, initial 15-30mL/day; may be increased to 60mL/day if necessary
· Portal-systemic encephalopathy: PO, initial 30-45mL tid-qid, then adjusted every 1-2 days to achieve 2-3 soft stools/day
· Portal-systemic encephalopathy: Rectal, 300mL diluted with 700mL of water or NS rectally as a retention enema (retain for 30 to 60min) q4-6h as needed

Pediatric
· Constipation: PO, 1-3mL/kg/day in divided doses, Max. 60mL/day
· Portal-systemic encephalopathy: PO, Infants: 2.5-10mL/day tid-qid

Children: 40-90mL/day tid-qid
(adjusted to achieve 2-3 soft stools/day)

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Syr: 60mL/Bot(28561); 500mL/bot(28571)

ADR:

COMMON
Bloating symptom, diarrhea, epigastric pain, flatulence, nausea, vomiting, cramp
SERIOUS
Hypernatremia, hypokalemia

NOTE: 室溫儲存

·《Contraindications》Low-galactose diet requirement; contains galactose ;
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 60mL黃色澄清液體，塑膠瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1039701

24.12F Miscellaneous

28563 **B / Caution**

DUPHALAC* Oral solution 亞培杜化液

Lactulose syr 667mg/mL, 300mL/bot

Dosage: 1常備品 28563

Adult
· Constipation: PO, initial 15-30mL/day; may be increased to 60mL/day if necessary
· Portal-systemic encephalopathy: PO, initial 30-45mL tid-qid, then adjusted every 1-2 days to achieve 2-3 soft stools/day
· Acute portal-systemic encephalopathy: PO, 30-45mL every hour until laxative effect is achieved
· Acute portal-systemic encephalopathy: Rectal, 300mL diluted with 700mL of water or NS rectally as a retention enema (retain for 30 to 60min) q4-6h as needed

Pediatric
· Constipation: PO, 1-3mL/kg/day in divided doses, Max. 60mL/day
· Portal-systemic encephalopathy: PO,
Infants: 2.5-10mL/day tid-qid
Children: 40-90mL/day tid-qid
(adjusted to achieve 2-3 soft stools/day)

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Syr: 60mL/Bot(28561), 300mL/bot(28563)

ADR:

COMMON
Bloating symptom, diarrhea, epigastric pain, flatulence, nausea, vomiting, cramp
SERIOUS
Hypernatremia, hypokalemia

NOTE: 室溫儲存

·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 300mL黃色澄清液體，白色塑膠瓶，白底綠字標籤，有綠/黃色圖形

24.14 Cholelitholytic Agents

25014 **B /**

URSOLIC* TABLETS 100MG (URSODEOXYCHOLIC ACID) "政德" 膽速力錠１００毫克（吾膽利喜）

Ursodeoxycholic acid 100mg tab

Dosage: 1常備品 25014

Adult
· Gallstone disease, treatment: PO, 8-10 mg/kg/day div into 2-3 doses
· Gallstone disease, prophylaxis: PO, 300 mg bid
· Primary biliary cirrhosis: PO, 13-15 mg/kg/day in four divided doses

Pediatric
· Cholestatic liver disease: PO, 10-18 mg/kg/day
· Extrahepatic biliary atresia: PO, 10-18 mg/kg/day

Dosing adjustments in hepatic impairment:

Dose reductions should be considered in acute severe hepatic insufficiency.

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 100mg (25014)

ADR:

COMMON
back pain, diarrhea, nausea, vomiting

NOTE: 室溫儲存

Contraindications: calcified cholesterol stones, radiopaque stones, radiolucent bile pigment stones, compelling reason for cholecystectomy

藥名相似:

外觀相似: Mephenoxalone* 200mg (22136)

外觀描述: 白色圓形錠，一面有"GP"字樣，另一面中間有刻痕及"249"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=137720

24.16 Digestants

24005 C /

PROTASE ENTERIC COATED CAPSULES 優妙化腸溶微粒膠囊

Pancrelipase 280mg (Lipase 20,000U, Protease 75,000U, Amylase 66,400U) cap

Dosage: 1常備品 24005

Adult
·Pancreatic exocrine insufficiency: PO, 1 cap tid with meal
·Cystic fibrosis: PO, 1,500-3,000 lipase units/kg tid with meal; Max. 6,000 lipase units/kg/meal

Pediatric
·Pancreatic exocrine insufficiency: PO,
< 6 yrs: Based on clinical experience
≥6 yrs: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: Protease*(24005)

ADR:

Nausea, vomiting, bloating, cramping, constipation, diarrhea, allergic reactions, hyperuricemia(high doses), hyperuricosuria(high doses)

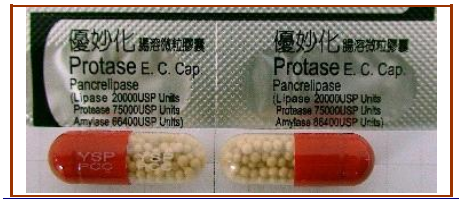
NOTE: 室溫儲存

·Do not crush or chew
·It may be opened and added to a small amount of soft food with a pH less than 5.5. The soft food should be swallowed immediately without chewing and followed with a glass of water or juice

藥名相似:

外觀相似:

外觀描述: 紅褐色/透明膠囊,有YSP及PCC字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046067

24.16 Digestants

24836 /

INFLORAN CAPSULES 益腹寧膠囊

Lactobacillus acidophilus 24mg(>1000 million CFU) & Bifidobacterium bifidum 24mg(>1000 million CFU), 250mg cap

Dosage: 1常備品 24836

Adult
· Acute enterocolitis/diarrhea: 1 cap tid-qid or prn

Pediatric
· Acute enterocolitis/diarrhea:
3-5 yrs: 1/4 of adult dose
6-11 yrs: 1/2 of adult dose
≥12 yrs: same as adult dose

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: 250 mg (24836)

ADR:

Flatulence

NOTE: 冰箱保存

· The capsule can be opened and shake out the powder into milk.
· 含有兩種活性冷凍乾燥整腸活菌成份，每粒250 毫克膠囊含凍晶活性成分
Bifidobacterium bifidum (150Xl0? cfu/g) ---24 毫克 (最少10億個以上cfu)
Lactobacillus acidophilus (150Xl09 cfu/g)--24 毫克 (最少10億個以上cfu)
· 需冷藏於2-8度，以保持一定活性。在室溫25度下可維持至少一個月活性。

藥名相似:

外觀相似:

外觀描述: 紅色/黃色膠囊,有Infloran字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024257

24.16 Digestants

24966 /

STAZYME F.C. TABLETS "STANDARD" "生達" 速泰消膜衣錠

Biodiastase2000 20mg, Cellulase AP3 10mg, Lipase AP6 15mg & Prozyme6 5mg

Dosage: 1常備品 24966

Adult
·Digestive disorders: PO, 1-2 tab tid-qid

Pediatric
·Digestive disorders: PO, ≥12yrs: same as adult ; 6-12yrs: 1tab tid-qid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

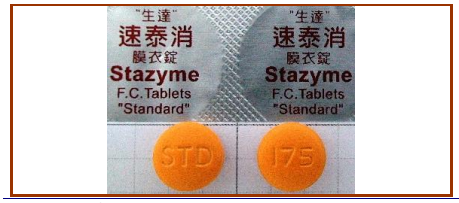
NOTE: 室溫儲存

Each Tab contains: biodiastase2000 8000U(20mg), cellulase AP3 300U(10mg), lipase AP6 900U(15mg), prozyme6 300U(5mg)

藥名相似:

外觀相似:

外觀描述: 橘色圓扁錠,有175及STD字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1019353

24.18 Lipotropic Agents

23670 /

Silymarin Capsules 150mg "TBC" 賜康保肝膠囊150毫克

Silymarin 150mg cap

Dosage: 1常備品 23670

Adult

· Hepatic disorders: PO, 150 mg bid-tid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: 150mg(23670)

ADR:

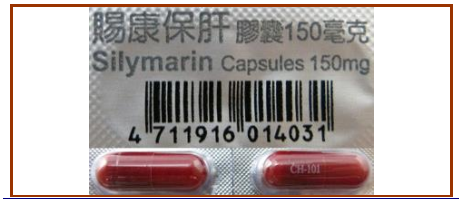
Nausea, vomiting, abdominal pain, diarrhea, sweating, weakness

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 紅褐色膠囊，有CH-101字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1047901

24.20 Anti-inflammatory Agents

21204 B / Caution

PENTASA PROLONGED-RELEASE TABLETS 500MG 頗得斯安持續性藥效錠５００公絲

Mesalazine (Mesalamine, 5-aminosalicylic acid) 500mg SR tab

Dosage: 1常備品 21204

Adult

· Treatment of active ulcerative colitis: PO, 4g/day in divided doses

· Maintenance of remission of ulcerative colitis: PO, 2g/day in divided doses

Pediatric(>2 yrs)

· Treatment of active ulcerative colitis, maintenance of remission of ulcerative colitis: PO, 20-30mg/kg/day in divided doses

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Not recommended

P: Tab: 500mg(21204); Supp: 1g(29557); Enema: 2g/100mL(29046)

ADR:

COMMON
Diarrhea, flatulence, nausea, upper abdominal pain, headache, nasopharyngitis
SERIOUS
Pericarditis, pancreatitis, rectal hemorrhage, agranulocytosis, aplastic anemia, leukopenia, neutropenia, pancytopenia, thrombocytopenia, cholestatic hepatitis, hepatotoxicity, liver failure, hypersensitivity reaction, renal impairment, drug intolerance syndrome

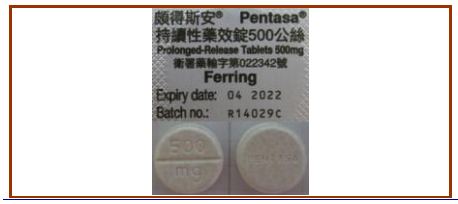
NOTE: 室溫儲存

· Do not crush or chew. It can be halved or suspended in water or juice immediately before use

藥名相似:

外觀相似:

外觀描述: 灰白色圓扁錠，一面有刻痕及500mg字樣，一面有PENTASA字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022342

24.20 Anti-inflammatory Agents

21205 ɔt be ruled out / Infant risk can

Mezavant XL, 1200mg gastro-resistant, prolonged release tablets "安適凡特"長效腸溶膜衣錠1200毫克

急用Mesalazine (Mesalamine, 5-aminosalicylic acid) 1200mg GR PR tab

Dosage: 2急用藥 21205

Adult

· Treatment of active ulcerative colitis: PO, 2.4-4.8g qd with a meal

· Maintenance of remission of ulcerative colitis: PO, 2.4g qd with a meal

Pediatric(>18 yrs)

· Safety and efficacy have not been established in patients less than 18 years old

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Not recommended

P: Tab: 1200mg(21205); 500mg(21204); Supp: 1g(29557); Enema: 2g/100mL(29046)

ADR:

COMMON
Rash, abdominal pain, burping, diarrhea, nausea, vomiting, arthralgia, asthenia, headache, nasopharyngitis, rhinitis, pain

SERIOUS
Myocarditis, pericarditis, exacerbation of ulcerative colitis, gastrointestinal hemorrhage, pancreatitis, rectal hemorrhage, agranulocytosis, aplastic anemia, leukopenia, neutropenia, pancytopenia, thrombocytopenia, cholestatic hepatitis, hepatotoxicity, liver failure, sclerosing cholangitis, hypersensitivity reaction, renal impairment, infectious disease, syndrome of intolerance to drug

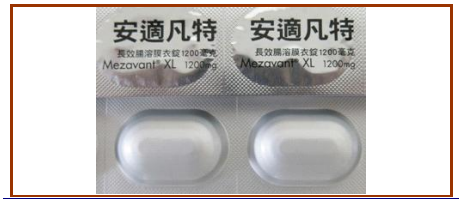
NOTE: 室溫儲存

· 《Contraindications》Hypersensitivity to mesalamine, other salicylates (including aspirin) or aminosalicylates, or to any product component ;
· 特別警告及使用前注意事項(仿單)：光敏感性-較嚴重的反應發生在既有皮膚疾病(如異位性皮膚炎)的病人中。
· 特定不良反應說明(仿單)：顱內壓上升-曾有使用後出現有視乳突水腫(papilledema；假性腦瘤或良性顱內高壓)的顱內壓上升的報告。若未發現可能導致視野缺損，且進展為永久性失明。出現此症狀時應停止使用。
· Do not crush or chew.
· Take it with meal.

藥名相似:

外觀相似:

外觀描述: 紅棕色橢圓形膜衣錠，一面有"S476"刻字



24.20 Anti-inflammatory Agents

21207 **B / Caution**

PENTASA Sachet, Prolonged Release Granules, 2g 頌得斯安 持續性藥效顆粒劑 2 g

Mesalazine (Mesalamine, 5-aminosalicylic acid) 2g prolonged release granules

Dosage: 1常備品 21207

Adult & Children> 40Kg
· Treatment of active ulcerative colitis: PO, 4g qd or in divided doses
· Maintenance of remission of ulcerative colitis: PO, 2g qd or in divided doses

Pediatric (≧ 6yr and < 40Kg)
· Treatment of active ulcerative colitis: PO, 30-50mg/kg/day in divided doses; Max: 75 mg/kg/day (not exceed 4 g/day)
· Maintenance of remission of ulcerative colitis: PO, initial 15-30 mg/kg/day in divided doses. Max: not exceed 2 g/day

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Not recommended

P:

ADR:

COMMON
Rash, abdominal pain, burping, diarrhea, nausea, vomiting, arthralgia, asthenia, headache, nasopharyngitis, rhinitis, pain
SERIOUS
Myocarditis, pericarditis, exacerbation of ulcerative colitis, gastrointestinal hemorrhage, pancreatitis, rectal hemorrhage, agranulocytosis, aplastic anemia, leukopenia, neutropenia, pancytopenia, thrombocytopenia, cholestatic hepatitis, hepatotoxicity, liver failure, sclerosing cholangitis, hypersensitivity reaction, renal impairment, drug intolerance syndrome, infectious disease

NOTE: 儲存30℃以下

· Do not crush or chew.
· 本品賦形劑不含阿斯巴甜。
· 仿單更新 (2017.10.03-廠商來文，文號：乙1060011913)
(1)有肺功能損傷的患者，尤其是氣喘患者，在治療期間須要非常小心的監測。
(2)接受azathioprine、6-mercaptopurine或thioquanine治療者，併用本藥可能增加血液疾病的危險性。加註建議在併用治療後持續追蹤治療反應14天，之後以4週作一個循環，追蹤2至3次。若一切正常，則改為每3個月追蹤一次。若出現其他症狀，則應立即採取進一步的臨床評估。
· 仿單更新 (2019.06.25-廠商來文，文號：乙1080009008)
(1)治療前及治療中應監測肝功能指數。
(2)治療前及治療中應定期監測腎功能，若腎功能異常，應懷疑是mesalazine引起之腎毒性。腎功能不全者不建議用藥。

藥名相似:

外觀相似:

外觀描述: 2g 銀色黑字鋁箔包裝

24.20 Anti-inflammatory Agents

29046 **B / Caution**

COLASA ENEMA 20MG/ML 阿腸克浣腸劑 2 0 毫克/毫升

Mesalamine (Mesalazine, 5-aminosalicylic acid) Enema 20mg/mL, 100mL/bot

Dosage: 1常備品 29046

Adult
· Ulcerative colitis, ulcerative proctitis, proctosigmoiditis: Retention enema, 4g (2 bot) hs and retained for 8 hrs for 3-6 wks

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 400mg(21203); Supp: 500mg(29556); Enema: 2g/100mL(29046)

ADR:

COMMON

Diarrhea, flatulence, nausea, upper abdominal pain, headache, nasopharyngitis
SERIOUS
Pericarditis, pancreatitis, rectal hemorrhage, agranulocytosis, aplastic anemia, leukopenia, neutropenia, pancytopenia, thrombocytopenia, hepatotoxicity, hypersensitivity reaction, renal impairment, drug intolerance syndrome

NOTE: 室溫儲存

· Warm it in warm water for about 10 min before use
· Shake bottle well
· May discolor urine brown-yellow
· Do not administer with lactulose or other medications that can lower intestinal pH

藥名相似: Tab: 400mg(21203); Supp: 500mg(29556); En

外觀相似:

外觀描述: 「白」塑膠灌注瓶，另接灌注頭以透明袋包裝，外有紙盒包裝，有白底藍/紅色字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045696

24.20 Anti-inflammatory Agents

29557 **B / Caution**

PENTASA SUPPOSITORIES 1G 頗得斯安栓劑

Mesalazine (Mesalamine, 5-aminosalicylic acid) 1g supp

Dosage: 1常備品 29557

Adult
· Ulcerative proctitis: Rectally, 1g qd~bid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Not recommended

P: Tab: 500mg(21204); Supp: 1g(29557); Enema: 2g/100mL(29046)

ADR:

COMMON
Diarrhea, flatulence, nausea, upper abdominal pain, headache, nasopharyngitis
SERIOUS
Pericarditis, pancreatitis, rectal hemorrhage, agranulocytosis, aplastic anemia, leukopenia, neutropenia, pancytopenia, thrombocytopenia, cholestatic hepatitis, hepatotoxicity, liver failure, hypersensitivity reaction, renal impairment, drug intolerance syndrome

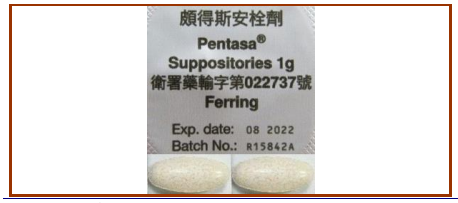
NOTE: 儲存30℃.以下

· Suppository should be retained for at least 1-3 hrs to achieve maximum benefit

藥名相似:

外觀相似:

外觀描述: 灰白色長橢圓錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022737

24.22 Monoclonal Antibodies

31139 **B / Infant risk can**

REMSIMA* 類希瑪

急用Infliximab inj 100mg pow in vial

Dosage: 2急用藥 31139

Adult: IV infusion over 2 hrs
· Moderately to severely active Crohn's disease: 5mg/kg at 0, 2 and 6 wks, followed by 5mg/kg every 8 wks. If no response after 2 doses, no additional treatment should be given.
· Fistulising Crohn's disease: 5mg/kg at 0, 2 and 6 wks, followed by 5mg/kg every 8 wks. If no response after 3 doses, no additional treatment should be given.
· Ulcerative colitis: 5mg/kg at 0, 2 and 6 wks, followed by 5mg/kg every 8 wks. If no response by week 14, continued therapy should be carefully reconsidered.

Pediatric (6~17 yrs): IV infusion over 2 hrs
· Crohn's disease: 5mg/kg at 0, 2 and 6 wks, followed by 5mg/kg every 8 wks. Further treatment is not recommended in those who do not respond within the first 10 wks.
· Ulcerative colitis: 5mg/kg at 0, 2 and 6 wks, followed by 5mg/kg every 8 wks. Further treatment is not recommended in those who do not respond within the first 8 wks.

Dosing adjustments in hepatic impairment:

NDA (Has not been studied)

Dosing adjustments in renal impairment:

NDA (Has not been studied)

P: P Inj: 100mg vial (31141 REMICADE*; 急用31139 REMSIMA*; 捐贈37724 REMSIMA*; 捐贈37713 REMICADE*)

ADR:

COMMON
Rash, abdominal pain, nausea, headache, cough, pharyngitis, sinusitis, upper respiratory infection, fatigue
SERIOUS
Acute coronary syndrome, bradyarrhythmia, cardiac dysrhythmia, heart failure, hypertension, hypotension, myocardial infarction, myocardial ischemia, systemic vasculitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bowel obstruction, hemolytic anemia, leukopenia, neutropenia, pancytopenia, thrombocytopenia, autoimmune hepatitis, acute hepatic failure, hepatitis, hepatotoxicity, allergic reaction, anaphylaxis, hepatosplenic T-cell

lymphoma, hypersensitivity reaction, malignant lymphoma, sarcoidosis, cerebrovascular accident, demyelinating disease of central nervous system, unexplained visual loss, cervical cancer, pulmonary edema, tuberculosis, cancer, histoplasmosis, infectious disease, infusion reaction, mycosis

NOTE: 冰箱冷藏，不可冷凍。

1.It should not be administered in patients with moderate to severe heart failure (NYHA Class III/IV); use with caution in patients with mild heart failure (NYHA Class I, II); discontinue therapy if new or worsening symptoms of heart failure appear.
2.Premedication with antihistamines, acetaminophen, and/or corticosteroids may be considered to prevent infusion reaction.
3.Use in-line low protein binding filter (≦1.2 micron).

藥名相似:

外觀相似:

外觀描述: 『白』蓋透明玻璃小瓶

24.22 Monoclonal Antibodies

31141 **B / Infant risk can**

Remicade powder for concentrate for solution for infusion 類克凍晶注射劑

Infliximab inj 100mg pow in vial

Dosage: 1常備品 31141

Adult: IV infusion > 2 hrs
· Crohn's disease (moderate to severe or fistulizing): 5 mg/kg at 0, 2, and 6 wks, followed by 5 mg/kg every 8 wks; dose may be increased to 10 mg/kg in patients who respond but then lose their response. If no response by week 14, consider discontinuing therapy
· Ulcerative colitis: 5 mg/kg at 0, 2, and 6 wks, followed by 5 mg/kg every 8 wks
· Rheumatoid arthritis in combination with MTX: 3 mg/kg at 0, 2, and 6 wks, followed by 3 mg/kg every 8 wks; dose may be increased to 10 mg/kg or 3 mg/kg every 4 wks in patients with an incomplete response
· Ankylosing spondylitis: 5 mg/kg at 0, 2, and 6 wks, followed by 5 mg/kg every 6 wk

Pediatric (6~17 yrs): IV infusion > 2 hrs
· Crohn's disease or ulcerative colitis: 5 mg/kg at 0, 2, and 6 wks, followed by 5 mg/kg every 8 wks

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Inj: 100mg vial (31141 REMICADE*; 急用31139 REMSIMA*; 捐贈37724 REMSIMA*; 捐贈37713 REMICADE*)

ADR:

COMMON
Rash, abdominal pain, nausea, headache, cough, pharyngitis, sinusitis, upper respiratory infection, fatigue
SERIOUS
Acute coronary syndrome, bradyarrhythmia, cardiac dysrhythmia, heart failure, hypertension, hypotension, myocardial infarction, myocardial ischemia, systemic vasculitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bowel obstruction, hemolytic anemia, leukopenia, neutropenia, pancytopenia, thrombocytopenia, autoimmune hepatitis, acute hepatic failure, hepatitis, hepatotoxicity, allergic reaction, anaphylaxis, hepatosplenic T-cell lymphoma , hypersensitivity reaction, malignant lymphoma, sarcoidosis, cerebrovascular accident, demyelinating disease of central nervous system, unexplained visual loss, cervical cancer, pulmonary edema, tuberculosis, cancer, histoplasmosis, infectious disease, infusion reaction, mycosis

NOTE: 冰箱冷藏，不可冷凍

1.Do not initiate infliximab therapy in patients with active infections including clinically significant localized infections. Evaluate the benefit/risk ratio of infection prior to initiating infliximab therapy in patients with chronic or recurrent infection, TB exposure, history of opportunistic infection, endemic TB or mycosis area (travel or residence), underlying conditions with a predisposition to infection
2.Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor (TNF) blockers, including infliximab.
3.Do not administer doses greater than 5 mg/kg in patient with moderate to severe heart failure
4.Infuse over at least 2 hours using a filter set with an inline, low-protein-binding filter (pore size 1.2 microns or less)

藥名相似:

外觀相似:

外觀描述: 『白』蓋透明玻璃小瓶

24.22 Monoclonal Antibodies

37620 **B / Caution**

ENTYVIO* powder for concentrate for solution for infusion 安潰悠凍晶注射劑300毫克

急用Vedolizumab inj 300mg vial

Dosage: 2急用藥 37620

Adult
· Crohn's disease, ulcerative colitis: IV infusion over 30 mins, 300mg at 0, 2, and 6 wks and then every 8 wks. Discontinue use in patients without evidence of

therapeutic benefit by week 14

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA(Has not been studied)

Dosing adjustments in renal impairment:

NDA(Has not been studied)

P: Inj: 300mg vial(37620)

ADR:

COMMON
Nausea, arthralgia, headache, nasopharyngitis, upper respiratory infection, fatigue, fever
SERIOUS
Increased aminotransferase, hepatitis, serum bilirubin raised, anaphylaxis, hypersensitivity reaction, infusion reaction, progressive multifocal leukoencephalopathy, tuberculosis, cancer, infectious disease, sepsis

NOTE: 冰箱冷藏，不可冷凍

藥名相似:

外觀相似:

外觀描述: 『白』蓋透明玻璃小瓶

24.22 Monoclonal Antibodies

37713 **B / Infant risk can**

REMICADE* powder for concentrate for solution for infusion 類克凍晶注射劑

捐贈急用Infliximab 100mg vial

Dosage: 2急用藥 37713

Adult: IV infusion over 2 hrs
· Moderately to severely active Crohn's disease: 5mg/kg at 0, 2 and 6 wks, followed by 5mg/kg every 8 wks. If no response after 2 doses, no additional treatment should be given.
· Fistulising Crohn's disease: 5mg/kg at 0, 2 and 6 wks, followed by 5mg/kg every 8 wks. If no response after 3 doses, no additional treatment should be given.
· Ulcerative colitis: 5mg/kg at 0, 2 and 6 wks, followed by 5mg/kg every 8 wks. If no response by week 14, continued therapy should be carefully reconsidered.

Pediatric (6~17 yrs): IV infusion over 2 hrs
· Crohn's disease: 5mg/kg at 0, 2 and 6 wks, followed by 5mg/kg every 8 wks. Further treatment is not recommended in those who do not respond within the first 10 wks.
· Ulcerative colitis: 5mg/kg at 0, 2 and 6 wks, followed by 5mg/kg every 8 wks. Further treatment is not recommended in those who do not respond within the first 8 wks.

Dosing adjustments in hepatic impairment:

NDA (Has not been studied)

Dosing adjustments in renal impairment:

NDA (Has not been studied)

P: P Inj: 100mg vial (31141 REMICADE*; 急用31139 REMSIMA*; 捐贈37724 REMSIMA*; 捐贈37713 REMICADE*)

ADR:

COMMON
Rash, abdominal pain, nausea, headache, cough, pharyngitis, sinusitis, upper respiratory infection, fatigue
SERIOUS
Acute coronary syndrome, bradyarrhythmia, cardiac dysrhythmia, heart failure, hypertension, hypotension, myocardial infarction, myocardial ischemia, systemic vasculitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bowel obstruction, hemolytic anemia, leukopenia, neutropenia, pancytopenia, thrombocytopenia, autoimmune hepatitis, acute hepatic failure, hepatitis, hepatotoxicity, allergic reaction, anaphylaxis, hepatosplenic T-cell lymphoma, hypersensitivity reaction, malignant lymphoma, sarcoidosis, cerebrovascular accident, demyelinating disease of central nervous system, unexplained visual loss, cervical cancer, pulmonary edema, tuberculosis, cancer, histoplasmosis, infectious disease, infusion reaction, mycosis

NOTE: 冰箱冷藏，不可冷凍

1.It should not be administered in patients with moderate to severe heart failure (NYHA Class III/IV); use with caution in patients with mild heart failure (NYHA Class I, II); discontinue therapy if new or worsening symptoms of heart failure appear.
2.Premedication with antihistamines, acetaminophen, and/or corticosteroids may be considered to prevent infusion reaction.
3.Use in-line low protein binding filter (≦1.2 micron).

藥名相似:

外觀相似:

外觀描述: 『白』蓋透明玻璃小瓶

24.22 Monoclonal Antibodies

37724 **B / Infant risk can**

REMSIMA* 類希瑪

捐贈急用Infliximab 100mg inj

Dosage: 2急用藥 37724

Adult: IV infusion over 2 hrs
· Moderately to severely active Crohn's disease: 5mg/kg at 0, 2 and 6 wks, followed by 5mg/kg every 8 wks. If no response after 2 doses, no additional treatment should be given.
· Fistulising Crohn's disease: 5mg/kg at 0, 2 and 6

wks, followed by 5mg/kg every 8 wks. If no response after 3 doses, no additional treatment should be given.
· Ulcerative colitis: 5mg/kg at 0, 2 and 6 wks, followed by 5mg/kg every 8 wks. If no response by week 14, continued therapy should be carefully reconsidered.

Pediatric (6~17 yrs): IV infusion over 2 hrs
· Crohn's disease: 5mg/kg at 0, 2 and 6 wks, followed by 5mg/kg every 8 wks. Further treatment is not recommended in those who do not respond within the first 10 wks.
· Ulcerative colitis: 5mg/kg at 0, 2 and 6 wks, followed by 5mg/kg every 8 wks. Further treatment is not recommended in those who do not respond within the first 8 wks.

Dosing adjustments in hepatic impairment:

NDA (Has not been studied)

Dosing adjustments in renal impairment:

NDA (Has not been studied)

P: P Inj: 100mg vial (31141 REMICADE*; 急用31139 REMSIMA*; 捐贈37724 REMSIMA*; 捐贈37713 REMICADE*)

ADR:

COMMON
Rash, abdominal pain, nausea, headache, cough, pharyngitis, sinusitis, upper respiratory infection, fatigue
SERIOUS
Acute coronary syndrome, bradyarrhythmia, cardiac dysrhythmia, heart failure, hypertension, hypotension, myocardial infarction, myocardial ischemia, systemic vasculitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bowel obstruction, hemolytic anemia, leukopenia, neutropenia, pancytopenia, thrombocytopenia, autoimmune hepatitis, acute hepatic failure, hepatitis, hepatotoxicity, allergic reaction, anaphylaxis, hepatosplenic T-cell lymphoma, hypersensitivity reaction, malignant lymphoma, sarcoidosis, cerebrovascular accident, demyelinating disease of central nervous system, unexplained visual loss, cervical cancer, pulmonary edema, tuberculosis, cancer, histoplasmosis, infectious disease, infusion reaction, mycosis

NOTE: 冰箱冷藏，不可冷凍。

1.It should not be administered in patients with moderate to severe heart failure (NYHA Class III/IV); use with caution in patients with mild heart failure (NYHA Class I, II); discontinue therapy if new or worsening symptoms of heart failure appear.
2.Premedication with antihistamines, acetaminophen, and/or corticosteroids may be considered to prevent infusion reaction.
3.Use in-line low protein binding filter (≤1.2 micron).

藥名相似:

外觀相似:

外觀描述: 『白』蓋透明玻璃小瓶

24.24 Miscellaneous

22434 **B /**

XENICAL CAPSULES 120MG 羅鮮子膠囊120毫克

Orlistat 120mg cap

Dosage: 1常備品 22434

Adult
· Obesity: 120 mg tid with meal (during or up to 1 hr after the meal). If a meal is missed or contains no fat, the dose may be omitted.

Pediatric
· Obesity: PO
12-16 yrs: same as adult
<12 yrs: safety and efficacy of orlistat has not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: 120mg (22434)

ADR:

Abdominal pain/discomfort, fatty/oily stools, fecal urgency, increased defecation

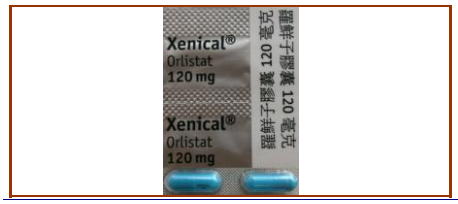
NOTE: 室溫儲存25℃以下

1. Patients using orlistat are advised to take a daily multivitamin that contains vitamins A, D, E, K and beta-carotene; the multivitamin should be taken at least 2 hrs before or after orlistat.
2. If a meal is missed or contains no fat, the dose may be omitted.

藥名相似:

外觀相似:

外觀描述: 藍色膠囊，有ROCHE及XENICAL 120



TFDA許可證
http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023051

24.24 Miscellaneous

31255 **UK / Caution**

STRONGER NEO MINOPHAGEN C INJECTION 新明發健注射液

Glycyrrhizin 2mg/mL, glycine 20mg/mL, cysteine 1mg/mL, 20mL/amp

Dosage: 1常備品 31255

Adult
· Hepatic disorders, drug or food allergies: IV, IV infusion, 5-20mL qd, may be increased to 40-60mL

qd; Max. 100mL/day
· Drug or food allergies: IV, IV infusion, 5-20mL qd

Pediatric

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 20mL Amp (31255)

ADR:

Pseudoaldosteronism (e.g. sodium retention, hypertension, hypokalemia, peripheral edema, weight gain), skin rash, shock

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 20mL透明注射液透明安瓿

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021173

26.02A Hematopoietic Agents

34840 C / Infant risk can

EPREX INJECTION 10000IU/ML “瑞士”宜保利血注射液１００００單位/毫升

Epoetin alfa (Erythropoietin) 4000 IU/0.4 mL syringe

Dosage: 1常備品 34840

· Anemia in myelodysplastic syndrome(Monotherapy in low-risk patients): SC, initial 450 IU/kg, Max 40,000 IU, QW; may increase by one step at a time(787.5 IU/kg/wk and 1050 IU/kg/wk), Max 1050 IU/kg/wk(80,000 IU/wk), at least 4 wks between dose increases, if patients without erythroid response and Hb levels < 11 g/dL(6.8 mmol/L) after 8 wks.
(1)Hb levels should be kept in the range of 10 g/dL to 12 g/dL (6.2 to 7.5 mmol/L) of target value.
(2) When Hb levels> 12 g/dL(7.5 mmol/L), the dose should be stopped or reduced.
(3) When reducing the dose, if Hb levels drops ?1g/dL, the dose should be increased.

Pediatric
Safety and efficacy in pediatric patients <1 mon have not been established.
·Anemia in chronic renal failure (1 mon-16 yrs): SC/IV, initial 50 IU/kg three times/wk for 8 wks
·Anemia in chemotherapy-treated patients (6 mon-18 yrs): SC/IV, 25-300 IU/kg 3-7 times/wk
·Anemia in zidovudine-treated patients (8 mon-17 yrs): SC/IV, 50-400 IU/kg 2-3 times/wk

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 2000 IU/0.5 mL syringe(34841); 4000 IU/0.4 mL syringe(34840); 10000 IU/1mL syringe(34844)

ADR:

COMMON
Injection site pain, Pruritus , Rash, Nausea, Vomiting, Arthralgia, Myalgia, Dizziness , Headache, Cough, Fever.
SERIOUS
Increased Cardiovascular event risk, Congestive heart failure, Hypertension, Acute Myocardial infarction, Erythema, Erythema multiforme, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Anemia, Severe, antibody-mediated, Deep venous thrombosis , Pure red cell aplasia, Antibody-mediated, Venous thromboembolism, Hypersensitivity reaction, Cerebrovascular accident, Hypertensive encephalopathy, Seizure, Pulmonary embolism, Tumor progression.

NOTE: 冰箱冷藏，不可冷凍。

· Contraindications:
hypersensitivity to human albumin, hypersensitivity to mammalian cell-derived products, uncontrolled hypertension
· 治療初期因高血壓的危險性會增加，慢性腎衰竭病人在從事需集中精神的活動如駕駛或操作機械時應謹慎，直至達到最佳維持劑量。

藥名相似:

外觀相似:

外觀描述: 0.4mL含藥透明溶液注射器上有一『紅』色線條，灰色蓋頭『白』色推進器

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000580

26.02A Hematopoietic Agents

34846 UK /

Recormon solution for injection in pre-filled syringe 2000IU 容可曼針筒裝注射劑 2000 國際單位"德國維特廠"

Epoetin beta 2000 IU/0.3mL syringe

Dosage: 1常備品 34846

Adult
·Anemia in chronic renal failure: SC, initial 60 IU/kg/wk, dose may be increased by 60 IU/kg every 4 weeks; the total weekly dose may be divided into daily doses or three times a week; IV, initial 40 IU/kg 3 times/wk, dose may be increased to 80 IU/kg 3 times/wk after 4 weeks and by further increments of 20 IU/kg 3 times/wk at monthly intervals, if necessary. Max. 720 IU/kg/week
·Anemia in chemotherapy-treated patients: SC, initial 450 IU/kg/wk. The weekly dose can be divided into 3-7 doses. Dose may be doubled after 4 weeks, if necessary. Therapy should be continued for up to 3-4 weeks after the end of therapy. Max. 900 IU/kg/wk

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 2000 IU/0.3mL syringe(34846); 4000 IU/0.4mL syringe(34840); 10000 IU/1mL syringe(34844); 30000 IU/0.6mL syringe(34845)

ADR:

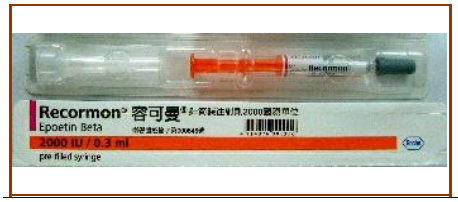
Hypertension, shunt thrombosis, headache, rash, pruritus, urticaria, injection site reactions, flu-like symptoms

NOTE: 冰箱保存

藥名相似:

外觀相似:

外觀描述: 0.3mL含藥透明溶液注射器，灰色蓋頭，橘色推進器)(附針頭



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000876

26.02A Hematopoietic Agents

34850 **C / Caution**

NESP Injection Plastic Syringe 20 mcg/0.5 ml 耐血比注射劑20微克/0.5毫升鎖

Darbepoetin Alfa inj 20mcg/0.5mL syringe

Dosage: 1常備品 34850

Adult
·Anemia associated with chemotherapy: SC, 2.25mcg/kg once weekly; can increase up to 4.5mcg/kg once weekly
·Anemia associated with chronic renal failure(CRF): IV/SC, initial 0.45mcg/kg once weekly, titrate to maintain Hb between 10-12g/dL (not to exceed 12g/dL)
·Conversion from EPO to Darbepoetin Alfa: for patients with CRF

EPO Dose (units/wk)	Nesp Dose (mcg/wk)
< 2,500	6.25
2,500-4,999	12.5
5,000-10,999	25
11,000-17,999	40
18,000-33,999	60
34,000-89,999	100
≧90,000	200

In patients receiving EPO 2-3 times/wk, darbepoetin alfa is administered once weekly. In patients receiving EPO once weekly, darbepoetin alfa is administered once every 2 wks

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P:

ADR:

COMMON
Edema, hypertension, hypotension, peripheral edema, abdominal pain, diarrhea, nausea, vomiting, injection site thrombosis, arthralgia, myalgia, pain in limb, spasm, dizziness, headache, cough, dyspnea, upper respiratory infection, fatigue, fever, infectious disease
SERIOUS
Cardiac arrest, cardiac dysrhythmia, congestive heart failure, disorder of cardiovascular system, acute myocardial infarction, severe anemia, deep venous thrombosis, pure red cell aplasia, thrombosis, venous thromboembolism, immune hypersensitivity reaction, cerebrovascular accident, hypertensive encephalopathy, seizure, transient ischemic attack, pneumonia, pulmonary embolism, tumor progression

NOTE: 冰箱保存

Do not dilute Nesp

藥名相似:

外觀相似:

外觀描述: 0.5mL透明注射液『灰』蓋注射針筒，附一支注射用針

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=60000955

26.02A Hematopoietic Agents

37983 **ɔt be ruled out / Infant risk can**

Mircera solution for injection in pre-filled syringe 100 mcg/0.3ml 美血樂針筒裝注射劑 100 微公克/0.3毫升

急用Methoxy polyethylene glycol-EPOETIN beta inj 100 mcg/0.3ml pre-filled syringe

Dosage: 2急用藥 37983

Adult
·Anemia in chronic renal failure:
ESA-naive: IV(preferred) or SC, initial 0.6 mcg/kg qow. Maintenance: twice that of the qow dose q1m; titrate as needed to keep Hb between 10 and 12 g/dL.
ESA treatment:
Receiving epoetin alfa or beta dose < 4000 units/wk or darbepoetin alfa dose < 20 mcg/wk: IV or SC, 80 mcg q1m or 40 mcg qow.
Receiving epoetin alfa or beta dose 4000 to 8000 units/wk or darbepoetin alfa dose 20 to 40 mcg/wk: IV or SC, 120 mcg q1m or 60 mcg qow.
Receiving epoetin alfa or beta dose 8000 to 16,000 units/wk or darbepoetin alfa dose 40 to 80 mcg/wk: IV or SC, 200 mcg q1m or 100 mcg qow.
Receiving epoetin alfa or beta dose > 16,000 units/wk or darbepoetin alfa dose > 80 mcg/wk: IV or SC, 360 mcg q1m or 180 mcg qow.
·Anemia of chronic renal failure

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Inj: 100mcg/0.3mL syringe(急用37983)

ADR:

COMMON
Hypertension, iron deficiency, headache
SERIOUS
Hypertensive crisis, thromboembolic disorder, pure red cell aplasia, anaphylactoid reaction, tumor progression (potential risk)

NOTE: 冰箱冷藏2-8℃，不可冷凍

1.每支預先充填好的注射劑不應在任何情況使用一次以上；該藥品僅供單次使用。
2.含苯甲醇做為防腐劑，不可用於嬰兒或3歲以下幼童。

藥名相似:

外觀相似:

外觀描述: 0.3mL含藥透明溶液注射器，灰色蓋頭藍綠色推進器，白底黑字標籤

26.02B Iron Preparations

25211 C / Caution

FOLIROMIN FILM-COATED TABLETS 50MG 服樂明膜衣錠 5 0 公絲

Sodium ferrous citrate (Fe 2+) 470.9mg FC tab

Dosage: 1常備品 25211

Adult
·Iron deficiency anemia: PO, based on elemental iron, 100-200mg/day in div.1-2 doses

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
No dosage adjustment needed.

P: Tab: 50mg Fe2+(25211); Soln: 50mg/mL Fe3+(28671); Inj: 100mg/5ml Fe3+(34835))

ADR:

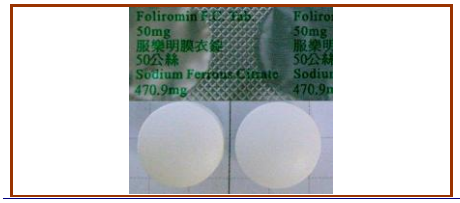
NOTE: 室溫儲存

As eq.to elemental iron 50mg

藥名相似: Tab: 50mg Fe2+(25211); Soln: 50mg/mL Fe3

外觀相似:

外觀描述: 白色圓扁錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022097

26.02B Iron Preparations

28671 ɔt be ruled out / Infant risk can

FERRUM HAUSMANN DROPS 富鐵好滴劑

Iron(lll)-hydroxide polymaltose complex 50 mg/1 mL 30 mL/bot

Dosage: 1常備品 28671

Adult
·Iron deficiency anemia: PO, 20 drops 2-3 times/day

Pediatric
·Iron deficiency anemia: PO
Children: 20 drops 1-2 times/day
Infants: initial 6 drops/day; gradually increased to 20 drops/day

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
No dosage adjustment required

P: Tab: 50mg Fe2+(25211); Soln: 50mg/mL Fe3+(28671); Inj: 100mg/5ml Fe3+(34835)

ADR:
Nausea, constipation, dark-colored stool

NOTE: 室溫儲存

·《仿單禁忌》：已知對任何相關成分過敏或耐受不良者；鐵過度負荷(如血色素沉著病、血鐵質沉著)；鐵質利用失常(如鉛中毒性貧血、鐵質利用不良性貧血、地中海型貧血)；非鐵缺乏症引起的貧血(如溶血性貧血、維生素B12缺發引起的巨紅血球型貧血)
It may be mixed with fruit, vegetable juice or other liquids.
1 mL (20 drops) contains 50 mg iron as iron (III)-hydroxide polymaltose complex
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 30mL棕色玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022368

26.02B Iron Preparations

34835 B /

FE-BACK INJECTION 2% "N.K." "南光" 鐵補 注射液 2 %

Iron Sucrose Complex (=Fe3+ 100mg/5mL) vial

Dosage: 1常備品 34835

Adult
·Iron deficiency anemia: IV infusion, 2.5 mL on day 1, 5mL on day 2, 10 mL on day 3, then 10 ml biw or depending on the levels of hemoglobin. Max. 10mL/day.
·Hemodialysis - receiving erythropoietin: Slow IV into the dialysis line (over 5 min/100mg). 100mg per consecutive hemodialysis session (total cumulative dose of 1000 mg).
·Peritoneal dialysis - receiving erythropoietin: IV infusion, 300mg over 1.5 hrs every 14 days for 2 doses , followed by 400 mg over 2.5 hrs 14 days later (total cumulative dose of 1000 mg within a 28-day period)

Pediatric
< 5kg: Max.1.25mL/day
5-10kg: Max. 2.5mL/day

Dosing adjustments in hepatic impairment:
Severe liver function impairment : not recommended

Dosing adjustments in renal impairment:
Severe renal impairment : not recommended

P: Tab: 50mg Fe2+(25211); Soln: 50mg/mL Fe3+(28671); Inj: 100mg/5ml Fe3+(34835)

ADR:
COMMON
hypotension, diarrhea, nausea, vomiting, leg cramp, headache
SERIOUS
anaphylaxis, loss of consciousness, seizure, dyspnea, collapse, necrotizing enterocolitis (may be a complication of prematurity in very low birth weight infants)

NOTE: 室溫儲存

1.Iron sucrose is administered by slow IV injection (20mg/min to minimize the risk of hypotension) or IV infusion (100mg diluted in normal saline, max

100 mL) over at least 15 minutes
2.Do not administer concommitant oral iron preparations

藥名相似:

外觀相似:

外觀描述: 5mL深棕色注射液，『綠』蓋透明玻璃瓶，蓋上有FLIP及OFF字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045362

26.02C Liver and Stomach Preparations

25200 A / Infant risk is

FOLACIN F.C. TABLETS 5MG (FOLIC ACID) "JOHNSON" "強生"葉酸膜衣錠 5 毫克

Folic acid 5 mg tab

Dosage: 1常備品 25200

Adult
·Folic acid deficiency: PO, initial 1 mg/day; MD 0.5 mg/day

Pediatric
·Folic acid deficiency: PO
Infants: initial 15 mcg/kg/dose daily or 50 mcg/day
Children: initial 1 mg/day; MD 0.1-0.4 mg/day
Children >11 yrs: same as adults

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 5mg (25200)

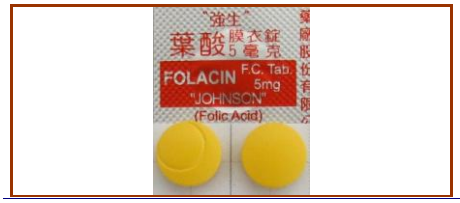
ADR:

NOTE: 室溫儲存

藥名相似: Tab: 5mg (25200)

外觀相似:

外觀描述: 黃色圓扁錠，一面有弦月刻痕)【自107.06.04變更廠牌



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1034670

26.02C Liver and Stomach Preparations

25205 C /

METHYCOBAL CAPSULES 500UG "EISAI" (MECOBALAMIN) "衛采"彌可保 R 膠囊 5 0 0 微公克 (甲鈷胺明)

Methylcobalamin (CH3-B12) 500 mcg cap

Dosage: 1常備品 25205

Adult
·Vitamin B12 deficiency: PO, 500 mcg tid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 500mcg/1mL amp (34834); Cap: 500 mcg (25205)

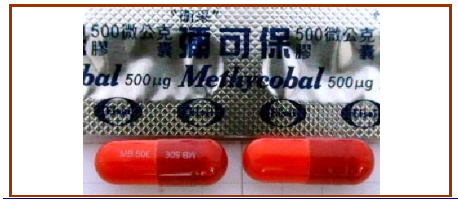
ADR:

NOTE: 室溫避光

藥名相似:

外觀相似: Cospanon* 40mg Cap(26405)

外觀描述: 深紅/紅色膠囊,有MB50ε字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1029630

26.02C Liver and Stomach Preparations

34834 C / Unknown(有

MECOBAL INJECTION 0.5 MG/ML "T.F" 血可補注射液0.5 毫克/毫升

Methylcobalamin inj(CH3-B12) 500 mcg/1 mL amp

Dosage: 1常備品 34834

Adult
·Vitamin B12 deficiency: IV/IM, 500 mcg 3 times weekly for 2 mon; MD 500 mcg every 1-3 mon

--

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 500mcg/1mL amp (34834); Cap: 500 mcg (25205)

ADR:

Hypokalemia, mild diarrhea, urticaria, skin rash, injection site pain

NOTE: 避光儲存

藥名相似:

外觀相似:

外觀描述: 1mL紅色透明液體『棕』色安瓿

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1032989

26.04A1 Coumarin and Indandione Derivatives

25231 X / Infant risk is

Cofarin tablets 5 mg "Gentle" "政德" 可化凝錠 5 毫克

■◆Warfarin Sod 5mg tab

Dosage: 1常備品 25231

Adult
·Prophylaxis of thrombosis: PO, initial 2-5 mg/day, MD 2-10 mg/day, with dosage adjustments base on the results of INR and/or PT ratio determinations.
·INR ranged based upon indications
atrial fibrillation: INR of 2-3
bioprosthetic heart valves: INR of 2-3
mechanical heart valves: INR of 2.5-3.5
post-myocardial infarction: INR of 3-4; INR of 2-3 if aspirin is used concomitantly
prophylaxis and treatment of venous thrombo-embolism (including pulmonary embolism): INR of 2-3

Pediatric
Base on the result of INR determinations.

Dosing adjustments in hepatic impairment:

Careful monitoring of the INR is required.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 5mg(25231), 1mg(25237, 急用藥)

ADR:

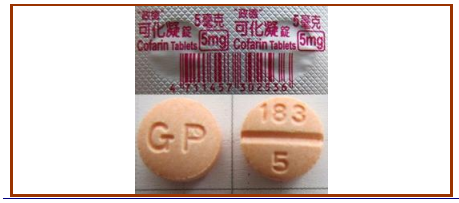
COMMON
Alopecia
SERIOUS
Cholesterol embolus syndrome, gangrenous disorder, tissue necrosis, hemorrhage, hypersensitivity reactions (infrequent), intraocular hemorrhage

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 橘色圓扁錠，中間有刻痕，一面印有GP，另一面印有183及5



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1055271

26.04A1 Coumarin and Indandione Derivatives

25237 **X / Infant risk is**

COFARIN TAB 1MG "GENTLE" "政德"可化凝錠 1 毫克

■◆Warfarin sodium 1mg tab

Dosage: 1常備品 25237

Adult
·Prophylaxis of thrombosis: PO, initial 2-5 mg/day, MD 2-10 mg/day, with dosage adjustments base on the results of INR and/or PT ratio determinations.
·INR ranged based upon indications
atrial fibrillation: INR of 2-3
bioprosthetic heart valves: INR of 2-3
mechanical heart valves: INR of 2.5-3.5
post-myocardial infarction: INR of 3-4; INR of 2-3 if aspirin is used concomitantly
prophylaxis and treatment of venous thrombo-embolism (including pulmonary embolism): INR of 2-3

Pediatric
Base on the result of INR determinations.

Dosing adjustments in hepatic impairment:

Careful monitoring of the INR is required.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 5mg(25231), 1mg(25237, 急用藥)

ADR:

COMMON
Alopecia
SERIOUS
Cholesterol embolus syndrome, gangrenous disorder, tissue necrosis, hemorrhage, hypersensitivity reactions (infrequent), intraocular hemorrhage

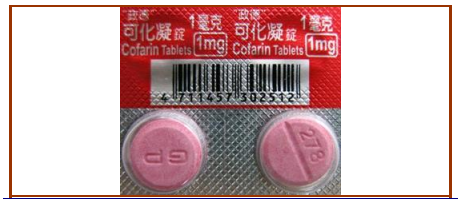
NOTE: 室溫儲存

·《Contraindications》Bacterial endocarditis; Blood dyscrasias; Cerebral aneurysms; CNS hemorrhage; Dissecting aorta; Eclampsia, preeclampsia, threatened abortion; Gastrointestinal, genitourinary, or respiratory tract ulcerations or overt bleeding; Hemorrhagic tendencies; Hypersensitivity to warfarin or any component of the product; Major regional or lumbar block anesthesia; Malignant hypertension; Pericarditis and pericardial effusion ; Pregnancy, except in pregnant women with mechanical heart valves, who are at high risk of thromboembolism; Recent or potential surgery of central nervous system or eye; Recent or potential traumatic surgery resulting in large open surface; Spinal puncture and other procedures with potential for uncontrollable bleeding; unsupervised and potentially noncompliant patients ;

藥名相似:

外觀相似:

外觀描述: 桃紅色圓扁錠,一面有"GP"，另一面中央有刻痕及"278"字樣



26.04A2 Heparins

34859 **C / Infant risk is**

Hepac Lock Flush 10 USP units/ml 海派封管沖洗液10 USP 單位/毫升

■Heparin sodium 30 unit/3mL syringe

Dosage: 1常備品 34859

Adult
·To prevent the formation of clots in the venous catheter: Inject a sufficient amount of heparin flush solution 10 or 100 units/mL to fill the entire device. Replace the heparin flush solution every time the device is used. Flush with saline before and after

medication administration if the medication is incompatible with heparin.

Pediatric
·In neonates, use only preservative-free heparin flush. To prevent the formation of clots in the venous catheter, inject sufficient amount of heparin flush solution 10 or 100 units/mL to fill the entire device. Replace the heparin flush solution every time the device is used. Flush with saline before and after medication administration if the medication is incompatible with heparin. Usually the heparin flush solution will maintain anticoagulation in the device for up to 4 hours

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Inj: 25000U/5mL(34860), 5000U/mL 以mL計價(34861). 30U/3mL(34859, Syringe). 1000U/10mL(34862, Syringe)

ADR:

COMMON
local irritation, erythema, mild pain, hematoma, ulceration (after deep subcutaneous injection)
SERIOUS
hemorrhage, thrombocytopenia (up to 30%), generalized allergic reactions, anaphylaxis, elevations in SGOT and SGPT, osteoporosis with long-term, high-dose administration

NOTE: 室溫儲存

·《Contraindications》Instances in which blood coagulation tests cannot be performed at necessary intervals (full-dose heparin only); Neonates or infants, do not administer product preserved with benzyl alcohol; Pregnant or nursing women, do not administer product preserved with benzyl alcohol; Severe thrombocytopenia; Uncontrolled active bleeding, except when due to DIC；
·仿單警語：新生兒或體重低於10公斤嬰兒有抗凝血的風險，因此，不可使用濃度100 USP單位/毫升的封管沖洗液。體重低於1公斤或接受頻繁沖洗靜脈導管的早產兒，在24小時內使用封管沖洗液可能達到肝素的治療劑量，因此，使用濃度10 USP單位/毫升的封管沖洗液時應謹慎。

藥名相似:

外觀相似:

外觀描述: 3mL預充式注射針筒，有『橘』色區塊，『透明』塑膠袋包裝，有黑色字樣

26.04A2 Heparins

34860 C / Infant risk is

HEPAC INJECTION 5000 UNITS/ML "N.K." "南光" 海派注射液5000單位/毫升

■Heparin sodium inj 25000 unit/5mL vial

Dosage: 1常備品 34860

Adult
·Thrombolytic-treated patients: Initial IV 5000-10000 units followed by IV infusion 20000-40000 units over 24 hrs, IV 5000-10000 units q4-6h, SC 8000-10000 units q8h or 15000-20000 units q12h.
·Prophylaxis of postoperative deep-vein thrombosis: SC, 5000 units 1-2 hours before surgery then q8-12h for 5-7 days.

Pediatric
·Thrombolytic-treated patients: Continuous IV infusion, initial 50 units/kg followed by 100 units/kg q4h or 20000 units/m2 q24h

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Inj: 25000U/5mL(34860), 5000U/mL 以mL計價(34861)

ADR:

COMMON
local irritation, erythema, mild pain, hematoma, ulceration (after deep subcutaneous injection)
SERIOUS
hemorrhage, thrombocytopenia (up to 30%), generalized allergic reactions, anaphylaxis, elevations in SGOT and SGPT, osteoporosis with long-term, high-dose administration

NOTE: 室溫儲存25℃以下

·《Contraindications》Instances in which blood coagulation tests cannot be performed at necessary intervals (full-dose heparin only); Neonates or infants, do not administer product preserved with benzyl alcohol; Pregnant or nursing women, do not administer product preserved with benzyl alcohol; Severe thrombocytopenia; Uncontrolled active bleeding, except when due to DIC；
·南光海派*仿單賦形劑：Methylparaben、Propylparaben、Benzyl alcohol、Water for injection。
·Protamine sulfate (IV) is the antidote.

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液，『黃』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044805

26.04A2 Heparins

34863 B / Infant risk can

CLEXANE INJECTION 克立生注射劑“麥森艾佛特”

■Enoxaparin 6000 anti-Xa int unit/0.6mL syringe

Dosage: 1常備品 34863

Adult
·Prevention of DVT in surgery: SC, 20 mg 1-2 hours prior to surgery, 20-40mg qd for 7-10 days
·Prevention of DVT in patients with restricted

mobility from acute illness: SC, 40mg qd for 6-11 days
·Prevention of ischemic complications of non-Q wave myocardial infarction or unstable angina in combination with aspirin: SC, 1mg/kg q12h for 2-8 days
·DVT with or without pulmonary embolism: SC, 1mg/kg q12h or 1.5 mg/kg q24h

Pediatric
Not FDA approved in children
·Prophylaxis, thromboembolic disorders: < 2 m/o 0.83-1.84 mg/kg SC q12h; 2 m/o-18 y/o, 0.62-1 mg/kg SC q12h
·Treatment, thromboembolic disorders: < 2 m/o, 1.76 mg/kg SC q12h; 2 m/o-18 y/o, 1.05 mg/kg SCq12h

Dosing adjustments in hepatic impairment:

Unknown

Dosing adjustments in renal impairment:

Clcr < 30 mL/min, consider reduced dosage, monitor anti-factor Xa

P: Inj: 2000 anti-Xa IU/0.2mL(34864), 6000 anti-Xa IU/0.6mL(34863)

ADR:

COMMON
erythema, hematoma, local irritation, pain, hypochromic anemia, fever, diarrhea, nausea, confusion, dyspnea, edema
SERIOUS
major hemorrhage (4% or less), spinal hematoma (rare), thrombocytopenia (<3%), atrial fibrillation, heart failure (<1%), pulmonary edema, pneumonia (<1%), anaphylactoid reaction (rare), LFT elevations (6%)

NOTE: 室溫儲存

60mg = 6000 anti-Xa IU

藥名相似:

外觀相似:

外觀描述: 0.6mL含藥透明溶液注射器，灰色蓋頭『橙』色推進器

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022354

26.04A2 Heparins

34864 **B / Infant risk can**

CLEXANE INJECTION 克立生注射劑

■Enoxaparin 2000 anti-Xa int unit/0.2mL syringe

Dosage: 1常備品 34864

Adult
·prior to surgery, 20-40mg qd for 7-10 days
·Prevention of DVT in patients with restricted mobility from acute illness: SC, 40mg qd for 6-11 days
·Prevention of ischemic complications of non-Q wave myocardial infarction or unstable angina in combination with aspirin: SC, 1mg/kg q12h for 2-8 days
·DVT with or without pulmonary embolism: SC, 1mg/kg q12h or 1.5 mg/kg q24h

Pediatirc
Not FDA approved in children
·Prophylaxis, thromboembolic disorders: < 2 m/o 0.83-1.84 mg/kg SC q12h; 2 m/o-18 y/o, 0.62-1 mg/kg SC q12h
·Treatment, thromboembolic disorders: < 2 m/o, 1.76 mg/kg SC q12h; 2 m/o-18 y/o, 1.05 mg/kg SCq12h

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr < 30 mL/min, consider reduced dosage, monitor anti-factor Xa

P: Inj: 2000 anti-Xa IU/0.2mL(34864), 6000 anti-Xa IU/0.6mL(34863)

ADR:

COMMON
erythema, hematoma, local irritation, pain, hypochromic anemia, fever, diarrhea, nausea, confusion, dyspnea, edema
SERIOUS
major hemorrhage (4% or less), spinal hematoma (rare), thrombocytopenia (<3%), atrial fibrillation, heart failure (<1%), pulmonary edema, pneumonia (<1%), anaphylactoid reaction (rare), LFT elevations (6%)

NOTE: 室溫儲存

20mg = 2000 anti-Xa IU

藥名相似:

外觀相似:

外觀描述: 0.2mL含藥透明溶液注射器，灰色蓋頭『白』色推進器

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022177

26.04A3 Direct Factor Xa Inhibitors

25240 **UK / Unsafe**

Xarelto film-coated tablets 10mg 拜利妥膜衣錠10毫克

■Rivaroxaban 10mg FC tab

Dosage: 1常備品 25240

Adult
·Prophylaxis of venous thromboembolism after hip or knee replacement surgery: PO, 10mg qd; initial dose should be given within 6-10 hrs after surgery and establishment of hemostasis

Pediatric
·Safety and efficacy have not been established in patients less than 18 years old.

Dosing adjustments in hepatic impairment:

hepatic impairment, moderate or severe (Child-

Pugh B or C) or any hepatic disease associated with coagulopathy: Avoid use

Dosing adjustments in renal impairment:

·renal impairment in nonvalvular atrial fibrillation,
CrCl > 50 mL/min: 20 mg qd with the evening meal
CrCl 15 to 50 mL/min: 15 mg qd with the evening meal
CrCl < 15 mL/min: Avoid use
·renal impairment in postoperative prophylaxis of DVT and treatment and prevention of recurrent DVT/pulmonary embolism,
CrCl <30 mL/min: Avoid use
·acute renal failure: Discontinuation recommended

P: Tab: 10mg(25240); 20mg(25244)

ADR:

Post-procedural hemorrhage, anemia, nausea, increased GGT, increase in transaminase, increased lipase/amylase/bilirubin/LDH/alkaline phosphatase, tachycardia, thrombocythemia, syncope, dizziness, headache, constipation, diarrhea, abdominal and gastrointestinal pain, dyspepsia, dry mouth, vomiting, renal impairment, pruritus, rash, urticardia, contusion, pain in extremity, wound secretion, hemorrhage, hypotension, localized edema, peripheral edema, feeling unwell, fever, jaundice

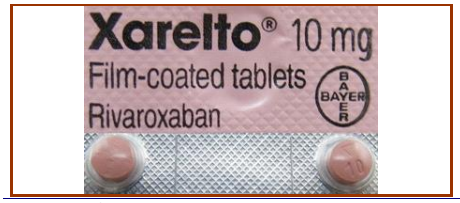
NOTE: 室溫儲存

·Duration of therapy: 5 weeks after hip surgery; 2 weeks after knee surgery.

藥名相似:

外觀相似:

外觀描述: 淺紅色圓扁錠，一面有商標字樣，一面有三角形刻痕與10字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022177

26.04A3 Direct Factor Xa Inhibitors

25245 **B / Caution**

Eliquis Film-Coated Tablet 5mg 艾必克凝膜衣錠5毫克

■Apixaban 5mg FC tab

Dosage: 1常備品 25245

Adult
·Atrial fibrillation, Nonvalvular - Cerebrovascular accident & embolism prophylaxis: PO, 5 mg bid. Elderly, 80 years or older: PO, 2.5 mg bid if Scr >= 1.5 mg/dL (133 mcmol/L) or BW <= 60 kg. Body weight 60 kg or less: PO, 2.5 mg bid if Scr >= 1.5 mg/dL (133 mcmol/L) or aged >= 80 years.CYP3A4 and P-gp efflux transport strong dual inhibitors(ketoconazole, itraconazole, ritonavir, clarithromycin): 2.5 mg bid; avoid use in patients already receiving apixaban 2.5 mg bid.
·Deep venous thrombosis, Pulmonary embolism: PO, 10 mg bid for the first 7 days of therapy; after 7 days, 5 mg bid.
·Deep venous thrombosis, Pulmonary embolism, Recurrence; Prophylaxis: PO, 2.5 mg bid following a minimum of 6 months of treatment for DVT or PE.

Pediatric
·Safety and efficacy not established

Dosing adjustments in hepatic impairment:

Hepatic impairment, mild (Child-Pugh class A): No dosage adjustment necessary
Hepatic impairment, severe (Child-Pugh class C): Not recommended

Dosing adjustments in renal impairment:

·renal impairment in nonvalvular atrial fibrillation
Dosage: 2.5 mg orally twice daily in patients with at least 2 of the following characteristics, age 80 years or older, body weight 60 kg or less, or serum creatinine 1.5 mg/dL (133 mcmol/L) or higher
·renal impairment in DVT prophylaxis following hip or knee replacement, treatment or secondary prophylaxis of DVT or pulmonary embolism (PE)
No dosage adjustment is necessary in renal impairment, including patients with ESRD on dialysis (MICROMEDEX)

P: Tab: 5mg(25245)

ADR:

COMMON
Contusion, Bleeding gums, Hematoma, Menorrhagia, Epistaxis, Hemoptysis
SERIOUS
Gastrointestinal hemorrhage, Hematochezia, Rectal hemorrhage, Hemorrhage, Hemorrhage, Hemorrhage, Major, Hemorrhage, Operative, Alkaline phosphatase raised, Liver function tests abnormal, Serum bilirubin raised, Hypersensitivity reaction, Hemorrhage of muscle, Extradural intracranial hematoma, Intracranial hemorrhage, Non-traumatic spinal subdural hematoma, Traumatic spinal subdural hematoma, Conjunctival hemorrhage, Retinal hemorrhage, Hematuria

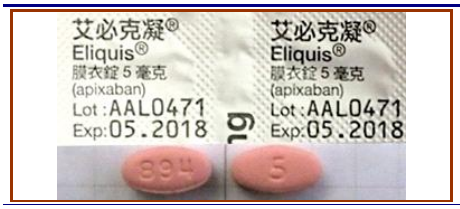
NOTE: 儲存30°C以下

1.無法吞服整顆錠劑，可將錠劑壓碎懸浮於水中(鼻胃管投予懸浮於60 mL水)立即服用。在水中可維持穩定最多4小時。
2.當施行椎管內麻醉(脊椎/硬膜外麻醉)或脊椎穿刺程序時，接受治療者有發生硬膜外或脊椎血腫的風險，血腫可能導致長期或永久性癱瘓，應考慮此風險。請告知需注意脊椎或硬脊膜外血腫的徵象與症狀(如腿部麻痺或無力、腸道或膀胱功能異常)。
3.目前並無特定的解毒劑，也無已確立的方法可以逆轉服用ELIQUIS患者的出血。ELIQUIS的藥效學作用在投予最後一劑之後，其作用預計會持續至少24小時，亦即大約兩個藥物半衰期。4.Clarithromycin雖然是P-gp及CYP3A4強效抑制劑，但藥物動力學資料學證實其併用時無須調整劑量。
4.Clarithromycin雖然是P-gp及CYP3A4強效抑制劑，但藥物動力學資料學證實其併用時無須調整劑量。

藥名相似:

外觀相似:

外觀描述: 粉紅色橢圓形雙凸膜衣錠，一面5字樣，一面有894字樣



26.04A3 Direct Factor Xa Inhibitors

25246 C / Caution

Xarelto Film-coated Tablets 15 mg 拜瑞妥膜衣錠15毫克

■Rivaroxaban 15mg FC tab

Dosage: 1常備品 25246

Adult
·Atrial fibrillation, Nonvalvular - Cerebrovascular accident; Prophylaxis - Embolism, Systemic; Prophylaxis: PO, 15mg qd with the evening meal.
·Deep venous thrombosis and Pulmonary embolism, Treatment or secondary prophylaxis following initial 6 months of treatment:
Treatment, PO, 15mg bid with food for 21 days then 20 mg qd with food.
Secondary prophylaxis, PO, 10mg qd or 20mg qd with or without food, after at least 6 months of standard anticoagulant therapy.
·Postoperative deep vein thrombosis; Prophylaxis - Arthroplasty of knee: PO, 10mg qd beginning at least 6 to 10 hours after surgery and continued for 12 days
·Postoperative deep vein thrombosis; Prophylaxis - Repair of hip: PO, 10mg qd beginning at least 6 to 10 hours after surgery and continued for 35 days

Pediatric
·Safety and effectiveness in pediatric patients have not been established

Dosing adjustments in hepatic impairment:

Significant hepatic impairment associated with coagulopathy(including Child-Pugh B & C): Use is contraindicated

Dosing adjustments in renal impairment:

Clcr >50 mL/min : 20 mg qd
Clcr 30 - 50 mL/min: 15 mg qd
Clcr <30mL/min: Use is contraindicated

P: Tab: 10mg(25240); 15mg(25246)

ADR:

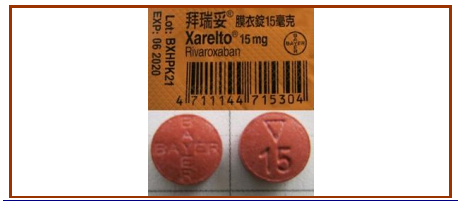
COMMON
Bleeding (hip/knee replacement, 5.8%; DVT/pulmonary embolism: 17.4% to 28.3%)
SERIOUS
Syncope , GI hemorrhage , Bleeding, Major (nonvalvular atrial fibrillation, 5.6%; hip/knee replacement, 0.3%; DVT/pulmonary embolism, 1%), Epidural hematoma, Hematoma, Spinal , Anaphylaxis, Immune hypersensitivity reaction, Drug withdrawal, Stroke and non-CNS embolism

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 紅色圓扁錠，一面有商標字樣，一面有三角形刻痕與15字樣



26.04A3 Direct Factor Xa Inhibitors

25247 ɔt be ruled out / Infant risk can

LIXIANA* F.C.Tablets 60mg 里先安膜衣錠60毫克

■▼Edoxaban 60mg FC tab

Dosage: 1常備品 25247

·Arthroplasty of knee, Total - Postoperative deep vein thrombosis; Prophylaxis: PO, 30 mg QD starting 6 to 24 hours after surgery and continuing for 11 to 14 days
·Atrial fibrillation, Nonvalvular - Cerebrovascular accident; Prophylaxis - Embolism; Prophylaxis: PO, 60 mg QD
·Deep venous thrombosis: PO, 60 mg QD beginning 5 to 10 days after initiating therapy with a parenteral anticoagulant
·Pulmonary embolism: PO, 60 mg QD beginning 5 to 10 days after initiating therapy with a parenteral anticoagulant

·Safety and efficacy not established

Dosing adjustments in hepatic impairment:

Hepatic impairment, moderate or severe (Child-Pugh B and C): Use not recommended
Hepatic impairment, mild (Child-Pugh A): No adjustment required

Dosing adjustments in renal impairment:

CrCl >= 95 mL/min in nonvalvular atrial fibrillation: Do not use; increased risk of ischemic stroke
Renal impairment (CrCl 15 - 50 mL/min): 30 mg QD
Renal impairment (CrCl <= 15 mL/min) or dialysis patients: Not recommended
Renal impairment (CrCl >15, <= 30 mL/min) in Japanese patients with nonvalvular atrial fibrillation: 15 mg QD

P: Tab: 60mg(25247)

ADR:

COMMON
Rash, Anemia, Nonmajor Clinically Relevant Hemorrhage, Liver function tests abnormal.
SERIOUS
Major Hemorrhage, Hemorrhagic cerebral infarction, Intracranial hemorrhage, Interstitial lung disease.

NOTE: 室溫儲存30℃以下

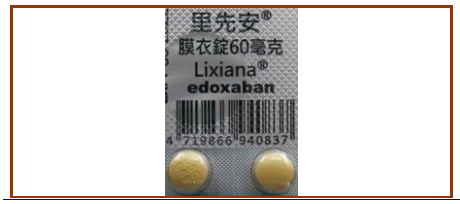
·先前無使用抗凝血劑者，應在進行心臟整流術(cardioversion)前至少2小時給予，以確保適當的抗凝血效果；並手術應在當天給藥後12小時內進行。
·併用其他影響止血之藥品，會提高出血風險，這些藥品包括：乙醯水楊酸(acetylsalicylic acid; ASA)、P2Y12血

小板抑制劑、其他抗血栓藥物、血栓溶解治療、選擇性血清素再回收抑制劑(selective serotonin reuptake inhibitors; SSRIs)或血清素 - 正腎上腺素再回收抑制劑(serotonin norepinephrine reuptake inhibitors; SNRIs)，以及長期使用的非類固醇消炎藥(nonsteroidal anti-inflammatory drugs; NSAID)。
·有抗磷脂質症候群(antiphospholipid syndrome，APLS)之血栓病史者，不建議使用Direct acting Oral Anticoagulants (DOACs)，可能增加復發性血栓事件的比例。
·本藥主要由上消化道吸收。因此，增加胃排空速率與腸道蠕動的藥品或疾病，可能會降低溶解與吸收。

藥名相似:

外觀相似:

外觀描述: 黃色圓形膜衣錠，刻有「DSC L60」字樣



26.04A3 Direct Factor Xa Inhibitors

25248 ɔt be ruled out / Infant risk can

Lixiana F.C.Tablets 30mg 里先安膜衣錠30毫克

■▼Edoxaban 30mg FC tab

Dosage: 1常備品 25248

ADULT
·Atrial fibrillation, nonvalvular - cerebrovascular accident; prophylaxis - embolism, systemic; prophylaxis: PO, 60mg QD
·Cancer - venous thromboembolism, following parenteral therapy: PO, 60mg QD after at least 5 days of parenteral anticoagulation
·Deep venous thrombosis and/or pulmonary embolism, following parenteral therapy: PO, 60mg QD beginning 5 to 10 days after initiating therapy with a parenteral anticoagulant

PEDIATRIC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

·Mild (Child-Pugh A): No dosage adjustment needed
·Moderate or severe (Child-Pugh B and C): Use not recommended

Dosing adjustments in renal impairment:

·CrCl > 95 mL/min in nonvalvular atrial fibrillation: Do not use; increased risk of ischemic stroke
·CrCl 15 - 50 mL/min: 30mg QD
·CrCl 15 - < 30 mL/min in Japanese patients with nonvalvular atrial fibrillation: 15 mg QD
·CrCl < 15 mL/min or dialysis patients: Not recommended

P: P Tab: 30mg(25248), 60mg(25247)

ADR:

COMMON
Rash, anemia, Nonmajor clinically relevant hemorrhage, liver function tests abnormal
SERIOUS
Major hemorrhage, hemorrhagic cerebral infarction, intracranial hemorrhage, interstitial lung disease

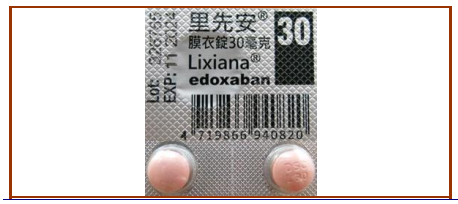
NOTE: 室溫儲存

·Switching from warfarin (or other vitamin K antagonist): Discontinue current anticoagulant and initiate edoxaban when INR is 2.5 or less.
·Switching from oral anticoagulants other than warfarin or from low-molecular-weight heparin: Discontinue current anticoagulant and initiate edoxaban at the time of the next scheduled dose of the discontinued medication.
·Switching from unfractionated heparin: Discontinue the infusion and initiate edoxaban 4 hours later.
·Switching to warfarin: Reduce dose by 50%, initiate warfarin, and continue edoxaban until stable INR of 2 or greater achieved; measure INR at least weekly and just prior to edoxaban dose. Alternatively, discontinue edoxaban and initiate parenteral anticoagulant and warfarin at the next scheduled edoxaban dose, then discontinue the parenteral anticoagulant and continue warfarin when INR is stable at 2 or greater
·Switching to anticoagulant other than warfarin: Discontinue edoxaban and administer the new oral or parenteral anticoagulant at the next scheduled edoxaban dose.
·Surgery or invasive procedure: Discontinue at least 24 hours prior and restart once adequate hemostasis established; expect 1 to 2 hours for pharmacodynamic effect; if oral therapy is restricted, parenteral anticoagulant may be used until edoxaban can be initiated

藥名相似:

外觀相似:

外觀描述: 粉紅色圓形膜衣錠，刻有「DSC L30」字樣



26.04A4 Direct Thrombin Inhibitors

25242 C / Caution

Pradaxa Capsules 110 mg 普栓達膠囊110毫克

■▼Dabigatran etexilate 110mg cap

Dosage: 1常備品 25242

Adult
·Prevention of stroke and systemic embolism with non-valvular AF: PO, 110-150 mg bid. For p't with a higher risk of bleeding: 110 mg bid may be considered.

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Severe impairment (Child-Pugh class C), or with increased liver enzymes ?2 times ULN: Not recommended.

Dosing adjustments in renal impairment:

CrCl < 30 mL/min or dialysis patients: Not recommended.

P: Cap: 110mg(25242)

ADR:

COMMON
Esophagitis, gastritis, gastroesophageal reflux disease, gastrointestinal hemorrhage, gastrointestinal ulcer, indigestion, bleeding
SERIOUS
Myocardial infarction, major gastrointestinal hemorrhage, major bleeding, thrombosis, anaphylaxis, epidural hematoma, intracranial hemorrhage, traumatic spinal subdural hematoma, alveolar bleeding

NOTE: 室溫儲存

·《Contraindications》Active pathological bleeding; Mechanical prosthetic heart valve; Serious hypersensitivity reaction (eg, anaphylactic reaction or anaphylactic shock) to dabigatran or any components of the product；
·併用P-醣蛋白抑制劑glecaprevir/ pibrentasvir會使此藥血漿濃度升高，可能增加出血風險。
·抗磷脂症候群者(尤其抗磷脂抗體三陽性者)發生血栓栓塞事件的風險增加。建議用藥前考量所有的治療選擇(包括諸如維他命K拮抗劑的標準療法)。
·Swallow whole. Chewing, breaking, or opening the cap may result in increased systemic exposure to the drug.

藥名相似:

外觀相似:

外觀描述: 藍色膠囊，印有R110及廠商商標

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025459

26.04A4 Direct Thrombin Inhibitors

25243 **ɔt be ruled out / Infant risk can**

PRADAXA* Capsules 150 mg 普栓達膠囊150毫克

■▼Dabigatran etexilate 150mg cap

Dosage: 1常備品 25243

Adult
·Postoperative deep vein thrombosis, Pulmonary embolism; Prophylaxis - Repair of hip: PO, 110mg 1-4hrs after surgery, then 220mg qd for 28-35 days.
·Postoperative deep vein thrombosis, Pulmonary embolism; Prophylaxis - Repair of knee: PO, 110mg 1-4hrs after surgery, then 220mg qd for 10 days.
·Atrial fibrillation - Thromboembolic disorder; Prophylaxis: PO, 150mg bid.
·Deep venous thrombosis and Pulmonary embolism, Following parenteral therapy: PO, 150mg bid.

Pediatric
· Safety and efficacy not established in pediatric patients

Dosing adjustments in hepatic impairment:

Severe impairment (Child-Pugh class C), or with increased liver enzymes ≧2X ULN: Not recommended.

Dosing adjustments in renal impairment:

CrCl < 30 mL/min or dialysis patients: Not recommended.

P: P Cap: 150mg(25243), 110mg(25242)

ADR:

COMMON
Esophagitis, gastritis, gastroesophageal reflux disease, gastrointestinal hemorrhage, gastrointestinal ulcer, indigestion, bleeding
SERIOUS
Myocardial infarction, major gastrointestinal hemorrhage, major bleeding, thrombosis, anaphylaxis, epidural hematoma, intracranial hemorrhage, traumatic spinal subdural hematoma, alveolar bleeding

NOTE: 室溫儲存

·《Contraindications》Active pathological bleeding; Mechanical prosthetic heart valve; Serious hypersensitivity reaction (eg, anaphylactic reaction or anaphylactic shock) to dabigatran or any components of the product；
·併用P-醣蛋白抑制劑glecaprevir/ pibrentasvir會使此藥血漿濃度升高，可能增加出血風險。
·抗磷脂症候群者(尤其抗磷脂抗體三陽性者)發生血栓栓塞事件的風險增加。建議用藥前考量所有的治療選擇(包括諸如維他命K拮抗劑的標準療法)。
·Swallow whole. Chewing, breaking, or opening the cap may result in increased systemic exposure to the drug.

藥名相似:

外觀相似:

外觀描述: 淺藍/乳白色膠囊，印有R150及廠商商標

26.04C Hemostatics

25261 **B / Infant risk can**

TRANSAMIN CAPSULES 斷血炎膠囊

Tranexamic acid 250mg cap

Dosage: 1常備品 25261

Adult
·Hemorrhage: PO, 750-2000mg/day div. 3-4 doses.

Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

SrCr 1.36-2.83 mg/dL: 15 mg/kg bid
SrCr 2.83-5.66 mg/dL: 15 mg/kg qd
SrCr > 5.66 mg/dL: 15 mg/kg qod or 7.5 mg/kg qd

P: Cap: 250mg(25261); Inj: 250mg/5mL amp(34908)

ADR:

COMMON
Abdominal pain, Diarrhea, Nausea, Anemia, Arthralgia, Backache, Cramp, Musculoskeletal pain,

Spasm, Headache, Migraine, Nasal sinus problem, Fatigue.
SERIOUS
Thromboembolic disorder, Anaphylactoid reaction, Anaphylaxis, Cerebral ischemia, Retinal artery occlusion, Retinal vascular occlusion, Visual disturbance, Pulmonary embolism.

NOTE: 室溫儲存

·《Contraindications》Women using hormonal contraception with oral administration; Hypersensitivity to tranexamic acid; or any of the ingredients; Active intravascular clotting with IV administration; Subarachnoid hemorrhage; cerebral edema or infarction may occur with IV administration; Active thromboembolic disease (eg, DVT, pulmonary embolism, or cerebral thrombosis) with oral administration; History of thrombosis or thromboembolism, including retinal vein or artery occlusion with oral administration; Intrinsic risk of thrombosis or thromboembolism (eg, thrombogenic valvular disease, thrombogenic cardiac rhythm disease, or hypercoagulopathy) with oral administration ;

藥名相似:

外觀相似:

外觀描述: 橘紅/淡黃色膠囊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12015392

26.04C Hemostatics

29481 UK / No report(毫

Tisseel Solution for sealant "百特"組織修復凝合劑(第二代)

Protein clottable (human)(fibrinogen 72-110mg) 91mg/mL, Aprotinin(bovine) 3000KIU/mL, Thrombin 500IU/mL, Calcium chloride 5.88mg/mL, 2mL/syringe

Dosage: 1常備品 29481

Adult
·Saeling of surface: 1pack of TISSEEL 2mL (i.e.1mL tisseel soln plus 1 mL thrombin soln) with be sufficient for thr area of at least 10 cm2.

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Soln: 2mL(29481), 4mL(29482)

ADR:

COMMON
nausea, intestinal obstruction, urticaria, flushing, delayed wound healing, edema, fever, seroma
SERIOUS
anaphylactic responses, bradycardia, tachycardia, drop in blood pressure, hematoma(NOS), dyspnoea

NOTE: 冷凍儲藏

For application on wound surfaces only. Not for IV application.

藥名相似:

外觀相似:

外觀描述: 2mL預裝針筒

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000925

26.04C Hemostatics

29482 UK / No report(毫

TISSEEL* soln for sealant 4mL 百特組織修復凝合劑(第二代)

Protein clottable (human)(fibrinogen 72-110mg) 91mg/mL, Aprotinin(bovine) 3000KIU/mL, Thrombin 500IU/mL, Calcium chloride 5.88mg/mL, 4mL/syringe

Dosage: 1常備品 29482

Adult
·Saeling of surface: 1pack of TISSEEL 2mL (i.e.1mL tisseel soln plus 1 mL thrombin soln) with be sufficient for thr area of at least 10 cm2.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Soln: 2mL(29481), 4mL(29482)

ADR:

COMMON
nausea, intestinal obstruction, urticaria, flushing, delayed wound healing, edema, fever, seroma
SERIOUS
anaphylactic responses, bradycardia, tachycardia, drop in blood pressure, hematoma(NOS), dyspnoea

NOTE: 冷凍儲藏

For application on wound surfaces only. Not for IV application.

藥名相似:

外觀相似:

外觀描述: 4mL預裝針筒

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000925

26.04C Hemostatics

29483 UK / No report(毫

Tisseel Solution for sealant "百特"組織修復凝合劑(第二代)

Protein clottable (human)(fibrinogen 72-110mg)

91mg/mL, Aprotinin(bovine) 3000KIU/mL, Thrombin 500IU/mL, Calcium chloride 5.88mg/mL, 10mL/syringe

Dosage: 1常備品 29483

Adult
·Saeling of surface: 1pack of TISSEEL 2mL (i.e.1mL tisseel soln plus 1 mL thrombin soln) with be sufficient for thr area of at least 10 cm2.

Pediatric

Dosing adjustments in hepatic impairment:

No data available

Dosing adjustments in renal impairment:

No data available

P: Soln: 2mL(29481), 4mL(29482)

ADR:

COMMON
nausea, intestinal obstruction, urticaria, flushing, delayed wound healing, edema, fever, seroma
SERIOUS
anaphylactic responses, bradycardia, tachycardia, drop in blood pressure, hematoma(NOS), dyspnoea

NOTE: 冷凍儲藏

For application on wound surfaces only. Not for IV application.

藥名相似:

外觀相似:

外觀描述: 2mL預裝針筒

26.04C Hemostatics

34892 ɔt be ruled out / Infant risk can

ADYNOVATE* 500IU 艾諾威長效第八因子注射劑500國際單位

Antihemophilic Factor 500IU (Recombinant), PEGylated

Dosage: 1常備品 34892

Adult
IV administration only; infuse over 5 mins as tolerated
dosage calculation, depend on desired factor Ⅷ level units required: BW(kg) ×desired factor Ⅷ increase(in % of normal) ×0.5 IU/kg
·Hemophilia A
Mild hemorrhage (increased to 20-40% of normal): IV, 10-20IU/kg for one dose ; repeated every 12-24hrs if needed
Moderate to major hemorrhage (increased to 30-60% of normal): IV, 15-30IU/kg for one dose; repeated at 12-24hrs if needed
Major to life-threatening hemorrhage (increased to 80~100% of norma): IV, 30-50IU/kg for one dose; repeated at 8-24hrs if needed
·Surgical procedures:
minor (increased to 60-100% of normal): IV, 30-50IU/kg 1hr before OP; repeated at 24hrs if needed
major (increased to 80-120% of normal): IV, 40-60IU/kg 1hr before OP, additional doses should be given as necessary every 8-24hrs until healing is complete
·Prophylaxis: IV, 40-50IU/kg twice weekly.

Pediatric
>12 age: Same as adult
<12age:
·Surgical procedures:
major (increased to 80-120% of normal): IV, 40-60IU/kg 1hr before OP, additional doses should be given as necessary every 6-24hrs until healing is complete
·Prophylaxis: IV, 55 IU/kg twice weekly.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 500IU(34892), 1000IU(34893)

ADR:

Common
Nausea (0.8%), Headache (2.1%)
Serious
Antibody development, Hypersensitivity reaction (0.4%)

NOTE: 冰箱冷藏，不可冷凍。

·《仿單禁忌》：ADYNOVATE禁用於先前曾對以下物質產生全身型過敏反應(anaphylactic reaction)的病人：ADYNOVATE、其母分子(ADVATE)、小鼠或倉鼠蛋白，或是ADYNOVATE的賦形劑(例如三羥甲基氨基甲烷、甘露醇、海藻糖、穀胱甘?及/或聚山梨醇酯80)。
冰箱冷藏貯存,不可冷凍,需避免過度暴露於光照;配製完成的注射劑須於3小時內使用
Contraindications: hypersensitivity to mouse protein

藥名相似:

外觀相似:

外觀描述: 白色乾粉，"綠"蓋透明玻璃小瓶。5mL稀釋液，"灰"蓋透明玻璃小瓶，附BAXJECT II Hi-Flow無針頭輸液裝置。

26.04C Hemostatics

34893 C / Unknown(有

ADYNOVATE* 1000IU 艾諾威長效第八因子注射劑1000國際單位

Antihemophilic Factor 1000IU (Recombinant), PEGylated

Dosage: 1常備品 34893

Adult
IV administration only; infuse over 5 mins as tolerated
dosage calculation, depend on desired factor Ⅷ level units required: BW(kg) ×desired factor Ⅷ

increase(in % of normal) ×0.5 IU/kg
·Hemophilia A
Mild hemorrhage (increased to 20-40% of normal): IV, 10-20IU/kg for one dose ; repeated every 12-24hrs if needed
Moderate to major hemorrhage (increased to 30-60% of normal): IV, 15-30IU/kg for one dose; repeated at 12-24hrs if needed
Major to life-threatening hemorrhage (increased to 80~100% of norma): IV, 30-50IU/kg for one dose; repeated at 8-24hrs if needed
·Surgical procedures:
minor (increased to 60-100% of normal): IV, 30-50IU/kg 1hr before OP; repeated at 24hrs if needed
major (increased to 80-120% of normal): IV, 40-60IU/kg 1hr before OP, additional doses should be given as necessary every 8-24hrs until healing is complete
·Prophylaxis: IV, 40-50IU/kg twice weekly.

Pediatric
>12 age: Same as adult
<12age:
·Surgical procedures:
major (increased to 80-120% of normal): IV, 40-60IU/kg 1hr before OP, additional doses should be given as necessary every 6-24hrs until healing is complete
·Prophylaxis: IV, 55 IU/kg twice weekly.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 500IU(34892), 1000IU(34893)

ADR:

SERIOUS
hemolytic anemia (large dose), anaphylaxis

NOTE: 冰箱冷藏，不可冷凍。

·《仿單禁忌》：ADYNOVATE禁用於先前曾對以下物質產生全身型過敏反應(anaphylactic reaction)的病人：ADYNOVATE、其母分子(ADVATE)、小鼠或倉鼠蛋白，或是ADYNOVATE的賦形劑(例如三羥甲基氨基甲烷、甘露醇、海藻糖、穀胱甘?及/或聚山梨醇酯80)；
·冰箱冷藏貯存,不可冷凍,需避免過度暴露於光照;配製完成的注射劑須於3小時內使用
·Contraindications: hypersensitivity to mouse protein

藥名相似:

外觀相似:

外觀描述: 白色乾粉，"綠"蓋透明玻璃小瓶。5mL稀釋液，"灰"蓋透明玻璃小瓶，附BAXJECT II Hi-Flow無針頭輸液裝置。

特基因工程第八凝血因子製劑 1000國際單位

Factor VIII 1000U (recombinant)

Dosage: 1常備品 34895

Adult
IV administration only; infuse over 5-10 mins as tolerated
dosage calculation, depend on desired factor Ⅷ level units required: BW(kg) ×desired factor Ⅷ increase(in % of normal) ×0.5 IU/kg
·Hemophilia A
Mild hemorrhage (increased to 20-40% of normal): IV, 10-20IU/kg for one dose ; repeated every 12-24hrs if needed
Moderate to major hemorrhage (increased to 30-60% of normal): IV, 15-30IU/kg for one dose; repeated at 12-24hrs if needed
Major to life-threatening hemorrhage (increased to 80~100% of norma): IV, 40-50IU/kg and additional doses of 20-25IU/kg every 8-12hrs
·Surgical procedures:
minor (increased to 30-60% of normal): IV, 15-30IU/kg; repeated at 12-24hrs if needed
major (increased to approximately 100% of normal): IV, 50IU/kg, additional doses should be given as necessary every 6-12hrs for 10-14 days until healing is complete
·Dental procedures (60-80% correction): IV, 30-40IU/kg immediately prior to procedure, readminister if necessary
·Prophylaxis (15% correction): IV, 7.5IU/kg once daily or every other day

Pediatric
Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 500IU(34897), 1000IU(34895)

ADR:

SERIOUS
hemolytic anemia (large dose), anaphylaxis

NOTE: 冰箱冷藏2-8℃，不可冷凍

·《仿單禁忌》：ADVATE禁用於先前曾對小鼠或倉鼠蛋白，或本品中主成分或其他成份(甘露醇、海藻糖、氯化鈉、組胺酸、三羥甲基氨基甲烷、氯化鈣、聚山梨醇酯80及/或麩胱甘?)產生危及生命過敏性反應的病人，包括全身型過敏反應。
冰箱冷藏貯存,不可冷凍,需避免過度暴露於光照;配製完成的注射劑須於3小時內使用
Contraindications: hypersensitivity to mouse protein

藥名相似:

外觀相似:

外觀描述: 白色乾粉，"橘"蓋透明玻璃小瓶。5mL稀釋液，"灰"蓋透明玻璃小瓶，附BaxjectII安全無針配藥裝置。

26.04C Hemostatics

34895 **C / Unknown(有**

Advate 1000 IU Powder And Solvent For Injection 艾非

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000838

26.04C Hemostatics

34897 **C / Unknown(有**

Advate 500 IU Powder And Solvent For Injection 艾非特基因工程第八凝血因子製劑 500國際單位

Factor VIII inj 500IU(recombinant) pow in vial

Dosage: 1常備品 34897

Adult
IV administration only; infuse over 5-10 mins as tolerated
dosage calculation, depend on desired factor Ⅷ level units required: BW(kg) ×desired factor Ⅷ increase(in % of normal) ×0.5 IU/kg
·Hemophilia A
Mild hemorrhage (increased to 20-40% of normal): IV, 10-20IU/kg for one dose ; repeated every 12-24hrs if needed
Moderate to major hemorrhage (increased to 30-60% of normal): IV, 15-30IU/kg for one dose; repeated at 12-24hrs if needed
Major to life-threatening hemorrhage (increased to 80-100% of norma): IV, 40-50IU/kg and additional doses of 20-25IU/kg every 8-12hrs
·Surgical procedures:
minor (increased to 30-60% of normal): IV, 15-30IU/kg; repeated at 12-24hrs if needed
major (increased to approximately 100% of normal): IV, 50IU/kg, additional doses should be given as necessary every 6-12hrs for 10-14 days until healing is complete
·Dental procedures (60-80% correction): IV, 30-40IU/kg immediately prior to procedure, readminister if necessary
·Prophylaxis (15% correction): IV, 7.5IU/kg once daily or every other day

Pediatric
Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 500IU(34897), 1000IU(34895)

ADR:

COMMON
·Musculoskeletal: Arthralgia (12% to 25%), Traumatic injury, Limb (10%)
·Neurologic: Headache (21% to 26%)
·Respiratory: Cough (11% to 19%), Nasopharyngitis (17%)
·Other: Fever (21%)
SERIOUS
·Immunologic: Anaphylaxis, Factor VIII inhibitor disorder (Xyntha(R), 4.17% ; Advate(R), 20%), Hypersensitivity reaction

NOTE: 冰箱冷藏2-8℃，不可冷凍

·《仿單禁忌》：ADVATE禁用於先前曾對小鼠或倉鼠蛋白，或本品中主成分或其他成份(甘露醇、海藻糖、氯化鈉、組胺酸、三羥甲基氨基甲烷、氯化鈣、聚山梨醇酯80及/或麩胱甘?)產生危及生命過敏性反應的病人，包括全身型過敏反應。
·冰箱冷藏貯存,不可冷凍,需避免過度暴露於光照;配製完成的注射劑須於3小時內使用
·Contraindications: hypersensitivity to mouse protein
·500IU pow +Dis water 5mL

藥名相似:

外觀相似:

外觀描述: 白色乾粉，"橘"蓋透明玻璃小瓶。5mL稀釋液，"灰"蓋透明玻璃小瓶，附BaxjectII安全無針配藥裝置

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000836

26.04C Hemostatics

34906 **C / Infant risk is**

PHYTONADIONE INJECTION 10MG "TBC" "信東" 血納定注射液１０毫克

Phytonadione(Vitamin K1) inj 10mg/1mL amp

Dosage: 1常備品 34906

Adult
·Anticoagulant-induced hypoprothrobinemia: when bleeding is not present, IV, IM, SC,initially, 2.5-10 mg, up to 25 mg, may repeat dose in 6-8 hr if there is inadequate response. Bleeding is present, slow IV, 10-50 mg.
·Hypoprothrombinemia due to malabsorption syndrome or other medications: IM, SC, 2-25 mg, may be repeated if necessary.
·Prophylaxis hypoprothrombinemia: IM 5-10 mg qW.

Pediatric
·Hemorrhagic disease of newborn, prophylaxis: IM, SC, 0.5-1 mg within 1 hr of birth; treatment: IM, SC, 1 mg.

Dosing adjustments in hepatic impairment:

Dosage adjustment required.

Dosing adjustments in renal impairment:

NDA

P: Tab: 5mg(27531, 急用藥); Inj: 10mg/1mL Amp(34906)

ADR:

NOTE: 室溫儲存

1.IV push not to exceed 1 mg/min.
2.Fatalities have occurred with IV and IM administration.
3.Does not counteract anticoagulation effect of heparin.

藥名相似:

外觀相似:

外觀描述: 1mL黃色注射液『棕』色安瓿頸部有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12002090

26.04C Hemostatics

34908 B / Infant risk can

TRANSAMIN INJECTION "DAIICHI SANKYO" "台灣第一三共" 斷血炎注射液

Tranexamic Acid inj 250mg/5mL amp

Dosage: 1常備品 34908

Adult
·Hemorrhage: IM, IV, 250-500 mg/day div. 1-2 doses; IV infusion, 0.5-2.5g during or after surgery if necessary.

Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

SrCr 1.36-2.83 mg/dL: 10 mg/kg bid
SrCr 2.83-5.66 mg/dL: 10 mg/kg qd
SrCr >5.66 mg/dL: 10 mg/kg qod

P: Cap: 250mg(25261); Inj: 250mg/5mL amp(34908)

ADR:

COMMON
Abdominal pain, Diarrhea, Nausea, Anemia, Arthralgia, Backache, Cramp, Musculoskeletal pain, Spasm, Headache, Migraine, Nasal sinus problem, Fatigue.
SERIOUS
Thromboembolic disorder, Anaphylactoid reaction, Anaphylaxis, Cerebral ischemia, Retinal artery occlusion, Retinal vascular occlusion, Visual disturbance, Pulmonary embolism.

NOTE: 室溫儲存

·《Contraindications》Women using hormonal contraception with oral administration; Hypersensitivity to tranexamic acid; or any of the ingredients; Active intravascular clotting with IV administration; Subarachnoid hemorrhage; cerebral edema or infarction may occur with IV administration; Active thromboembolic disease (eg, DVT, pulmonary embolism, or cerebral thrombosis) with oral administration; History of thrombosis or thromboembolism, including retinal vein or artery occlusion with oral administration; Intrinsic risk of thrombosis or thromboembolism (eg, thrombogenic valvular disease, thrombogenic cardiac rhythm disease, or hypercoagulopathy) with oral administration ;
·Transamin should be administered with care in patients with thrombosis or consumption coagulopathy.

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液，頸部有『藍』點，透明安瓿

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045154

26.04C Hemostatics

34914 C / Unknown(有

BENEFIX{RFIX} COAGULATION FACTOR IX (RECOMBINANT) 賓凝適第九凝血因子凍晶注射劑

Factor IX Recombinant 500IU vial

Dosage: 1常備品 34914

Dosage calculation(depend on desired factor IX units required): BW(kg) ×desired factor IX increase(in % of normal) ×1.2 IU/kg
·Hemophilia B - Hemorrhage
Minor hemorrhage (increased to 20-30% of normal): IV, 24-36IU/kg every 12-24hrs for 1-2 days
Moderate hemorrhage (increased to 25-50% of normal): IV, 30-60IU/kg every 12-24hrs, treat until bleeding stops & healing begins
Major hemorrhage (increased to 50-100% of normal): IV, 60-120IU/kg every 12-24hrs for 7-10 days
·severe Hemophilia B - Hemorrhage, Routine prophylaxis: IV, average 40IU/Kg(13~78IU/kg) every 3-4days.

Dosage calculation(depend on desired factor IX units required): BW(kg) ×desired factor IX increase(in % of normal) ×1.4 IU/kg
·Hemophilia B - Hemorrhage
Minor hemorrhage (increased to 20-30% of normal): IV, 28-42IU/kg every 12-24hrs for 1-2 days
Moderate hemorrhage (increased to 25-50% of normal): IV, 35-70IU/kg every 12-24hrs, treat until bleeding stops & healing begins
Major hemorrhage (increased to 50-100% of normal): IV, 70~140IU/kg every 12-24hrs for 7-10 days
·severe Hemophilia B - Hemorrhage, Routine prophylaxis: IV, average 40IU/Kg(13~78IU/kg) every 3-4days.

Dosing adjustments in hepatic impairment:

unknown, but should be used with caution in patients with liver disease(esp. in neonates group, there is a risk of hepatitis with higher morbidity and mortality due to using this drug)

Dosing adjustments in renal impairment:

NDA

P:

ADR:

COMMON
Antibody development, Headache.
SERIOUS
Thromboembolic disorder, Anaphylaxis, Nephrotic syndrome.

NOTE: 儲存2-30℃，不可冷凍。

配置完成的溶液必須在3小時內使用
Contraindications: hypersensitivity to hamster protein
·病人可能對第九凝血因子濃縮製劑發生過敏反應，因此在初期給予時(約前10-20次)，應在醫療監督設備下進行。

·中和性抗體(抑制體)-在已經產生第九凝血因子抑制體的病人上，若連續投予第九凝血因子，會增加發生嚴重過敏反應或急性過敏性反應(anaphylaxis)的危險性。應評估出現過敏反應的病人是否有抑制體的存在。

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『藍』蓋透明玻璃小瓶，5mL預先充填專用稀釋液之注射器、連結藥瓶與注射器的轉接器、無菌靜脈輸注管路套組、兩片酒精棉片、一片固定用的膠帶及紗布

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000608

26.04C Hemostatics

35361 **C / Unsafe**

PITRESSIN INJECTION 20 UNITS/ML (ARGININE VASOPRESSIU) 必壓生注射液 2 0 單位/公撮(氨胍戊酸血管加壓素)

■Pitressin Aqua (Vasopressin) 20 IU/1 mL Amp

Dosage: 1常備品 35361

Adult
·Diabetes insipidus: IM, SC, 5-10 IU bid-qid
·GI hemorrhage: IV infusion, initial 0.2-0.4 IU/min and progressively increased to 0.9 IU/min, dil. In NS or D5W to conc.Of 0.1-1IU/mL.
·Abdominal distention and abdominal radiographic procedures: IM, 5 IU st, 10 IU q3-4h as needed.

Pediatric
·Diabetes insipidus: IM, SC, 2.5-5 IU bid-qid.
·GI hemorrhage: IV infusion, 0.01 IU/kg/min.

Dosing adjustments in hepatic impairment:

In the treatment of variceal hemorrhage, some patients with cirrhosis will respond to intravenous vasopress in doses as low as 0.13 unit/minute.

Dosing adjustments in renal impairment:

Chronic nephritis with nitrogen retention until reasonable nitrogen blood levels are attained.

P: Inj: 20 IU/1mL amp(35361)

ADR:

COMMON
abdominal cramps, nausea, passage of gas, vomiting, cutaneous gangrene, sweating, urticaria, pounding in head, tremor, vertigo
SERIOUS
anaphylaxis, arrhythmias, cardiac arrest, decreased cardiac output, gangrene, myocardial ischemia, bronchial constriction,
water intoxication.

NOTE: 室溫保存

Contraindication: Chronic nephritis with nitrogen retention until reasonable nitrogen blood levels are attained.

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液透明安瓿頸部有紅點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1033429

26.04C Hemostatics

35362 **X / Unknown(有**

TERLISSIN* INJECTION 1MG 坦沛思凍晶注射劑

■Terlipressin acetate inj 1mg(=terlipressin 0.85mg) vial

Dosage: 1常備品 35362

Adult
·Bleeding esophageal varices: IV, Initial terlipressin acetate 2mg over 1 min, MD, 1-2mg q4h for up to 24-36 hr; Max.120mcg/kg/day.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 1mg vial(35362)

ADR:

Headache, hypertension, bradycardia, hypokalemia, ischemic colitis, abdominal cramps.

NOTE: 室溫儲存

1.Increase in blood pressure following the use of glypressin in patients with known hypertension has been controlled with clonidine 150 mcg I.V.
2.Contraindication: Pregnancy
3.Use cautiously in asthma, hypertension, advanced arteriosclerosis, coronary insufficiency, arrhythmias, renal insufficiency.

藥名相似:

外觀相似:

外觀描述: 白色乾粉『綠』蓋透明玻璃小瓶；附5mL透明稀釋液，透明玻璃安瓿，頸部有紅點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1052453

26.04C Hemostatics

35363 **ɔt be ruled out / Infant risk can**

MINIRIN SOLUTION FOR INJECTION 4MCG/ML 迷你寧

注射劑

■Desmopressin(DDAVP) inj 4mcg/1mL amp

Dosage: 1常備品 35363

Adult
·Central diabetes insipidus: IV, 1-4mcg 1-2 times daily
·Hemophilia A and von willebrand's disease: IV infusion (over 15-30 min), 0.3mcg/kg. If a positive effect is obtained, the initial dose may be repeated 1-2 times with intervals of 6-12 hrs

Pediatric
·Central diabetes insipidus: IV ,
< 1 year: 0.2-0.4 mcg 1-2 times daily
> 1 year: 0.4-1 mcg 1-2 times daily
·Hemophilia A and von willebrand's disease:
>3 mon: IV infusion (over 15-30 min), 0.3 mcg/kg

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Tab: 0.1mg(25606); Nasal spray: 10mcg/puff, 25puff/B(29067); Inj: 4mcg/1mL Amp(35363)

ADR:
COMMON
flushing, headache, nausea
SERIOUS
hyper- or hypotension, palpitations, tachycardia, anaphylaxis (rare), thrombotic events (rare), hyponatremia, seizures (rare)

NOTE: 冰箱冷藏，不可冷凍

Monitor patient to determine necessity of further doses, tachyphylaxis may occur if given more often than every 48 hours

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液透明安瓿頸部有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2020824

26.04C Hemostatics

37783 **C / Unknown(有**

急用FEIBA 500 U/20mL (anti-inhibitor coagulant complex)

Dosage: 2急用藥 37783

Adult
·Associated with inhibitors of Factor VIII, XI, or XII - Hemorrhage、Hemophilia A,B for spontaneous bleeding or to cover surgical interventions
：IV, IV infusion, joint hemorrhage, 50-100 U/kg q12 h, mucous membrane hemorrhage, 50-100 U/kg q6h, soft tissue hemorrhage:100 U/kg q12 h,severe hemorrhage:100 U/kg q6-12 h; Max. 200 U/kg.

Pediatric
Same as adult

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Inj: 500 U pow in vial(with 20mL SWI)

ADR:
Common
Complication of infusion, headache, flushing, fever, chills, change in blood pressure/pulse rate
Serious
Myocardial infarction, hives, disseminated intravascular coagulation, DIC, thromboembolic disorder, anaphylactoid reaction

NOTE: Refrigerate, Protect from light

1.調劑後最好立刻使用或應於3小時內使用(20-25 C)。
2.配製好的藥品請勿再放回冰箱。
3.靜脈輸注速率勿超過2U/kg/min。

藥名相似:

外觀相似:

外觀描述: 白色乾粉、20mL無菌注射用水，附針頭與針筒、蝴蝶針輸注套組

26.04C Hemostatics

37832 **B /**

TRASYLOL INJECTION 10,000 KIU/ML 卡脈噴靜脈注射液/輸注液

急用Aprotinin inj 10000KIU/mL

Dosage: 2急用藥 37832

Adult
· Prevention of Bleeding Associated with CABG Surgery:A test dose of 10,000 units (1.4 mg) by IV injection at least 10 min, If no adverse reactions occur after the test dose, the LD IV slowly over 20-30 min. When the high-dose regimen is used, the loading dose is 2 million units (280 mg) of aprotinin; when the low-dose regimen is used, the loading dose is 1 million units (140 mg) of aprotinin. Total doses > 7million KIU have not been studied in controlled trials.

After administration of the loading dose, aprotinin is administered by continuous IV infusion until the surgical procedure is completed and the patient is removed from the operating room.1, 8, 9, 13, 16, 17, 29, 30 When the high-dose regimen is used, the dosage for continuous IV infusion is 500,000 units/hour (70 mg/hour); when the low-dose regimen is used, the dosage of continuous IV infusion is 250,000 units/hour (35 mg/hour).1

Pediatric
Not FDA approved

· Cardiac surgery: 10,000-50,000 units/kg IV loading dose after anesthesia induction, 10,000-50,000 units/ kg in the pump prime and 10,000-20,000 units/hour for 3 hours after bypass weaning has been used in children 2.5 months to 14 years old

Dosing adjustments in hepatic impairment:

The effect of hepatic impairment on the pharmacokinetics of aprotinin has not been established

Dosing adjustments in renal impairment:

The manufacturer states that mild renal impairment does not substantially alter the pharmacokinetics of the drug, and dosage adjustment is not necessary. However, because aprotinin is excreted principally by the kidneys. Some clinicians recommend that reduced dosages of the drug be used in patients with renal failure

P: Inj: 500000KIU/50mL (37832)

ADR:

SERIOUS
hypersensitivity/anaphylactic reactions (2.7% with reexposure, 5% for reexposure within 6 months, 0.9% for reexposure time greater than 6 months, 0.1% with no prior exposure)
thrombosis (1%), shock (<1%)

NOTE: 室溫儲存

All intravenous doses of should be administered through a central line. DO NOT ADMINISTER ANY OTHER DRUG USING THE SAME LINE.

藥名相似:

外觀相似:

外觀描述: 50mL透明注射液『紅』蓋透明玻璃瓶

26.06 Hematopoietic Agents

27491 **C / Unsafe**

Revolade film-coated tablets 25mg 返利凝25毫克膜衣錠

Eltrombopag olamine 31.9mg tab(=base 25mg/tab)

Dosage: 1常備品 27491

· Chronic idiopathic thrombocytopenic purpura: PO, ac, initial 25mg qd adjust the daily dose to achieve and maintain a platelet count≧50,000/μL; Max. 50mg/day.
· Severe Aplastic anemia with insufficient response to immunosuppressive therapy: PO, ac, initial, 50 mg QD adjust the daily dose by increments of 50 mg in 2-week intervals to achieve and maintain a platelet count ≧ 50,000/μL; Max. 150mg/day; if no hematologic response after 16 weeks or if all blood counts are stable for 8 weeks plus 8 weeks at reduced dosage, discontinue therapy.

·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Moderate to severe hepatic impairment (Child-Pugh ≧7): Not recommended to use

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 25mg(27491)

ADR:

COMMON
Diarrhea, nausea, pain in throat, pharyngitis, vomiting, ALT/SGPT level raised, AST/SGOT level raised, hyperbilirubinemia, myalgia, headache, cataract, urinary tract infectious disease, epistaxis, fatigue
SERIOUS
Bleeding, increased reticulin, portal vein thrombosis, thrombosis, hepatotoxicity, liver function tests abnormal, acute renal failure

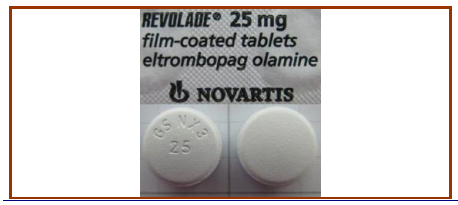
NOTE: 室溫儲存

· It should be taken on an empty stomach, at least 1 hour before or 2 hours after a meal.
· It should not be administered within 4 hours of other drugs, food or supplements that contain polyvalent cations(e.g., Fe, Ca, Al, Mg, Se, Zn).
· Wait for at least 2 weeks to see the effect of any dose adjustment on the patient’ s platelet response prior to considering another dose adjustment.
· It should be discontinued if ALT increase to ≧3X ULN and are progressive, or persist for 4 weeks or more, or accompanied by increased direct bilirubin or accompanied by clinical symptoms of liver injury or evidence for hepatic decompensation.

藥名相似:

外觀相似:

外觀描述: 白色圓形錠，有GS NX3及25字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025272

26.06 Hematopoietic Agents

34847 **C /**

FILGRASTIM INJECTION M300,300μg/0.7ML 惠爾血添 M３００

Filgrastim inj (G-CSF) 300mcg/0.7mL amp

Dosage: 1常備品 34847

Adult
·Bone marrow transplantation: IV, SC, 10 mcg/kg/day
·Cancer patients receiving myelosuppressive chemotherapy: IV, SC, 5 mcg/kg/day
·Congenital neutropenia: SC, 6 mcg/kg twice daily
·Idiopathic or cyclic neutropenia: SC, 5 mcg/kg/day
·Peripheral blood progenitor cell mobilization: SC, 10 mcg/kg/day

Pediatirc

Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 100mcg Vial(with SWI 1ml)(34849), 75mcg Amp(39978, 兒癌), 150mcg Amp(39979, 兒癌), 300mcg Amp(34847)(39980, 兒癌)

ADR:

COMMON
Alopecia, Rash, Diarrhea, Anemia, Bone pain, Headache, Cough, Dyspnea, Epistaxis, Fatigue, Fever, Pain
SERIOUS
Aortitis, Capillary leak syndrome, Vasculitis of the skin, Myelodysplastic syndrome, Sickle cell anemia with crisis, Anaphylaxis, Hypersensitivity reaction, Glomerulonephritis, Acute respiratory distress syndrome, Rupture of spleen

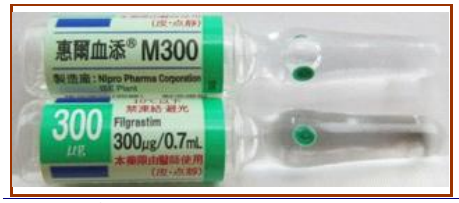
NOTE: 冰箱冷藏10℃以下，不可冷凍。

1.Do not dilute to concentrations less than 5 mcg/mL; do not dilute with saline.
2.Obtain CBC with platelets before initiating therapy; monitor twice weekly during therapy.

藥名相似:

外觀相似:

外觀描述: 0.7mL透明注射液透明安瓿，頸部有綠點



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000670

26.06 Hematopoietic Agents

34849 **C / Infant risk can**

GRANOCYTE 100 顆球諾得 1 0 0

Lenograstim(G-CSF) 100mcg vial (with SWI 1mL)

Dosage: 1常備品 34849

t

·Bone marrow transplantation: IV infusion(over 30 min), SC, 150 mcg/m(2)/day
·Chemotherapy induced neutropenia: SC, 150mcg/m(2)/day
·Peripheral blood progenitor cell mobilization: SC, 150mcg/m(2)/day

Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj:100mcg Vial(with SWI 1ml) (34849) (39975, 兒癌用藥); 250mcg Vial (with SWI 1ml) (34848) (39976, 兒癌用藥)

ADR:

COMMON
·Alopecia, Rash (Myelosuppressive chemotherapy, 14%)
·Gastrointestinal: Diarrhea
·Hematologic: Anemia
·Musculoskeletal: Bone pain (Myelosuppressive chemotherapy, 11%; peripheral blood progenitor cell collection, 30%)
·Neurologic: Headache (Peripheral blood progenitor cell collection and therapy, 10%)
·Respiratory: Cough (Myelosuppressive chemotherapy, 14%), Dyspnea (Myelosuppressive chemotherapy, 13%), Epistaxis
·Other: Fatigue (Myelosuppressive chemotherapy, 20%), Fever (Myelosuppressive chemotherapy, 48%; peripheral blood progenitor cell collection, 16%), Pain (Myelosuppressive chemotherapy, 12%)
SERIOUS
·Cardiovascular: Capillary leak syndrome
·Dermatologic: Vasculitis of the skin
·Hematologic: Myelodysplastic syndrome, Sickle cell anemia with crisis
·Immunologic: Anaphylaxis, Hypersensitivity reaction
·Renal: Glomerulonephritis
·Respiratory: Acute respiratory distress syndrome
·Other: Rupture of spleen

NOTE: 室溫保存

·《仿單禁忌》：
（１）對本劑或其他顆粒球群落形成刺激因子製劑有過敏症的病人。
（２）骨髓中的芽球並未充分減少的骨髓性白血病病人及週邊血液中有芽球的骨髓性白血病病人。【芽球有時會增加】
·使用本藥前應對病人充份詢問包括過敏史與藥物過敏史，以預測過敏等反應，若有過敏反應(Anaphylaxis)，應立即停藥並採取適當處置。
·仿單臨床顯著的副作用：休克及過敏性反應、間質性肺炎、芽球的增加、急性呼吸窘迫症候群、脾臟破裂、毛細血管滲漏症候群、大血管的血管炎(主動脈，頸總動脈，鎖骨下動脈或其他大血管的發炎)等現象，應採取適當的處置及停用本藥。
·Contraindications: Use to increase the dose intensity of cytotoxic chemotherapy beyond established dose regimens or time courses, concurrent use with cytotoxic chemotherapy, myeloid malignancy other than de novo acute myeloid leukemia, de novo acute myeloid leukemia patients below the age of 55 years, de novo acute myeloid leukemia patients with good cytogenetics

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『米黃』蓋透明玻璃小瓶，蓋上有100字樣，附1ml稀釋液安瓿頸部有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000757

26.06 Hematopoietic Agents

37618 **ɔt be ruled out / Infant risk can**

Neulasta 倍血添注射劑

急用Pegfilgrastim inj 6mg/0.6mL amp

Dosage: 2急用藥 37618

Adult
·Chemotherapy-induced neutropenia: SC 6 mg once per chemotherapy cycle, beginning 24-72 hrs after completion of chemotherapy

Pediatric
·Safety and efficacy have not been established in patients less than 18 years old

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: inj: 6mg/0.6mL syringe (37618)

ADR:

COMMON
Bone pain, Pain in limb.
SERIOUS
Aortitis, Capillary leak syndrome, Leukocytosis, Rupture of spleen, Sickle cell anemia with crisis, Anaphylaxis, Glomerulonephritis, Acute respiratory distress syndrome.

NOTE: 避光冷藏2-8℃，避免冷凍

·若發生鐮狀細胞危象時停用本藥。
·治療開始後的第一周可能就會發生主動脈發炎。表現可能包括發燒、腹痛、不適、背痛和增加發炎指標(如C-反應蛋白和白血球計數)的全身性體徵和症狀。如果懷疑為主動脈炎，請停止本藥。

藥名相似:

外觀相似:

外觀描述: 0.6mL注射液,預充填注射針筒

26.06 Hematopoietic Agents

39975 /
GRANOCYTE 100 顆球諾得１００

@兒癌Lenograstim 100mcg vial (with SWI 1mL)

Dosage: 2兒癌基金用藥 39975

Adult
·Bone marrow transplantation: IV infusion(over 30 min), SC, 150 mcg/m(2)/day
·Chemotherapy induced neutropenia: SC, 150mcg/m(2)/day
·Peripheral blood progenitor cell mobilization: SC, 150mcg/m(2)/day

Pediatric
Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj:100mcg Vial(with SWI 1ml) (34849) (39975, 兒癌用藥); 250mcg Vial (with SWI 1ml) (34848) (39976, 兒癌用藥)

ADR:

COMMON
bone pain, flu-like symptoms, N/V
SERIOUS
adult respiratory distress syndrome, interstitial pneumonitis, shock

NOTE: 室溫保存

Contraindications: Use to increase the dose intensity of cytotoxic chemotherapy beyond established dose regimens or time courses, concurrent use with cytotoxic chemotherapy,myeloid malignancy other than de novo acute myeloid leukemia, de novo acute myeloid leukemia patients below the age of 55 years, de novo acute myeloid leukemia patients with good cytogenetics

藥名相似:

外觀相似:

外觀描述:

26.06 Hematopoietic Agents

39976 /
GRANOCYTE 250 顆球諾得２５０

@兒癌Lenograstim 250mcg vial (with SWI 1mL)

Dosage: 2兒癌基金用藥 39976

Adult
·Bone marrow transplantation: IV infusion(over 30 min), SC, 150mcg/m(2)/day
·Chemotherapy induced neutropenia: SC, 150mcg/m(2)/day
·Peripheral blood progenitor cell mobilization: SC, 150mcg/m(2)/day

Pediatirc
Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj:100mcg Vial(with SWI 1ml) (34849) (39975, 兒癌用藥); 250mcg Vial (with SWI 1ml) (34848) (39976, 兒癌用藥)

ADR:

COMMON
bone pain, flu-like symptoms, N/V
SERIOUS
adult respiratory distress syndrome, interstitial pneumonitis, shock

NOTE: 室溫保存

Contraindications: Use to increase the dose intensity of cytotoxic chemotherapy beyond established dose regimens or time courses, concurrent use with cytotoxic chemotherapy,myeloid malignancy other than de novo acute myeloid leukemia, de novo acute myeloid leukemia patients below the age of 55 years, de novo acute myeloid leukemia patients with good cytogenetics

藥名相似:

外觀相似:

外觀描述:

26.08 Blood Derivative

34816 C / Infant risk can

ALBUMINAR-25 "愛默 " 人體血清白蛋白２５％注射液

Normal serum Albumin (Human) inj 25% 50mL bot

Dosage: 1常備品 34816

Adult
IV administrated rate: < 1mL/min
·Burns: achieve plasma albumin level of approximately 2.5g/dL (total plasma protein conc. Of 5.2g/dL, not recommend use in the first 8~16 hrs)
·Hypoproteinemia: IV, 50~75g(200~300mL); Max.2g(8mL)/kg/day
·Hypovolemic shock: IV, 25~50g(100~200mL), repeat in 15~30min (< 250g administered within 48hrs)
·Acute nephrosis: IV, initial 25~50g(100~200mL), repeated at 1- to 2-day intervals
·Priming the heart-lung machine for cardiopulmonary bypass: 0.0375g(0.15mL) per 100mL of pump prime

Pedatric
·Emergency situations
Children: IV, initial 25g(100mL).
·In non-emergency situations
Premature infants: IV, 1g(4mL)/kg
Children: IV, 25~50% adult dose
·Neonatal hemolytic disease(hyperbilirubinemia): IV, 1g(4mL)/kg (1hr prior to exchange transfusion)
·Hypoproteinemia: IV, 0.5~1g(2~4mL)/kg/dose over 30~120min, repeat every 1~2days; Max.2 g (8mL)/kg/day
·Hypovolemic shock: IV rapid infusion, 0.5~1 g(2~4mL)/kg/dose, repeat in 15~30min
·Priming the heart-lung machine for cardiopulmonary bypass: 0.0375g(0.15mL) per 100mL of pump prime

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Administration of large quantities of plasma protein fraction in patients with renal insufficiency has resulted in metabolic alkalosis from electrolyte imbalance. Dosage should be adjusted based on the patient's protein/oncotic needs and fluid status.

P: Inj: 25% 50mL (34816)

ADR:

SERIOUS
hypersensitivity including chills, fever, urticaria

NOTE: 室溫儲存

Contraindications: patients at risk for acute circulatory overload (cardiac failure, pulmonary edema, severe anemia)
Cautions: 25% concentration contraindicated in preterm infants because of risk of IVH. For infusion, use 5 micron filter or larger. Dilutions of the 25% product should be made with D5 W or NS.

藥名相似:

外觀相似:

外觀描述: 50mL注射液白蓋玻璃瓶

26.08 Blood Derivative

37796 C / No report(毫

BISEKO "百合" 血漿蛋白

急用Human serum protein inj 5% 50mL bot

Dosage: 2急用藥 37796

Adult
· Hypoalbuminemia, shock, burns: IV infusion, 250-500mL/day, Max. 2000mL/day

Pediatric
· Hypoalbuminemia, shock, burns: IV infusion, 15-20mL/kg/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 5% 50mL bot(37796)

ADR:

SERIOUS
Hypotension, immune hypersensitivity reaction, shaking, chills, urticaria

NOTE: 儲存2-8℃避光

· Each bottle contains approximately albumin 1.55g, human immunoglobulin 0.5g(IgG 0.355g, IgA 0.078g, IgM 0.024g) and electrolytes(Na, K, Ca, Mg, Cl)
· Initial infusion rate should not exceed 1mL/min. After 10 mins, the rate may gradually be increased to 3-4mL/min if well tolerated by the patient.
· It may impair the efficacy of live attenuated virus vaccines(e.g. measles, rubella, mumps and varicella)

for at least 6 wks and up to 3 mons.

藥名相似:

外觀相似:

外觀描述: 50mL微黃色透明注射液，『鋁』蓋玻璃瓶

26.08 Blood Derivative

37797 **C / Caution**

Normosang 25 mg/mL Concentrate for Solution for Infusion 血基賞濃縮輸注液 25 毫克/毫升

急用Human hemin inj 250mg/10mL amp

Dosage: 2急用藥 37797

Adult
·Acute attacks of hepatic porphyria (acute intermittent porphyria, porphyria variegata, hereditary
coproporphyria): IV infusion, 3mg/kg/day for 4 days, Max 250mg/day

Pediatric
·Acute attacks of hepatic porphyria (acute intermittent porphyria, porphyria variegata, hereditary
coproporphyria): Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

An empiric reduction in dosage in uremic patients has been suggested

P: inj: 250mg/10mL amp (37797)

ADR:

COMMON
Injection site reaction, Phlebitis, Headache, Fever.
SERIOUS
Iron overload, Serum ferritin high.

NOTE: 避光冷藏，不可冷凍

·《Contraindications》Known hypersensitivity to hemin；
·Each dose should be diluted in 100 mL of 0.9% NaCl in a glass bottle and infused intravenously over at least 30 mins into a large antebrachial or central vein using an inline filter.
·Each amp contains 1 g of ethanol (96 %), arginine and propylene glycol as excipients

藥名相似:

外觀相似:

外觀描述: 10mL深色注射液，褐色玻璃安瓿，白底黑字標籤

26.10 Hemorrheologic Agents

22561 **C / Infant risk can**

THRONE ENTERIC SUGAR COATED TABLETS 100MG "YUN G SHIN" "永信" 克栓腸溶糖衣錠１００公絲（配妥西菲林）

Pentoxifylline 100mg tab

Dosage: 1常備品 22561

Adult
·Intermittent claudication: 400mg tid for 8 wks (If adverse GI and/or CNS effects develop, reduced to 400mg twice daily)
·Acute alcoholic hepatitis: 400mg tid
·Diabetic complications: PO, 400mg tid
·Venous ulcers: PO, 800mg tid
·Vascular inner ear disease:1600mg/day div 2-4 doses
·Vascular retinal disease:1600mg/day div 2-4 doses

Pediatric
(not approved by FDA)
·Preventment of coronary artery lesions secondary to Kawasaki's disease: PO, 20mg/kg daily, adjunctive treatment in infants and children up to age 7

Dosing adjustments in hepatic impairment:

The presence of cirrhosis affects the pharmacokinetics of pentoxifylline, no dosage adjustment appears necessary in this patient population as extrahepatic metabolism may exist.

Dosing adjustments in renal impairment:

Clcr 10-50mL/min: 400 mg orally every 12-24hrs
Clcr < 10mL/min: 400mg orally every 24 hrs

P: Tab: 100mg(22561); SR tab: 400mg(22565); Inj: 100mg/5mL Amp(32134)

ADR:

COMMON
dyspepsia, nausea, vomiting, dizziness, headache
SERIOUS
angina, edema, hypotension, arrhythmias, confusion, depression, seizures, aplastic anemia, leukopenia, thrombocytopenia, hepatitis, jaundice, elevated LFTs

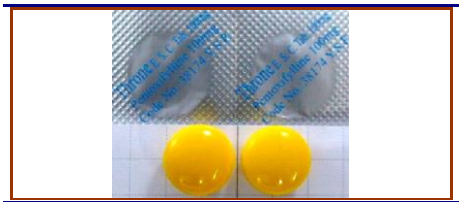
NOTE: 室溫儲存

可於餐間與食物併服
Contraindications: hypersensitivity to pentoxifylline or methylxanthines, recent cerebral hemorrhage, recent retinal hemorrhage

藥名相似: Tab: 100mg(22561); SR tab: 400mg(22565); I

外觀相似:

外觀描述: 黃色圓形糖衣錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1027011

26.10 Hemorrheologic Agents

22565 C / Infant risk can

FORFLOW SUSTAINEDRELEASED TABLETS 400MG (PENTOXIFYLLINE) "M.S." "美時"福流持續釋放錠400毫克(配妥西菲林)

Pentoxifylline 400mg SR tab

Dosage: 1常備品 22565

Adult
·Intermittent claudication: 400mg tid for 8 wks (If adverse GI and/or CNS effects develop, reduced to 400mg bid)
·Acute alcoholic hepatitis: 400mg tid
·Diabetic complications: 400mg tid
·Venous ulcers: 800mg tid
·Vascular inner ear disease: 1600mg/day div 2-4 doses
·Vascular retinal disease: 1600mg/day div 2-4 doses

Pediatric
·Preventment of coronary artery lesions secondary to Kawasaki's disease: PO, 20mg/kg daily, adjunctive treatment in infants and children up to age 7

Dosing adjustments in hepatic impairment:

The presence of cirrhosis affects the pharmacokinetics of pentoxifylline, no dosage adjustment appears necessary in this patient population as extrahepatic metabolism may exist.

Dosing adjustments in renal impairment:

Clcr 10-50mL/min: 400mg orally every 12-24hrs
Clcr< 10mL/min: 400mg orally every 24 hrs

P: Tab: 100mg(22561); SR tab: 400mg(22565); Inj: 100mg/5mL Amp(32134)

ADR:

COMMON
dyspepsia, nausea, vomiting, dizziness, headache
SERIOUS
angina, edema, hypotension, arrhythmias, confusion, depression, seizures, aplastic anemia, leukopenia, thrombocytopenia, hepatitis, jaundice, elevated LFTs

NOTE: 室溫儲存

1.整粒吞服,不可磨粉;可於餐間與食物併服
2.Contraindications: hypersensitivity to pentoxifylline or methylxanthines, recent cerebral hemorrhage,
recent retinal hemorrhage

藥名相似:

外觀相似:

外觀描述: 白色長橢圓錠，一面中央有痕及"LO｜09"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1040399

26.10 Hemorrheologic Agents

34802 C / Unknown(有

LOW MOLECULAR DEXTRAN DEXTROSE INJECTION "OTSUKA" "大塚"低分子血賜多朗滴注射液

Dextran D (low molecule) 500mL bot

Dosage: 1常備品 34802

Adult
·Pump prime: 10-20mL/kg; Max.20mL/kg (varies with volume of pump oxygenator)
·Prophylaxis of venous thrombosis & pulmonary embolism: IV, 500-1000mL(or 10mL/kg) on surgery day; followed by 500mL/day for 2-3 days.(may be given every second or third day, up to 2 wks.)
·Traumatic shock: IV, initial 500mL as rapidly as tolerated, Max.20mL/kg in first 24hrs; beyond 24 hrs, daily dose < 10mL/kg, for no more than 5 days

Pediatirc (not approved by FDA)
·Traumatic shock: IV, initial 10mL/kg, infused as rapidly as necessary to effect improvement; Max. 20mL/kg in first 24 hrs; beyond 24 hrs, Max.10 mL/kg, for no more than 5 days

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Dextrans are primarily eliminated by the kidney, dosage adjustment may be necessary in patients with renal insufficiency.(However, no significant alteration in elimination occurred when Clcr 30-142mL/min)

P: Inj: 500mL(34802)

ADR:

SERIOUS
acute renal failure, anaphylaxis, congestive heart failure, pulmonary edema, thrombocytopenia

NOTE: 室溫儲存

1. Dextran is not a substitute for blood products
2. Contraindications: pulmonary edema, renal disease with severe oliguria or anuria, severe bleeding disorders, severe congestive heart failure

藥名相似:

外觀相似:

外觀描述: 500mL透明注射液透明塑膠瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1012824

26.10 Hemorrheologic Agents

34811 UK /

GELOFUSINE "柏朗" 佳樂施 注射液

Succinylated gelatin 40mg/mL, 500mL/bot

Dosage: 1常備品 34811

Adult
·Mild hypovolemia: IV, 500-1000mL
·Severe hypovolemia: IV, 1000-2000mL
·In emergencies with vital indications: IV, 500mL as rapid infusion, after improvement of circulation parameters, further infusion to commensurate with the volume deficit
·Hemodilution: IV, corresponds to the volume of blood removed, no more than 20mL/kg/day
·Extra-corporeal circulation: IV, 500-1500mL

Dosing adjustments in hepatic impairment:

Adjust the dosage according to the individual clinical situation

Dosing adjustments in renal impairment:

Adjust the dosage according to the individual clinical situation

P: Inj: 40mg/mL, 500mL/B(34811)

ADR:

Allergic reactions

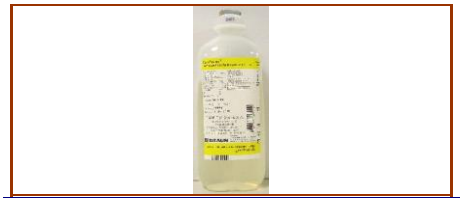
NOTE: 室溫儲存

·Patients should be observed carefully paticularly when administration of the first 20-30mL
·Maximum infusion rate depends on the particular cardio-circulatory situation
·Osmolarity: 274mOsm/L

藥名相似:

外觀相似:

外觀描述: 500mL淡黃透明注射液透明塑膠瓶，『金』色鋁箔封口



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024041

26.10 Hemorrheologic Agents

34812 C / Unknown(有

VOLUVEN 6% SOLUTION FOR INFUSION 量能靜脈輸注液

Hydroxyethyl starch 6% 500mL

Dosage: 1常備品 34812

Adult
·Hypovolemia: IV infusion, the daily dose and rate of infusion depend on the patient's blood loss, on the maintenance or restoration of hemodynamics and on the hemodilution, Max. 50mL/kg/day

Pediatric
·Safety and efficacy not established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr<10mL/min: Reduce volume by 20 to 50%

P:

ADR:

SERIOUS
Blood coagulation disorder, hepatotoxicity, intracranial hemorrhage, anaphylactoid reactions

NOTE: 室溫儲存

·Each mL contains: Poly(O-2-Hydroxyethyl) starch 60mg, Sodium chloride 9mg (Na+: 154mmol/L, Cl-:154mmol/L)
·Osmolarity: 308mOsm/L

藥名相似:

外觀相似:

外觀描述: 500mL透明注射液透明軟袋有『藍』色輸注口及『白』色添加藥物口

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024260

26.12C ADP Receptor Inhibitors

25232 B /

LICODIN F.C. TABLET 100MG (TICLOPIDINE) 利血達膜衣錠100毫克(梯可比定)

Ticlopidine HCl 100mg FC tab

Dosage: 1常備品 25232

Adult
·Coronary artery bypass graft, thromboembolic stroke; prophylaxis: PO, 250 mg bid
·Placement of stents in coronary artery, In combination with aspirin: PO, 250 mg bid for 30 days

Pediatric
·safety and efficacy have not been established in pediatric patients

Dosing adjustments in hepatic impairment:

No published data are available on dosage alterations in patients with liver disease, it would be prudent to carefully monitor these patients and alter dosage if bleeding times become excessively prolonged.

Dosing adjustments in renal impairment:

Bleeding time was significantly increased in patients with moderate renal impairment; reductions in dose may be required in renal impairment

P: Tab:100mg FC(25232)

ADR:

COMMON
anorexia, abdominal pain, diarrhea, dyspepsia, nausea, vomiting, abnormal pain, LFTs, dizziness, pruritus, purpura, rash
SERIOUS
neutropenia, thrombotic thrombocytopenia, purpura aplastic anemia

NOTE: 室溫儲存

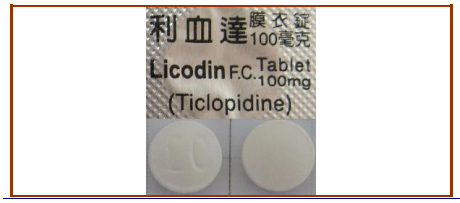
1.Contraindications: active bleeding disorders, neutropenia/thrombocytopenia, severe liver

impairment
2.The drug should be taken with food to maximize GI absorption and tolerance.

藥名相似: Tab:100mg FC(25232)

外觀相似:

外觀描述: 白色圓扁錠，有L C字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1031596

26.12C ADP Receptor Inhibitors

25233 B /

PLAVIX FILM-COATED TABLETS 75MG 保栓通膜衣錠75毫克

Clopidogrel 75mg tab

Dosage: 1常備品 25233

Adult
·Prophylaxis against thrombotic events in patients with recent MI, recent stroke or established peripheral arterial disease: PO, 75 mg once daily
·Prophylaxis against thrombotic events in patients with acute coronary syndrome, with and without PCI or CABG: PO, initial LD of 300 mg, followed by 75 mg daily given with aspirin 75-325 mg daily

Pediatric
·safety and efficacy have not been established in pediatric patients

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab:75mg(25239)(25233)

ADR:

COMMON
minor bleeding, abdominal pain, constipation, diarrhea, dyspepsia, gastritis, skin rash, purpura,edema, hypertension, headache, dizziness, arthralgia, backache, hypercholesterolemia, chest pain
SERIOUS
thrombotic thrombocytopenic purpura, GI ulcer, GI hemorrhage, intracranial hemorrhage, anemia, agranulocytosis, neutropenia, abnormal LFTs, hepatitis, anaphylaxis, erythema multiforme, ocular bleeding, atrial fibrillation, CHF, abnormal renal function, acute renal failure

NOTE: 室溫儲存

1.Contraindication: Intracranial hemorrhage, peptic ulcer or other active pathological bleeding
2.Discontinue clopidogrel 5 days prior to surgery

藥名相似: Tab:75mg(25239)(25233)

外觀相似:

外觀描述: 粉紅色圓扁錠 ，有75字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022932

26.12C ADP Receptor Inhibitors

25239 B /

Clopidogrel "Alvogen" F.C. tablets 75mg 可諾通"艾威群"膜衣錠75毫克

Clopidogrel 75mg tab

Dosage: 1常備品 25239

Adult
·Prophylaxis against thrombotic events in patients with recent MI, recent stroke or established peripheral arterial disease: PO, 75 mg once daily
·Prophylaxis against thrombotic events in patients with acute coronary syndrome, with and without PCI or CABG: PO, initial LD of 300 mg, followed by 75 mg daily given with aspirin 75-325 mg daily

Pediatric
·safety and efficacy have not been established in pediatric patients

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab:75mg(25239)(25233)

ADR:

COMMON
minor bleeding, abdominal pain, constipation, diarrhea, dyspepsia, gastritis, skin rash, purpura,edema, hypertension, headache, dizziness, arthralgia, backache, hypercholesterolemia, chest pain
SERIOUS
thrombotic thrombocytopenic purpura, GI ulcer, GI hemorrhage, intracranial hemorrhage, anemia, agranulocytosis, neutropenia, abnormal LFTs, hepatitis, anaphylaxis, erythema multiforme, ocular bleeding, atrial fibrillation, CHF, abnormal renal function, acute renal failure

NOTE: 室溫儲存

1.Contraindication: Intracranial hemorrhage, peptic ulcer or other active pathological bleeding
2.Discontinue clopidogrel 5 days prior to surgery

藥名相似:

外觀相似:

外觀描述: 粉紅色圓扁錠，中央有刻痕且有PL及T20字樣)

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1057819

26.12C ADP Receptor Inhibitors

25241 C /

BRILINTA Film-coated Tablets 90 mg 百無凝膜衣錠 90 毫克

Ticagrelor 90mg FC tab

Dosage: 1常備品 25241

Adult
·Acute coronary syndrome - Thrombosis; Prophylaxis: loading dose, PO, 180 mg with aspirin (usually 325 mg) once; maintenance, PO, 90 mg bid with aspirin 75-100 mg qd.
·Percutaneous coronary intervention - Thrombosis; Prophylaxis: loading dose, PO, 180 mg with aspirin (usually 325 mg) once; maintenance, PO, 90 mg bid with aspirin 75 to 100 mg qd.(duration of therapy for stent placement should be at least 12 months; continuation of therapy beyond 12 months may be considered for drug-eluting stents)

Pediatric
·safety and efficacy have not been established in pediatric patients

Dosing adjustments in hepatic impairment:

■hepatic impairment (severe): contraindicated
■hepatic impairment (mild): no dosage adjustments necessary

Dosing adjustments in renal impairment:

No dosage adjustments necessary

P: Tab:90mg(25241)

ADR:

COMMON
Bleeding-major and minor, Headache, Serum creatinine raised, Cough, Dyspnea
SERIOUS
Atrial fibrillation, Syncope, Bleeding-major

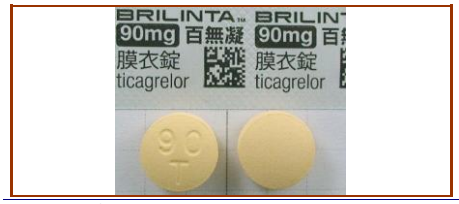
NOTE: 室溫儲存

Daily maintenance doses of aspirin above 100 mg are not recommended

藥名相似:

外觀相似:

外觀描述: 圓形、雙凸、黃色膜衣錠，一面有 90 及 T 字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025691

26.12C ADP Receptor Inhibitors

25249 ɔt be ruled out / Infant risk can

Efient* F.C. Tablets 3.75 mg 抑凝安* 膜衣錠3.75毫克

Prasugrel 3.75mg FC tab

Dosage: 1常備品 25249

ADULT
· Acute coronary syndrome - percutaneous coronary intervention - thrombosis; prophylaxis: PO, LD 60mg; MD >60 kg 10mg QD, <60 kg 5mg QD
· Taiwan and Japan EFIENT* package leaflet: PO, LD 20mg; MD 3.75mg QD

PEDIATRIC
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

· Mild to moderate (Child-Pugh A and B): No dosage adjustment needed
· Severe (Child-Pugh C): NDA

Dosing adjustments in renal impairment:

· No dosage adjustment needed

P: P Tab: 3.75mg(25249), 5mg(25250)

ADR:

COMMON
Hypertension, hyperlipidemia, backache, headache, bleeding from nose
SERIOUS
Atrial fibrillation, bradyarrhythmia, neoplasm of colon, major hemorrhage, leukopenia, thrombotic thrombocytopenic purpura, angioedema

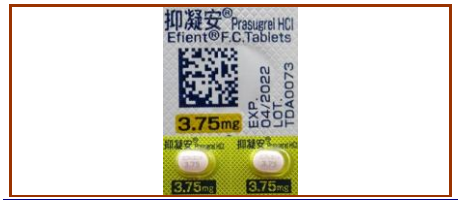
NOTE: 室溫儲存

· Discontinuation for surgery: When possible, discontinue prasugrel 5-7 days before any surgery

藥名相似:

外觀相似:

外觀描述: 白色微紅橢圓形錠，有3.75字樣



26.12C ADP Receptor Inhibitors

25250 ɔt be ruled out / Infant risk can

Efient* F.C. Tablets 5 mg 抑凝安* 膜衣錠5毫克

Prasugrel 5MG FC tab

Dosage: 1常備品 25250

ADULT
· Acute coronary syndrome - percutaneous coronary intervention - thrombosis; prophylaxis: PO, LD 60mg; MD >60 kg 10mg QD, <60 kg 5mg QD
· Taiwan and Japan EFIENT* package leaflet: PO, LD 20mg; MD 3.75mg QD

PEDIATRIC
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

· Mild to moderate (Child-Pugh A and B): No dosage adjustment needed
· Severe (Child-Pugh C): NDA

Dosing adjustments in renal impairment:

· No dosage adjustment needed

P: P Tab: 5mg(25250), 3.75mg(25249)

ADR:

COMMON
Hypertension, hyperlipidemia, backache, headache, bleeding from nose
SERIOUS
Atrial fibrillation, bradyarrhythmia, neoplasm of colon, major hemorrhage, leukopenia, thrombotic

thrombocytopenic purpura, angioedema

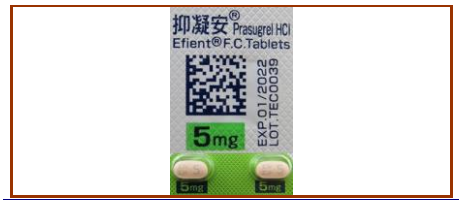
NOTE: 室溫儲存

· Discontinuation for surgery: When possible, discontinue prasugrel 5-7 days before any surgery

藥名相似:

外觀相似:

外觀描述: 紅色微黃橢圓形錠，中間有一刻痕及5字樣



26.12D Glycoprotein IIb/IIIa Antagonist

34866 **B / Unknown(有**

AGGRASTAT CONCENTRATE FOR INFUSION 雅瑞濃縮輸注液

■Tirofiban HCl 12.5mg/50mL vial

Dosage: 1常備品 34866

Adult

·Acute coronary syndrome in patient undergoing angioplasty/atherectomy or managed medically: IV infusion, 0.4 mcg/kg/min for 30 min then 0.1 mcg/kg/min for 12-24 hr after angioplasty/atherectomy

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Severe renal impairment (SCr<30 mL/min): give half the usual dose - 0.2 mcg/kg/min IV for 30 min then 0.05 mcg/kg/min

P: Inj:12.5mg/50mL Vial(34866)

ADR:

COMMON
bleeding,minor, bradycardia, dizziness
SERIOUS
bleeding, major, coronary artery dissection, thrombocytopenia

NOTE: 室溫保存

Contraindications: aortic dissection,bleeding, major surgery, trauma, stroke within 30 days,concomitant use of another parenteral GPIIb/IIIa inhibitor, hemorrhagic stroke history of intracranial hemorrhage, neoplasm, arteriovenous malformation, or aneurysm, pericarditis, severe hypertension (systolic BP greater than 180 mmHg and/or diastolic BP greater than 110 mmHg), thrombocytopenia following prior tirofiban administration

藥名相似:

外觀相似:

外觀描述: 50mL透明注射液『淺橙』蓋透明玻璃瓶，蓋上有FLIP及OFF字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022606

26.14 Platelet Reducing Agents

27504 **C /**

AGRYLIN 0.5MG CAPSULES 安閣靈 0.5毫克膠囊

Anagrelide HCl 0.5 mg cap

Dosage: 1常備品 27504

Adult

· Thrombocythemia: PO, initial 0.5 mg bid or 1 mg qd for at least 1 wk; MD, titrate to the lowest effective dose to maintain platelets < 600,000/mcL; Max. 10 mg/day or 2.5 mg in a single dose

Pediatric

Not FDA approved in children under 16 yrs

· Thrombocythemia: PO, initial 0.5 mg qd; Max. 10 mg/day or 2.5 mg in a single dose

Dosing adjustments in hepatic impairment:

>1.5 times upper limit of normal liver function tests: provide close monitoring.
hepatic disease: PO, initial 0.5 mg/day for at least 1 wk, then MAX 0.5 mg/day increase in any 1 wk.

Dosing adjustments in renal impairment:

SCr >2 mg/dL: provide close monitoring

P: Cap: 0.5 mg (27504)

ADR:

COMMON
·Cardiovascular: Chest pain (8%), Edema (Adult, 21%), Palpitations (Adult, 26%), Peripheral edema (Adult, 9%), Tachycardia (Adult, 8%)
·Dermatologic: Pruritus (Adult, 6%), Rash (Adult, 8%)
·Gastrointestinal: Abdominal pain (Adult, 16%), Diarrhea (Adult, 26%), Flatulence (Adult, 10%), Indigestion (Adult, 5%), Loss of appetite (Adult, 8%), Nausea (Adult, 17%), Vomiting (Adult, 10%)
·Musculoskeletal: Backache (Adult, 6%)
·Neurologic: Asthenia (Adult, 23%), Dizziness (Adult, 15%), Headache (44%)
·Respiratory: Cough (Adult, 6%), Dyspnea (12%)
·Other: Fever (9%), Malaise (Adult, 6%), Pain (Adult, 15%)
SERIOUS
·Cardiovascular: Prolonged QT interval, Torsades de pointes, Ventricular tachycardia (Adult, less than 1%)
·Hematologic: Hemorrhage (Adult, 1% to less than 5%)
·Respiratory: Interstitial lung disease

NOTE: 室溫儲存

· It should be taken during or within 20 mins of a full meal or a liquid nutritional supplement in order to enhance absorption.

藥名相似:

外觀相似:

外觀描述: 白色膠囊，有063字樣

26.16 Thrombolytic Agents

33605 **B / Unknown(有**

UROKINASE INJECTION 60000IU "YAO CHIH HSIANG"* "藥之鄉"佑樂克栓注射劑 6 萬國際單位

■Urokinase inj 60000 int unit pow in vial

Dosage: 1常備品 33605

Adult

·Pulmonary embolism: IV, LD, 4400 IU/kg over 10 minutes(90 mL/hr). Continuous infusion, 4400 IU/kg/hr for 12 hrs (15 mL/hr), flush line at end of infusion

Pediatric

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 60,000 IU Vial(33605)

ADR:

COMMON
decreased hematocrit
SERIOUS
anaphylaxis,infusion reaction (fever, chills, rigors, dyspnea, tachycardia, hypotension, acidosis, back pain, nausea, vomiting)
reperfusion ventricular arrhythmias, chest pain, vascular embolization,significant bleeding

NOTE: 室溫儲存

1.If heparin is to be used, do not administer a loading dose
2.Contraindications: Active internal bleeding, severe uncontrolled hypertension, recent intracranial or intraspinal surgery or trauma, intracranial neoplasm, arteriovenous malformation, or aneurysm, known bleeding diathesis, history of cerebrovascular accident

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『黃』蓋透明玻璃小瓶，蓋上有GMP及EASY OPEN字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045538

26.16 Thrombolytic Agents

33608 **C / Infant risk can**

ACTILYSE INJECTION 栓體舒注射液

■Alteplase,recombinant(rt-PA) 50mg pow in vial with 50mL vial solvent

Dosage: 1常備品 33608

Adult

·Acute ischemic stroke: IV, 0.9 mg/kg, MAX. 90mg; initial, IV bolus over 1 minute, 10% of the total dose, then the remainder IV infusion over 60 minutes.
·Pulmonary embolism: 10mg IV bolus, followed by 90mg IVD 2hrs, if BW< 65kg total dose not to exceed 1.5mg/kg.
·Acute myocardial infarction:
Symptoms appear within 6 hours: 90-minute infusion(Accelerated infusion):
≧65kg: 15mg bolus (over 1-2 mins), followed by 50mg IVD 30min, then 35mg IVD next 60min; total dose not to exceed 100mg.
< 65kg: 15mg bolus(over 1-2 mins), followed by 0.75mg/kg(dose not to exceed 50mg) IVD 30min, then 0.5mg/kg(dose not to exceed 35mg) IVD next 60min.
Symptoms appear between 6~12 hours: 3-hours infusion:
10mg bolus(over 1-2 mins), followed by 50mg IVD 1hrs, then 40mg IVD next 2hrs, if BW< 65kg total dose not to exceed 1.5mg/kg.
·Cerebrovascular accident, acute: 0.9 mg/kg IV (NOT to exceed 90 mg), infused over 60 minutes with 10% of the dose given as an initial bolus over 1 minute
·Pulmonary embolism: 100 mg IV infused over 2 hours; heparin should be instituted near the end of or immediately following the infusion when the partial thromboplastin time or thrombin time returns to twice normal or less
·Central venous catheter occlusion:
10 kg-29 kg: 1 mg/mL, dose equal to 110% of catheter lumen volume, Max. 2 mL
≧30 kg: 2mg/2mL instilled into occluded catheter, up to 2 doses may be used, separated by 120 minutes

Pediatric

·Central venous access device occlusion:
10 kg-29 kg: 1mg/mL, dose equal to 110% of catheter lumen volume, Max. 2 mL, instilled into occluded catheter, up to 2 doses may be used, separated by 120 minutes
< 10 kg: 0.5 mg in NS in a volume required to fill the lumen, dwell time of 2 to 4 hours, up to 2 doses, has been used

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 50mg vial(33608)

ADR:

SERIOUS
Cardiac dysrhythmia, Cardiac tamponade, Laceration - injury, Myocardial rupture, Pericardial effusion, Pericarditis, Gastrointestinal hemorrhage, Hemorrhage, Anaphylaxis, Hypersensitivity reaction,

Cerebral herniation, Cerebrovascular accident, Intracranial hemorrhage, Ischemic stroke, Seizure, Pleural effusion, Pulmonary edema, Angioedema, Orolingual.

NOTE: 30度以下,避光儲存

·在輸注期間及輸注後24小時內，應監測血管性水腫，如發生嚴重過敏反應(如,血管性水腫)應停止輸注，並採取適當治療，包含插管。
·仿單警語：可追溯性-為提高生物藥品的可追溯性，應將所施用的藥品名和批號清楚地記錄在病歷中。
1.It should be used within 6 hrs of onset of symptoms
2.Contraindicatioons:
·Patients known to be allergic to the main component alteplase, gentamicin (micro-residues in the process) or other excipients.
·Active internal bleeding
·Current intracranial hemorrhage
·Intracranial neoplasm, arteriovenous malformation, aneurysm, or other conditions that may increase the risk of bleeding
·Bleeding diathesis
·Intracranial or intraspinal surgery within 3 months
·Serious head trauma within 3 months
·Stroke, for patients with acute myocardial infarction or pulmonary embolism within 3 months
·Severe uncontrolled hypertension
·Subarachnoid hemorrhage

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『墨綠』蓋透明玻璃小瓶，50ml稀釋液『藍』蓋透明玻璃小瓶，附一支套管

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000743

28.02 Adrenals

25600 D /

Cortisone Acetate Tablets 25mg "Pine Lawer" "柏理" 乙酸可體松錠 2 5 毫克

Cortisone acetate 25mg tab

Dosage: 1常備品 25600

Adult
·Anti-inflammatory or immunosuppressive: PO, 25-300 mg/day, div q12-24h
·Physicologic replacement: PO, 12-15mg/m(2)/day, the daily dosage div. 2/3 in the morning and 1/3 in the afternoon

Pediatric
·Anti-inflammatory or immunosuppressive: PO, 2.5-10mg/kg/day, div q6-8h
·Physicologic replacement: PO, 0.5-0.75 mg/kg/day, div q8h.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment required

P: Tab: 25mg(25600)

ADR:

COMMON
Cushing's syndrome, euphoria/depression, GI distress, growth depression, hypertension, impaired skin healing, increased risk of infection, skin atrophy
SERIOUS
cataracts, adrenocortical insufficiency, glaucoma, hyperglycemia, osteoporosis

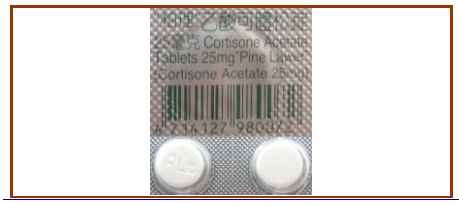
NOTE: 室溫儲存

Contraindications:
systemic fungal infections except during replacement therapy

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有PLt字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1013381

28.02 Adrenals

25601 C / Infant risk is

METISONE TABLETS 4MG (METHYLPREDNISOLONE) "S.D." "世達"蒙治爽錠4毫克

Methylprednisolone 4mg tab

Dosage: 1常備品 25601

Adult
·Adrenocortical insufficiency, anti-inflammatory, immunosuppressive: PO, 4-48mg/day depending on the severity and the specific disease.

Pediatric
·Anti-inflammatory or immunosuppressive: PO, 0.5-1.7mg/kg/day div doses q6-12h.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No adjustment in the dose is required for patients with renal dysfunction.

P: Tab: 4mg (25601); Inj: 40mg/1ml vial (35206), 500mg vial (35213)

ADR:

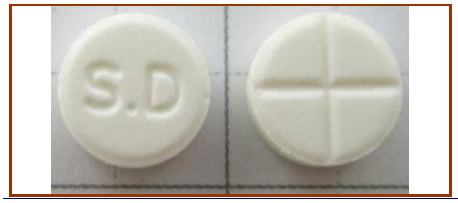
NOTE: 室溫儲存

Contraindications: Premature infants (preparations containing benzyl alcohol), systemic fungal infections, live vaccine or attenuated live vaccine in patients receiving immunosuppressive doses.

藥名相似:

外觀相似: Eltroxin* Thyroxine (25730)

外觀描述: 白色圓扁錠，一面有"S.D"字樣，另一面有十字刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1038955

28.02 Adrenals

25602 C / Infant risk is

Compesolon Tablets 5mg "Pine Lawer" (Prednisolone) "柏理" 康速龍錠 5 毫克 (培尼皮質醇)

Prednisolone 5mg tab

Dosage: 1常備品 25602

Adult
·Endocrine disorders, hematologic and neoplastic disorders, inflammatory: PO, 5-60mg/day.
·Multiple sclerosis exacerbations: PO, 200mg/day for 1wk, then 80mg qod for 1 mon.

Pediatric
·Anti-inflammatory, immunosuppressive: PO, 0.1-2mg/kg/day div doses 1-4 times/day.
·Acute asthma: PO, 1-2mg/kg/day div 1-2 times/day for 3-5 days.
·Nephrotic syndrome: PO, 2mg/kg/day (Max 80mg/day) div 3 times/day for 4wks, then reduce to 1-1.5mg/kg qod for 4wks

Dosing adjustments in hepatic impairment:

No dosage adiustment needed in patients with chronic liver disease

Dosing adjustments in renal impairment:

Dosage adiustment required

P: Tab: 5mg (25602); Oph susp: 1% 5mL/bot (29195); Oral Soln: 60mg/60mL/B (28703)

ADR:

COMMON
Euphoria/depression, GI distress, growth depression, impaired skin healing, skin atrophy, increased risk of infection,
osteoporosis
SERIOUS

Cataracts/glaucoma, Cushing's sundrome,
fluid and electrolyte disturbances,
HPA axis suppression/adrenal insufficiency,
hyperglycemia, tuberculosis reactivation

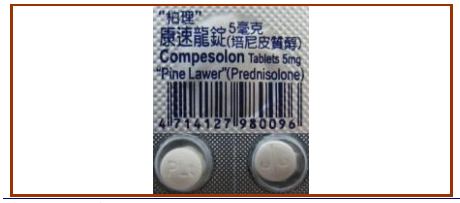
NOTE: 室溫儲存

· Pregnancy Category D if used in 1st trimester

藥名相似: Tab: 5mg (25602); Oph susp: 1% 5mL/bot (29

外觀相似: Lowen* 0.5mg Tab(23015), Calcium carbonat

外觀描述: 白色圓形錠，一面有PLt字樣，另一面中間有一刻痕，上下各有一個C字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1031676

28.02 Adrenals

25603 C /

FLORINEF TABLETS 0.1MG 富能錠0.1毫克

Fludrocortisone acetate 0.1mg tab

Dosage: 1常備品 25603

Adult
·Adrenocortical insufficiency in Addiso'n disease: PO, 0.1mg 3 times/wk to 0.2mg/day
·Salt-losing adrenogenital syndrome: PO, 0.1-0.2mg/day

Pediatric
·Adrenocortical insufficiency in Addiso'n disease, infant: PO, 0.1-0.2mg/day; child 0.05-0.1mg/day.
·Salt-losing adrenogenital syndrome, infant: PO, 0.1-0.2mg/day; child, 0.05-0.1mg/day.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 0.1mg(25603)

ADR:

COMMON
Edema, electrolyte abnormalities (ie, hypokalemia), headache, vertigo, abdominal distention, peptic ulcer, hyperglycemia, glycosuria, growth suppression in children,impaired wound healing, bruising, petechiae, menstrual irregularities, muscle weakness, myopathy, rash, urticaria
SERIOUS
Congestive heart failure, hypertension, adrenal suppression, cardiomegaly, increased intracranial pressure, seizures, thrombophlebitis.

NOTE: 冰箱冷藏，不可冷凍

·Contraindications: Systemic fungal infections
·在室溫(25℃)下最多可存放30天。不得將未使用的錠劑再放回冰箱內儲存，應妥善棄置這些錠劑。

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，有"FT01"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021043

28.02 Adrenals

25605 C /

DECONE TABLETS (DEXAMETHASONE) "SINPHAR" 得康錠（的剎美剎松）

Dexamethasone 0.5mg tab

Dosage: 1常備品 25605

Adult
· Antiemetic: IV, 20 mg before chemotherapy; IV/PO, 8 mg bid for 3 days after chemotherapy
· Arthritic conditions: Intraarticular, 2-4 mg in large joints, 0.8-1 mg in small joints, 2-3 mg in bursae, 0.4-1 mg in tendon sheaths; no more often than every 3-5 days
· Allergic disorders: acute, first day IM, 4-8 mg; second and third days, PO, 3 mg in two divided doses each day; fourth day, PO, 1.5 mg in two divided doses; fifth and sixth days, PO, 0.75 mg each day; seventh day, no treatment
· Antenatal administration in preterm delivery: IM, 6 mg q12h for 4 doses
· Cerebral edema: IV, initial 10 mg, followed by 4 mg IM q6h until symptoms of cerebral edema subside

Pediatric
· Antiemetic: IV ,10 mg/m(2) before chemotherapy, then 5 mg/m(2) q6h as needed; Max. 20 mg
· Airway edema: PO, IM, IV, 0.5-2 mg/kg/day in divided doses q6h
· Bacterial meningitis: (2 months or older) IV, 0.6 mg/kg/day divide every 6 hr for the first 4 days of antibiotic treatment
· Cerebral edema: IV, IM, initial 1-2 mg/kg followed by 1-1.5 mg/kg/day PO, IV, or IM divided every 4-6h; Max. 16 mg/day
· Extubation: PO, IV, IM, 0.5-2 mg/kg/day in divided doses q6h; begin 24 hr before extubation and continue for 4-6 doses afterward
· Inflammatory conditions: PO, IV, IM, 0.08 to 0.3 mg/kg/day or 2.5 to 10 mg/m(2)/day in divided doses q6-12h

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 0.5mg (25605), Inj: 5mg/1mL Vial (35201)

ADR:

COMMON
cataracts, Cushing's syndrome, euphoria/depression, GI distress, growth depression, hypertension, impaired skin healing, increased risk of infection, osteoporosis, skin atrophy, tuberculosis reactivation
SERIOUS
adrenocortical insufficiency, glaucoma,

hyperglycemia

NOTE: 室溫儲存

Contraindication: systemic fungal infection

藥名相似:

外觀相似: Phenobarbital 30mg Tab(22865)

外觀描述: 粉紅色圓扁錠，一面有刻痕，另一面有"P"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1019418

28.02 Adrenals

25607 C /

DORISON TABLETS (DEXAMETHASONE) "ROYAL" 得立生錠（的剎美剎松）

Dexamethasone 4mg tab

Dosage: 1常備品 25607

Adult

· Allergic disorders: acute, first day IM, 4-8 mg; second and third days, PO, 3 mg in two divided doses each day; fourth day, PO, 1.5 mg in two divided doses; fifth and sixth days, PO, 0.75 mg each day; seventh day, no treatment

· Malignant lymphoma: Optimal dosing and timing not yet defined

· Multiple myeloma: commonly administered as 40 mg ORALLY once daily for 4 days, every 3 to 4 weeks in combination with other agents

Pediatric

· Allergic disorder: 0.02 to 0.3 mg/kg/day (0.6 to 9 mg/m(2) bsa/day) ORALLY in 3 or 4 divided doses depending on disease being treated and patient response

· Neoplastic disease, Palliative management of leukemias and lymphomas: 0.02 to 0.3 mg/kg/day (0.6 to 9 mg/m(2) bsa/day) ORALLY in 3 or 4 divided doses depending on disease being treated and patient response

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 0.5mg (25605), 4mg (25607), Inj: 5mg/1mL Vial (35201)

ADR:

COMMON
cataracts, Cushing's syndrome, euphoria/depression, GI distress, growth depression, hypertension, impaired skin healing, increased risk of infection, osteoporosis, skin atrophy, tuberculosis reactivation
SERIOUS
adrenocortical insufficiency, glaucoma, hyperglycemia

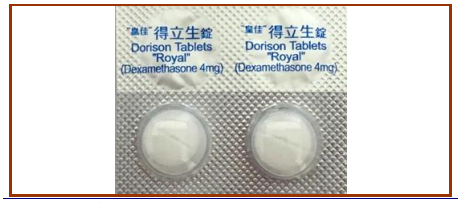
NOTE: 室溫儲存

Contraindication: systemic fungal infection

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1019643

28.02 Adrenals

25609 ɔt be ruled out / Infant risk can

Cortiment TM MMX TM 9 mg prolonged release tablets 可帝敏持續性釋放錠9毫克

Budesonide 9mg PR tab

Dosage: 1常備品 25609

Aldult

·Mild to moderate ulcerative colitis: PO, 9mg QD in the morning for up to 8 weeks

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P:

ADR:

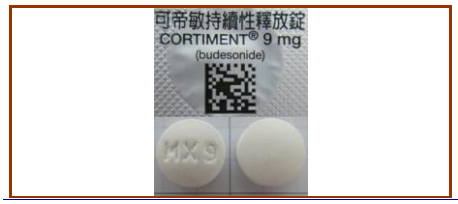
COMMON
Diarrhea, nausea, arthralgia, headache, respiratory tract infection, sinusitis
SERIOUS
Cushing's syndrome, hypocortisolism secondary to another disorder, anaphylaxis, hypersensitivity reaction, osteoporosis, cataract, glaucoma, pneumonia, angioedema

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色圓凸錠，一面有"M X 9"字樣刻痕



28.02 Adrenals

28703 C /

Kidsolone ORAL SOLUTION "CENTER" "晟德" 必爾生口服液

Prednisolone oral soln 60mg/60mL

Dosage: 1常備品 28703

Adult

·Allergic, Asthma, Inflammatory, Endocrine disorder, Neoplastic and Hematopoietic disease: PO, 5-60 mg/day

·Multiple sclerosis exacerbations: PO, 200mg/day for 1wk, then 80mg qod for 1 mon.

Pediatric
·Allergic, Inflammatory, Endocrine disorder, Neoplastic and Hematopoietic disease: PO, 0.14 to 2 mg/kg/day (4-60 mg/m(2)/day), div.3-4 doses
·Asthma, uncontrolled: PO, 1-2 mg/kg/day, qd or div.3-4 doses for 3-10 days or longer if necessary
·Nephrotic syndrome: PO, 2mg/kg/day or 60 mg/m(2)/day, div.3 doses for 4 wk, then 1-1.5mg/kg or 40 mg/m(2) qod for 4 wk

Dosing adjustments in hepatic impairment:

No dosage adjustment required in patients with chronic liver disease

Dosing adjustments in renal impairment:

No dosage adjustment required

P: Oral Soln: 60mg/60mL/B (28703); Tab: 5mg (25602); Oph Soln: 1% 5mL/B (29195)

ADR:

COMMON
Decreased body growth, Depression, Euphoria, Impaired skin healing, At risk of infection,
SERIOUS
Adrenal insufficiency, Hyperglycemia, Cataract, Glaucoma, Disorder of fluid, Osteoporosis

NOTE: 室溫儲存

·《Contraindications》systemic fungal infections; hypersensitivity to prednisoLONE or its components; live of live attenuated vaccines ;
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 60mL淡橘色澄清液體，半透明塑膠瓶，白底橘色區塊標簽

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046614

28.02 Adrenals

35201 **C / Unsafe**

DEXAMETHASONE INJECTION "生達" 力佳爽注射液

Dexamethasone Phosphate Disodium 5mg/1mL amp

Dosage: 1常備品 35201

Adult
· Antiemetic: IV, 20 mg before chemotherapy; IV/PO, 8 mg bid for 3 days after chemotherapy
· Arthritic conditions: Intraarticular, 2-4 mg in large joints, 0.8-1 mg in small joints, 2-3 mg in bursae, 0.4-1 mg in tendon sheaths; no more often than every 3-5 days
· Allergic disorders: acute, first day IM, 4-8 mg; second and third days, PO, 3 mg in two divided doses each day; fourth day, PO, 1.5 mg in two divided doses; fifth and sixth days, PO, 0.75 mg each day; seventh day, no treatment
· Antenatal administration in preterm delivery: IM, 6 mg q12h for 4 doses
· Cerebral edema: IV, initial 10 mg, followed by 4 mg IM q6h until symptoms of cerebral edema subside

Pediatric
· Antiemetic: IV ,10 mg/m(2) before chemotherapy, then 5 mg/m(2) q6h as needed; Max. 20 mg
· Airway edema: PO, IM, IV, 0.5-2 mg/kg/day in divided doses q6h
· Bacterial meningitis: (2 months or older) IV, 0.6 mg/kg/day divide every 6 hr for the first 4 days of antibiotic treatment
· Cerebral edema: IV, IM, initial 1-2 mg/kg followed by 1-1.5 mg/kg/day PO, IV, or IM divided every 4-6h; Max. 16 mg/day
· Extubation: PO, IV, IM, 0.5-2 mg/kg/day in divided doses q6h; begin 24 hr before extubation and continue for 4-6 doses afterward
· Inflammatory conditions: PO, IV, IM, 0.08 to 0.3 mg/kg/day or 2.5 to 10 mg/m(2)/day in divided doses q6-12h

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 0.5mg (25605); Inj: 5mg/1mL amp (35201)

ADR:

NOTE: 室溫儲存

Dosage of dexamethasone sodium phosphate is expressed in terms of dexamethasone sodium phosphate.

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液『棕』色安瓿頸部有『白』點，紫底白字與白底黑字標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1003881

28.02 Adrenals

35202 **C / Infant risk can**

HYDROCORTISONE INJECTION 100MG "CYH" 舒爾體爽注射劑100毫克

Hydrocortisone sodium succinate 100mg pow in vial

Dosage: 1常備品 35202

Adult
·Acute adrenal insufficiency: IV bolus 100mg, then 300mg/day div doses q8h or IVF for 48h; once stable change to oral.
·Anti-inflammatory, immunosuppressive: IM, IV, 15-240mg q12h.
·Status asthmaticus: adult & child, IV, 1-2mg/kg q6h for 24h, then MD 0.5-1mg/kg q6h.

Pediatric
·Acute adrenal insufficiency: initial IV bolus, 1-2mg/kg, then infants and young child 25-

150mg/day (older child 150-250mg/day) div doses q6-8h.
·Anti-inflammatory, immunosuppressive: infants and child, IM, IV, 1-5mg/kg/day div doses q12-24h.
·Physiologic replacement: IM, 0.25-0.35mg/kg/day.
·Status asthmaticus: IV, 1-2mg/kg q6h for 24h, then MD 0.5-1mg/kg q6h.

Dosing adjustments in hepatic impairment:

Dosage adiustment required

Dosing adjustments in renal impairment:

No dosage adiustment needed

P: Inj:100mg (35202); Cream: 1% 10g/Tube (29423); Enema: 60mL/B (29422); Oint: 50g/BX (29495), Proctosedyl Oint (29554); Proctosedyl Supp (29555)

ADR:

COMMON
Euphoria/depression, GI distress, growth depression, impaired skin healing, skin atrophy, increased risk of infection
osteoporosis
SERIOUS
Cataracts/glaucoma, Cushing's syndrome, fluid and electrolyte disturbances, HPA axis suppression/adrenal insufficiency, hyperglycemia, tuberculosis reactivation

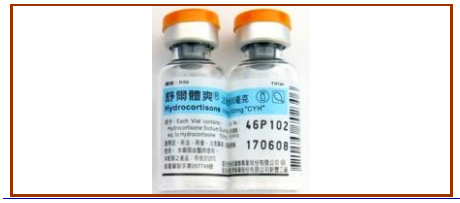
NOTE: 室溫儲存

Contraindications:
1. Live or live attenuated vaccines
2. Systemic fungal infections
3. Hypersensitivity to hydrocortisone or any of it's compenents.

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『黃』蓋透明玻璃小瓶



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1057749

28.02 Adrenals

35203 C / Unknown(有

BUFENCON INJECTION 炎康懸濁注射液

Betamethasone 5mg(as Dipropionate), Betamethasone 2mg (as Disodium phosphate) 1mL amp

Dosage: 1常備品 35203

Adult
·Dermatologic disorders, inflammatory or allergic states, bursitis, tenosynovitis, rheumatoid arthritis and osteoarthritis for relieves pain, soreness, stiffness in joints.
IM: 1-2ml
Intra-lesional: 0.25-1mL
Intra-dermal: 0.2mL/cm(2), not more than 1mL once weekly.
Intra-articular:
Dosage: (1)very large joint (hip) 1-2mL, (2)large joint (knee, ankle, shoulder) 1mL, (3)medium joint (elbow, wrist) 0.5-1 mL, (4)small joint (hand, chest) 0.25-0.5mL

Pediatric
·Adrenal insufficiency(physiologic replacement): IM, initial 0.0175 mg/kg/day div q6-12h

Dosing adjustments in hepatic impairment:

Dosage adiustment required

Dosing adjustments in renal impairment:

No dosage adiustment needed

P:

ADR:

COMMON
Euphoria/depression, GI distress, growth depression, hypertension, impaired skin healing, increased risk of infection, skin atrophy
SERIOUS
Osteoporosis, tuberculosis reactivation, adrenocortical insufficiency, cataracts, glaucoma, Cushing's syndrome, hyperglycemia

NOTE: 室溫儲存

Contraindications: hypersensitivity to betamethasone products, systemic fungal infections

藥名相似:

外觀相似:

外觀描述: 1mL白色混濁注射液透明安瓿，頸部有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1031695

28.02 Adrenals

35205 C / Infant risk can

RINDERON INJECTION 4MG/ML (BETAMETHASONE) 臨得隆注射液（貝皮質醇）

Betamethasone disodium phosphate inj 5.3mg/1mL amp(=4 mg betamethasone)

Dosage: 1常備品 35205

Adult (doses based on betamethasone base)
·Prevention of preterm neonatal morbidity and mortality: IM to the mother, 12mg q24h for 2 doses before delivery
·Bursitis, tenosynovitis, peritendinitis: Soft tissue injection, 0.4-6mg
·Shock, anaphylaxis shock, cerebral edema, acute adrenal insufficiency: IV, IM, 4-12mg q3-4h as needed or IV infusion 4-20mg qd or bid

Pediatric
·Adrenal insufficiency (physiologic replacement): IM, initial 0.0175mg/kg/day div q6-12h.

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Oph oint: Rinderon*-A 0.1% 3g/tube (29180); Oph

soln: Rinderon*-A 0.1% 5mL/B (29182); Eye drop: Garasone* 0.1% 5mL/B (29186); Soln: 0.064% 10g/B (29408); Cream: Rinderon*-VA 0.06% 5g/tube (29411); Inj: 4mg/amp(35205), 1mL/amp(35203)

ADR:

COMMON
Euphoria/depression, GI distress, growth depression, hypertension, impaired skin healing, increased risk of infection, skin atrophy
SERIOUS
Osteoporosis, tuberculosis reactivation, adrenocortical insufficiency, cataracts, glaucoma, Cushing's syndrome, hyperglycemia

NOTE: 避光儲存25℃以下

·投與本藥中發生水痘或麻疹感染時，會有致命危險，需注意(1)投與本藥前應確認是否曾接種水痘或麻疹疫苗。(2)未曾發生水痘或麻疹感染者，應小心觀察並防止水痘或麻疹之感染。疑似感染或已感染時，立即就診並接受醫師之指導，做適當之處置。(3)曾接種水痘或麻疹疫苗者，應留意水痘或麻疹發生之可能。
·投與腎上腺皮質荷爾蒙藥物予B型肝炎帶原病人，曾出現因B型肝炎病毒增殖而引起肝炎之案例。故本藥投與期間內與結束用藥後，應持續監控肝功能指數或肝炎病毒指標。
·長期或大量投與本藥，或停藥6個月內者，會有免疫機能低下之情形，應避免接種活體疫苗。
·支氣管氣喘者的氣喘發作現象會因本藥投與而惡化，用於藥物、食物或添加物等過敏之氣喘者時應特別注意。
·本藥投與硬皮症者時，應謹慎監控其血壓及腎功能，留心是否出現硬皮症腎危機的症狀。
·老年人長期投與時，可能會發生誘發感染症、糖尿病、骨質疏鬆症、高血壓、後囊下性白內障、青光眼等副作用，請慎重投與。
·小兒投與(1)有時會抑制低出生體重兒、新生兒、嬰兒、幼兒或兒童發育，需充分觀察。(2)低出生體重兒、新生兒、嬰兒、幼兒或兒童易引起投與部位組織之萎縮(凹陷)，應儘量避免肌肉內、皮內或皮下投與。
·經口投與Prednisolone時，曾發生大腸壁氣囊症、縱膈氣腫。

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液透明安瓿，頸部有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1027718

28.02 Adrenals

35206 C / Infant risk is

MEPRON POWDER FOR INJECTION "GENTLE" "政德" 美普隆乾粉注射劑

Methylprednisolone sodium succinate inj 40mg pow in vial

Dosage: 1常備品 35206

Adult
·Adrenocortical insufficiency, immunosuppression, Inflammatory conditions: IV, initial 10-40mg, subsequent IM, 40-120mg or IV, 10-250mg up 6 times daily by patient's response and condition.
Pediatric
·Anti-inflammatory or immunosuppressive: IV, 0.5-1.7mg/kg/day div doses q6-12hr. Pulse therapy: 15-30 mg/kg/dose over 30 min qd for 3 days
·Status asthmaticus: IV, LD: 2 mg/kg/dose, then additional doses of 0.5 to 1 mg/kg/dose may be given every 6 hours

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No adjustment in the dose is required for patients with renal dysfunction.

P: Tab: 4mg (25601); Inj: 40mg/1ml vial (35206), 500mg vial (35213)

ADR:

COMMON
Euphoria/depression, GI distress, peptic ulcer, mild elevations in liver function tests, growth depression, hypertension, sodium and fluid retention, hypokalemia, impaired wound healing, increased risk of infection
muscle weakness, skin atrophy
SERIOUS
Adrenocortical insufficiency, CHF, cataracts, glaucoma, Cushing's syndrome, hyperglycemia, increased intracranial, pressure, seizures, osteoporosis, tuberculosis reactivation

NOTE: 室溫儲存

Contraindications: hypremature infants (preparations containing benzyl alcohol), systemic fungal infections, live vaccine or attenuated live vaccine in patients receiving immunosuppressive doses

藥名相似:

外觀相似:

外觀描述: 白色乾粉，『橘』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043726

28.02 Adrenals

35210 C / Unknown(有

TRIAMCINOLONE SUSPENDED INJECTION 4% "TAI YU" "台裕" 安西諾隆注射液 4 %

Triamcinolone acetonide 40mg/mL vial

Dosage: 1常備品 35210

Adult
·Arthritic conditions: intra-articular, Intra-bursa, or tendon-sheath injections; initial, 2.5-15 mg, adjusted to 10-80mg/day
·Dermatologic lesions, inflammatory: Intra-dermal, intra-lesional, up 1mg/injection site, repeated at 1-wk or less frequent intervals
·Inflammatory conditions or immunosuppression: IM, initial 2.5-60mg/day, adjusted to 20-80mg/day
Pediatric

·Arthritic conditions: intra-articular, Intra-bursa, or tendon-sheath injections, Child ≧6yrs, 2.5-15 mg, repeat as needed
·Inflammatory conditions or immunosuppression: Child 6-12yrs, IM, initial 40mg at 4wk intervals

Dosing adjustments in hepatic impairment:

Dosage adiustment required

Dosing adjustments in renal impairment:

No dosage adiustment needed

P: Inj: 40mg/1ml (35210); Cream: 6gm (29412); Nasal spray: 120puff/B (29090); Mycomb* otic drops (29112)

ADR:

COMMON
Cushing's syndrome, euphoria/depression, GI distress, growth depression, hypertension impaired skin healing, increased risk of infection, osteoporosis, skin atrophy
SERIOUS
adrenocortical insufficiency, cataracts glaucoma, hyperglycemia, tuberculosis reactivation

NOTE: 室溫儲存

Contraindications:
1.hypersensitivity to triamcinolone
2.systemic fungal infections

藥名相似:

外觀相似:

外觀描述: 1mL白色粉狀混濁注射液透明安瓿，頸部有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1014914

28.02 Adrenals

35213 C / Infant risk is

STERILE SOLU-MEDROL 舒汝美卓佑注射劑

Methylprednisolone sodium succinate 500mg pow in vial

Dosage: 1常備品 35213

Adult
·Adrenocortical insufficiency, immunosuppression, Inflammatory conditions: IV, initial 10-40mg, subsequent IM, 40-120mg or IV, 10-250mg up 6 times daily by patient's response and condition

Pediatric
·Anti-inflammatory or immunosuppressive: IV, 0.5-1.7mg/kg/day div doses q6-12hr. Pulse therapy: 15-30 mg/kg/dose over 30 min qd for 3 days
·Status asthmaticus: IV, LD: 2 mg/kg/dose, then additional doses of 0.5 to 1 mg/kg/dose may be given every 6 hours

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No adjustment in the dose is required for patients with renal dysfunction

P: Tab: 4mg (25601); Inj: 40mg/1ml vial (35206), 500mg vial (35213)

ADR:

COMMON
Hypertension, Atrophic condition of skin, Impaired wound healing, Body fluid retention, Decreased body growth, Hypernatremia, Hypokalemia, Disorder of gastrointestinal tract, Peptic ulcer disease, Mild Liver function tests abnormal, At risk for infection, Muscle weakness, Depression, Euphoria.
SERIOUS
Congestive heart failure, Cushing’ s syndrome, Hyperglycemia, Primary adrenocortical insufficiency, Hepatotoxicity, Osteoporosis, Cerebrovascular accident, Infarction of spinal cord, Nerve injury, Paraplegia, Raised intracranial pressure, Seizure, Tetraplegia, Cataract, Cortical blindness, Glaucoma, Acute scleroderma renal crisis, Pulmonary tuberculosis.

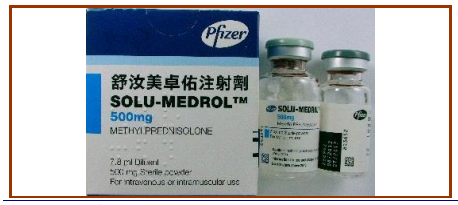
NOTE: 室溫儲存

·本品含有防腐劑成分，不應以椎管內或硬脊膜外注射給藥。
·Contraindications: premature infants (preparations containing benzyl alcohol), systemic fungal infections, live vaccine or attenuated live vaccine in patients receiving immunosuppressive doses

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『銀灰』蓋透明玻璃小瓶，蓋上有FLIP及OFF字樣，附7.8ml稀釋液『深灰』蓋透明玻璃小瓶，蓋上有FLIP及OFF字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2004922

28.04A Androgens

25630 X /

KODAZOL CAPSULES 200MG (DANAZOL) "KOJAR" "國嘉"可達娜膠囊200毫克(單那若)

Danazol 200mg cap

Dosage: 1常備品 25630

Adult
·Endometriosis: PO, 200-800mg/day div into 2 doses, continue therapy uninterrupted for 3-6 mon (up to 9 mon).
·Fibrocystic breast disease: PO, 100-400mg/day div into 2 doses.
·Hereditary angioedema: PO, 400-600mg/day div into 2-3 doses.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: 200mg(25630)

ADR:

Hepatic dysfunction, weight gain, acne, menstrual disturbances

NOTE: 室溫儲存15-30℃

Contraindications: breastfeeding, markedly impaired hepatic, renal or cardiac function, pregnancy, porphyria, undiagnosed abnormal gential bleeding

藥名相似:

外觀相似:

外觀描述: 橘色膠囊，印有KJ及144字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1031544

28.04A Androgens

25631 UK / Infant risk can

Gestrin Capsule 2.5mg "P.L." "培力" 佑汝膠囊2.5毫克

Gestrinone 2.5mg cap

Dosage: 1常備品 25631

Adult

·Endometriosis: PO, 2.5 mg twice weekly; the first dose is taken on the first day of the menstrual cycle with the second dose taken three days later; thereafter the doses should be taken on the same two days of each week, usually for a period of 6 mon.

--

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: 2.5mg(25631)

ADR:

menstrual disturbances and amenorrhoea (occasionally persistent), hot flushes, sweating, reduction in breast size, changes in libido, vaginal dryness and irritation, nervousness,acne, oily skin or hair, mild hirsutism, oedema, weight gain, deepening of the voice, androgenic alopecia

NOTE: 室溫避光

Contraindication:
1.pregnancy
2.breastfeeding

藥名相似:

外觀相似:

外觀描述: 白/粉紅色膠囊，有"Peili"及"C12"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1047913

28.04A Androgens

29608 X / Unsafe

ANDROGEL GEL 昂斯妥凝膠

Testosterone gel 1% 5g/PK

Dosage: 1常備品 29608

Adult

·Deficiency or absence of testosterone: Topical, 5g qd (preferably in the morning). After 2 wks, serum testosterone levels should be measured and if necessary, the daily dose may be increased to 7.5g or 10g.

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Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Gel: 1% 5g/PK(29608); Inj: 250mg/1mL vial in oil soln(35231)

ADR:

COMMON
Acne, application site reaction (burn-like blistering, erythema, pruritus), gynecomastia, headache
SERIOUS
Cholestatic jaundice syndrome, liver carcinoma, neoplasm of liver, peliosis hepatis, benign prostatic hyperplasia, prostate cancer

NOTE: 室溫儲存

·The gel should be applied to skin that is clean, dry and intact on the shoulders, upper arms, or abdomen and should not be applied to the genitals.
·For optimal absorption of testosterone, it appears reasonable to wait at least 5-6 hours after application prior to showering or swimming.
·Androgel* 5g contains 50mg of testosterone.
·Approximately 10% of the testosterone dose applied on the skin surface is absorbed into systemic circulation.

藥名相似:

外觀相似:

外觀描述: 5克凝膠，長條型鋁箔包裝，白底黑字，有銀色箭頭圖案

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023988

28.04A Androgens

35233 X / Unsafe

TESTOSTERONE CYPIONATE INJECTION "TAI YU" "台裕"持效睪丸素注射液

Testosterone cypionate 200mg/1mL amp

Dosage: 1常備品 35233

Adult

·Male hypogonadism: IM, 50-400mg q2-4 wks

Pediatric

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

NDA

P: Inj: 200mg/1mL Amp in oil(35233)

ADR:

COMMON
Acne, gynecomastia, headache, inflammation and pain at injection site
SERIOUS
Cholestatic jaundice syndrome, neoplasm of liver, peliosis hepatis, benign prostatic hyperplasia, prostate cancer

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液，透明安瓿頸部有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1013985

28.04A Androgens

35234 X / Unsafe

Nebido 1000 mg / 4 ml solution for injection 耐必多注射劑

Testosterone undecanoate 1000mg/4mL amp

Dosage: 1常備品 35234

Adult(<65 yrs)
·Male hypogonadism: IM, 1000mg q10-12 wks; the first injection interval may be reduced to a minimum of 6 wks

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Gel: 1% 5g/pk(29608); Inj: Testosterone undecanoate 1000mg/4mL Amp(35234), Testosterone cypionate 200mg/1mL Amp(35233)

ADR:

Diarrhea, leg pain, arthralgia, dizziness, increased sweating, headache, respiratory disorder, acne, breast pain, gynecomastia, pruritus, skin disorder, testicular pain, injection site pain, subcutaneous hematoma at the injection site

NOTE: 室溫儲存

·Testosterone undecanoate 1000mg corresponds to testosterone 631.6mg

藥名相似:

外觀相似:

外觀描述: 4mL透明注射液『棕』色安瓿頸部有紅色線條

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024688

28.04B2 5 α-reductase Inhibitor

25645 X / Unsafe

Duodart Capsules 多適達膠囊0.5mg/0.4mg

Dutasteride 0.5mg & Tamsulosin 0.4mg cap

Dosage: 1常備品 25645

Adult
·Benign prostatic hyperplasia(BPH): PO, 1 cap (dutasteride 0.5mg/tamsulosin 0.4 mg) once daily 30 minutes after the same meal each day

Pediatric
safety and effectiveness is not establishe

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Cap: DUODART*(25645)，Dutasteride 0.5mg(27235)，Tamsulosin 0.2mg(22466)

ADR:

COMMON
Disorder of breast (3.1%),dizziness (1.7%),disorder of ejaculation (9.7%), erectile dysfunction (7.8%), reduced libido (5.9%)
SERIOUS
Heart failure (0.7%), syncope, Stevens-Johnson syndrome, breast cancer(male), hypersensitivity reaction, intraoperative floppy iris syndrome, priapism, high-grade prostate cancer(1%), angioedema

NOTE: 室溫儲存

1. Contraindicated in women and children
2. Should not be handled by women who are pregnant or who may become pregnant
3.blood donation within 6 months of last dose; may present fetal risk if transfusion recipient is pregnant

藥名相似:

外觀相似:

外觀描述: 淺橘色/褐色膠囊、淺橘色一端有"GS"及"7CZ"字樣

28.04B2 5 α-reductase Inhibitor

27219 X / Unknown(有

PROPECIA F.C. TABLETS 1MG 柔沛膜衣錠 1 毫克

Finasteride 1mg FC tab

Dosage: 1常備品 27219

Adult
·Androgenetic alopecia(men only): 1mg qd, general use ≧3 mon is necessary before benefit is observed.

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Chronic renal insufficiency: no dosage adjustment

P: Tab: 5mg(27223), 1mg(27219)

ADR:

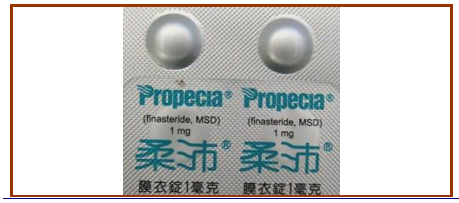
COMMON
Breast enlargement, breast tenderness, decreased libido, ejaculation disorder, erectile dysfunction.

NOTE: 室溫保存

藥名相似:

外觀相似:

外觀描述: 暗粉紅色八邊形扁錠，有PROPECIA字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022605

28.04B2 5 α-reductase Inhibitor

27223 X / Caution

Finaride Film Coated Tablets 5mg "Yung Shin" "永信" 法路寧膜衣錠5毫克

Finasteride 5mg F.C. tab

Dosage: 1常備品 27223

Adult
·Benign prostatic hyperplasia: 5mg qd. Clinical responses occur within 12wks - 6mon.
·Androgenetic alopecia(men only): 1mg qd, general use ≧3 mon is necessary before benefit is observed.

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Chronic renal insufficiency: no dosage adjustment needed

P: Tab: 5mg(27223), 1mg(27219)

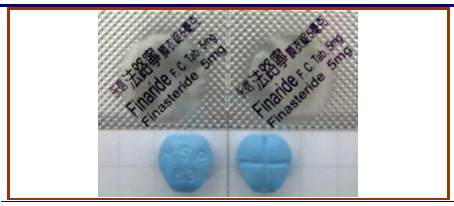
ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 藍色六角形扁錠，一面有十字刻痕，另一面有YSP及83字



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048557

28.04B2 5 α-reductase Inhibitor

27235 X / Unsafe

AVODART SOFT CAPSULES 0.5MG 適尿通軟膠囊0.5毫克

Dutasteride 0.5mg soft cap

Dosage: 1常備品 27235

Adult
·Benign prostatic hyperplasia: PO, 0.5mg once a day.

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: 0.5mg (27235)

ADR:

COMMON
gynecomastia, disorder of ejaculation, impotence, reduced libido
SERIOUS
rash, pruritus, urticaria, localized edema

NOTE: 室溫儲存

1. Contraindicated in women and children
2. Should not be handled by women who are pregnant or who may become pregnant
3. May be given with or without food

藥名相似:

外觀相似:

外觀描述: 黃色長橢軟膠囊，有GX CE2字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023952

28.06A Estrogens

25670 X / Caution

ESTROMON F.C.TABLETS 0.625MG "STANDARD" "生達" 伊使蒙膜衣錠０．６２５毫克

Conjugated Estrogen 0.625mg tab

Dosage: 1常備品 25670

Adult
·Uterine bleeding: acute/heavy, PO 1.25mg, may repeat q4hr for 24hrs, then 1.25mg qd for 7-10days; nonacute/lesser, PO 1.25mg qd for 7-10days.(Unlabled use)
·Postmenopausal osteoporosis, prevention: PO 0.625mg/day continuously or cyclical regimens (25 days on, 5 days off)

·Vasomotor symptoms: PO 0.625mg/day continuously or cyclical regimens.
·Vulvar and vaginal atrophy: PO 0.3-1.25mg (or more) continuously or cyclical regimens.
·Breast cancer: oral 10mg tid for at least 3 months.
·Prostate cancer: PO 1.25-2.5mg tid.
·Hypoestrogenism (Female castration or primary ovarian failure): PO 1.25mg/day, cyclically (3 wks on, 1 wk off).
·Female hypogonadism: PO 0.3-0.625mg/day cyclically (3 wks on, 1 wk off).

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P: Tab: 0.625mg(25670), Premelle Lite (25658); Premarin*Vag Cream(29026)

ADR:

N/V, vaginal bleeding, endometrial cancer, venous, thromboembolism, breast tenderness, depression, weight changes

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 粉紅色圓扁錠,有S字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1039304

28.06A Estrogens

25674 **X / Caution**

ESTRADE TABLETS 2MG 益斯得錠 2 毫克

Estradiol valerate 2mg tab

Dosage: 1常備品 25674

Adult
·Atrophic vaginitis: PO, 1-2mg/day in a cyclical pattern (3 weeks on, 1 week off)
·Palliative treatment of breast cancer in appropriately selected men or postmenopausal women: PO, 10mg 3 times daily at least 3 mon.
·Hypoestrogenism: PO, 1-2mg/day, titrate and adjust dose as necessary to control symptoms.
·Menopause: PO 1-2mg/day in a cyclical pattern (3 weeks on, 1 week off).
·Osteoporosis prevention: PO, 0.5mg/day in a cyclical pattern (23 days on, 5 days off)
·Prostate cancer: PO, 1-2mg 3 times daily
·Vulvar atrophy: PO, 1-2mg/day in a cyclical pattern (3 weeks on, 1 week off).
.

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

The dose of oral estradiol in women with ESRD should be 50% of the dose typically prescribed to women without ESRD.

P: Tab: Estrate* 2mg(25674), Divina(25672), Covina(25671);Gel: Oestrogel* 0.06% 30g(29023), Inj:Testodiol* Depot(35263)

ADR:

Amenorrhea, breakthrough bleeding, spotting, breast enlargement, breast tenderness, chloasma, melasma, pruritis, depression, headache, edema, weight changes, leukorrhea, vaginal discomfort, nausea, vomiting

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面中央有刻痕及"SYN"與" 2"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1039822

28.06A Estrogens

29015 **X / Caution**

PREMARIN VAGINAL CREAM 普力馬林陰道乳膏

Conjugated estrogens vaginal cream 0.625mg/g,14g/tube

Dosage: 1常備品 29015

Adult
·Vulvar and vaginal atrophy: intravaginal cream 0.5-2g/day cyclically (3 wks on, 1 wk off).

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 0.625mg(25670); Vaginal cream: 0.625mg/g,14g/tube (29015)

ADR:

COMMON
Edema, Vasodilatation, Hirsutism, Pruritus, Weight change finding, Abdominal pain, Diarrhea, Flatulence, Nausea,Vomiting, Backache, Asthenia, Headache, Migraine, Depression, Disorder of menstruation, Pain of breast, Vaginitis, Withdrawal bleeding, Cough, Pharyngitis.
SERIOUS
Heart disease, Hypertension, Myocardial infarction, Body fluid retention, Breast cancer, Diabetes mellitus, Hypercalcemia, Disorder of gallbladder, Pancreatitis, Venous thrombosis, Anaphylaxis, Cerebrovascular accident, Dementia, Impaired cognition, Thrombosis of retinal vein, Cervical cancer, Malignant neoplasm of endometrium of corpus uteri, Ovarian cancer, Pulmonary embolism.

NOTE: 室溫儲存

仿單內容變更，摘述如下：（版本 USPI 201205-2）
1.警告加註雌激素製劑增加罹患子宮內膜癌之風險。
2.禁忌症增列(A)已知會對本藥產生過敏反應或血管性水腫。(B)已知的C蛋白、S蛋白、或抗凝血酵素缺損或其他血栓好發者的疾病。
3.警語及注意事項：(A)心血管疾病段落加註若發生或懷疑有中風，應立即停用雌激素與黃體素併用療法。(B)加註過敏性反應。?有遺傳性血管性水腫的婦女，可能會加重血管性水腫症狀。
4.不良反應增列惡性腫瘤。
5.更新臨床試驗及上市後經驗不良反應的相關資訊。
6.特殊族群使用：(A)懷孕婦女：加註在因使用雌激素和黃體素併用當避孕藥而不經意懷孕者對出生小孩產生缺陷的危險性似乎很少或幾乎無。(B)哺乳婦女：加註使用應小心。

藥名相似:

外觀相似:

外觀描述: 14克乳膏,軟管,紙盒,有粉紅色區塊及黑色字體

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2019489

28.06A Estrogens

29023 **X / Caution**

LADIOL GEL 0.6MG/GM (ESTRADIOL) "SINPHAR" "杏輝"麗露凝膠 0．6 毫克/公克（氫偶素）

17-β Estradiol 0.06% 30g tube

Dosage: 1常備品 29023

Adult
Menopause symptoms: 2.5g (by a dose-metering ruler) daily, spread as widely as possible, preferably on the arms, forearms, shoulder, a large-area of intact skin, but avoiding to the breast and vular mucosa.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: Estrate* 2mg(25674), Divina(25672), Covina(25671); Gel: Ladiol* 0.06% 30g(29023), Inj: Testodiol* Depot(35263)

ADR:

Headache, nausea, HTN, MI, thromboembolism, vaginal bleeding changes

NOTE: 室溫儲存

1.Measure dose with the central groove of the plastic ruler then removed from the ruler with the fingers.
2.Apply it preferably to arms, forearms, shoulder but avoiding to the breast and vulvar mucosa.

藥名相似:

外觀相似:

外觀描述: 30g軟管

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1037386

28.06A Estrogens

29601 **demonstrated / Infant risk can**

DIVIGEL* 0.1% Gel 迪維舒 凝膠 1毫克/克

Estradiol gel 0.1% 1g/PK

Dosage: 1常備品 29601

·Menopause symptoms: one packet (1g gel contains estradiol 1 mg/g) TOPICALLY once daily, 0.5 g to 1.5 g per day for individual needs, equivalent to 0.5 mg to 1.5 mg Estradiol per day.

·Safety and efficacy in pediatric patients have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: Estrate* 2mg(25674), Divina(25672), Covina(25671); Gel: Divigel*0.1% 1g, Ladiol* 0.06% 30g(29023), Inj: Testodiol* Depot(35263)

ADR:

COMMON
Abdominal pain, Breast tenderness, Disorder of menstruation, Pain of breast, Upper respiratory infection.
SERIOUS
Myocardial infarction, Body fluid retention, Hypercalcemia, Venous thromboembolism, Breast cancer, Ovarian cancer, Pulmonary embolism, Angioedema.

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 1克凝膠，黑字鋁箔包裝小袋

28.06B Progestins

25659 **/ Caution**

Duphaston film-coated tablet 10mg "亞培"得胎隆膜衣錠10毫克

Dydrogesterone 10mg tab

Dosage: 1常備品 25659

Adult

· Hormone replacement therapy：PO, 10mg qd for 14 consecutive days per cycle of 28 days (with continuous estrogen therapy) or 10mg qd during the last 12-14 days of estrogen therapy(with cyclical estrogen therapy).
· Dysmenorrhoea, endometriosis：PO, 10mg bid from day 5 to day 25 of the cycle.
· Dysfunctional bleeding (to arrest bleeding)：PO, 10mg bid for 5-7 days.
· Dysfunctional bleeding (to prevent bleeding), premenstrual syndrome, irregular cycles：PO, 10mg bid from day 11 to day 25 of the cycle.
· Amenorrhoea：PO, 10mg bid from day 11 to day 25 of the cycle (with estrogen qd from day 1 to day 25 of the cycle).
· Threatened abortion：PO, 40mg at once, then 10mg q8h until symptoms remit.
· Habitual abortion：PO, 10mg bid until the twentieth week of pregnancy.
· Infertility due to luteal insufficiency：PO, 10mg qd from day 14 to day 25 of the cycle, continue for at least 6 consecutive cycles.
· The luteal phase supplement during artificial reproductive treatment：PO, 10mg tid (30mg per day), starting from the day of taking the ovum, confirming the pregnancy, continue to take 10 weeks.

Pediatric(<18yrs)
·safety and efficacy have not been established in pediatric patients

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 10mg(25659)

ADR:

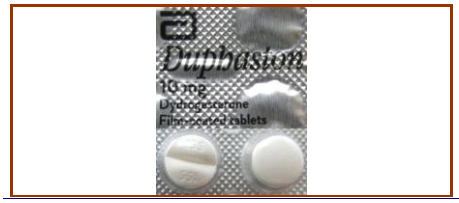
Breakthrough bleeding, abnormal liver function, asthenia, malaise, jaundice, abdominal pain, allergic skin rash, pruritus, urticaria.

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面中間有一刻痕，有155字樣



28.06B Progestins

25673 **B / Caution**

Utrogestan soft capsule 100mg 優潔通軟膠囊100毫克

Progesterone 100mg soft cap

Dosage: 1常備品 25673

Adult
·Amenorrhea, premenatrual syndrome: PO, intravaginally; 200-400 mg at bedtime for 10 days (usually 17th-26th day)
·Endometrial hyperplasia(postmenopausal state), prophylaxis: PO, intravaginally; 200mg at bedtime for 12 days per 28-day cycle(the last 2 weeks of the cycle)

--

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap:100mg(25673);Vag gel: 8% 1.125g/tube(29018); Inj: 50mg/mL Amp(35270)

ADR:

NOTE: 室溫儲存

Contraindications: allergy to progesterone products, peanut oil , breast/genital cancer, liver disease, missed abortion, pregnancy, undiagnosed abnormal vaginal bleeding, thromboembolic disorders

藥名相似:

外觀相似:

外觀描述: 白色圓形軟膠囊，每片15顆

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025923

28.06B Progestins

25675 **X / Infant risk is**

Medrone Tablets 5MG 美得能錠5毫克

Medroxyprogesterone acetate 5mg tab

Dosage: 1常備品 25675

Adult
·Amenorrhea: PO, 5-10mg daily for 5-10 days
·Abnormal uterine bleeding: PO, 5-10mg daily for 5-10 days, starting on day 16 or 21 of the menstrual cycle
·Menopausal symptoms: PO, 2.5-10mg daily during the last 10-13 days of estrogen administration
·Reduction of endometrial hyperplasia: PO, 5-10mg qd for 12-14 consecutive days per month; beginning on day 1 or day 16 of the cycle in postmenopausal women receiving conjugated estrogens 0.625mg.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

NDA

P: Tab: 500mg(25662), 5mg(25675); Divina (25672)

ADR:

COMMON
amenorrhea, breakthrough bleeding, change in menstrual flow, spotting, asthenia, dizziness,

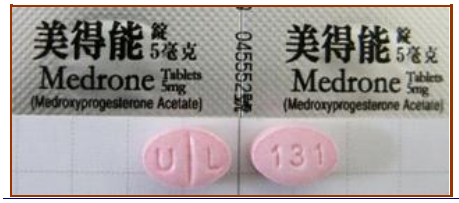
headache, nervousness
breast tenderness, galactorrhea, change in weight, edema, depression, abdominal pain or discomfort, nausea, insomnia, somnolence
SERIOUS
cholestatic jaundice, deep vein thrombosis, pulmonary embolism, thrombophlebitis

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 粉紅色橢圓扁錠，一面中央有刻痕和"UL"字樣，另一面有"131"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045552

28.06B Progestins

27525 X /

POSTINOR-2 TABLETS 后定諾錠0.75公絲

急用Levonorgestrel 0.75mg tab

Dosage: 2急用藥 27525

Adult:
· Emergency contraception: PO, 1 tab as soon as possible within 72 hours after unprotected intercourse and another one 12 hours after taking the first tab. May be used at any time during menstrual cycle.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 0.75mg (27525); Intrauterine device: 52mg/ST (29033)

ADR:

COMMON
Acne, weight gain, abdominal pain, nausea, dizziness, headache, depression, breast tenderness, cyst of ovary, irregular periods, fatigue

NOTE: 室溫保存

If vomiting occurs within 2 hours after drug intake, the dose should be repeated

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，有INOR字樣

28.06B Progestins

27560 ɔt be ruled out / Infant risk has

Visanne 2 mg tablet 異位寧2毫克

Dienogest 2mg tab

Dosage: 1常備品 27560

Adlut
·Endometriosis: PO, 2 mg qd.

Pediatric
·Endometriosis(≧12 yrs): PO, 2 mg qd.

Dosing adjustments in hepatic impairment:

Mild to moderate impairment: No dosage adjustment.
Severe impairment: Use is contraindicated in patients with a history of or current severe hepatic disease.

Dosing adjustments in renal impairment:

No dosage adjustment necessary.
Severe renal insufficiency should be used with caution.

P: TAB 2mg

ADR:

COMMON
Headache, weight gain, nausea, abdominal pain, mood depression/change, nervousness, acne, hair loss, breast upset, hot flush, uterine/vaginal bleeding.

UNCOMMON
Anemia, weight loss, increased appetite, anxiety, depression, autonomic nervous system imbalance, dry eyes, dyspnea, diarrhea, constipation, dry skin, pruritus, photosensitivity reaction.

NOTE: 室溫保存

禁忌症
Visanne不應使用於有下列任何病症(部分來自於其他僅含黃體素之製劑的相關資訊)的患者。如果Visanne使用期間出現下列任何病症，必須立即停藥：
1.活性期靜脈血栓栓塞疾病
2.目前罹患動脈及心血管疾病或有其病史(例如心肌梗塞、腦中風、缺血性心臟病)
3.合併血管相關併發症之糖尿病
4.現有或曾患嚴重肝臟疾病且肝功能的各項數值未回復至正常值
5.現有或曾有肝臟腫瘤 (良性或惡性)
6.已知或疑似罹患性荷爾蒙依賴型惡性腫瘤
7.未經診斷的陰道出血
8.對本品主成分或任一賦形劑過敏者

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有"B"字樣

28.06B Progestins

29018 B /

CRINONE 8% PROGESTERONE VAGINAL GEL 快孕隆8% 陰道凝膠

Progesterone Vag gel 8% 1.125g/tube

Dosage: 1常備品 29018

Adult
·Infertility due to inadequate luteal phase: Intravaginal, one application qd, starting after documented ovulation or arbitrarily on the 18th-21st day of the cycle
·In-vitro fertilisation: Intravaginal, one application qd should be continued for 30days if there is laboratory evidence of pregnancy

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: 100mg(25673); Vag gel: 8% 1.125g/tube(29018); Inj: 50mg/mL Amp(35270)

ADR:

Somnolence, headache, nervousness, breast tenderness, abdominal pain, constipation, nausea, perineal pain, arthralgia

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024078

28.06B Progestins

29033 demonstrated / Infant risk can

MIRENA (LEVONORGESTREL 20UG/24H) INTRAUTERINE SYSTEM 蜜蕊娜子宮內投藥系統

Levonorgestrel IUS 20mcg/24h 52mg/ST

Dosage: 1常備品 29033

Adult
·Menorrhagia, intrauterine contraception: insert into the uterine cavity within 7 days of the onset of menstruation or immediately after first-trimester abortion for up to 5 years.

--

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Intrauterine device: 52mg/ST(29033); Tab: 0.75mg(27525,Postinor* 急用藥)

ADR:

COMMON
Abdominal pain, nausea, acne, breast tenderness, depression, dizziness, fatigue, headache, menstrual changes, ovarian cysts, weight increase
SERIOUS
Pelvic inflammatory disease (rare), sepsis (rare)

NOTE: 室溫儲存

1. An intrauterine system releases levonorgestrel at a rate of approximately 20 mcg daily for 5 years or until removed.
2. Contraindications: active hepatic disease or liver tumor, active thrombophlebitis or thromboembolic disorders, hemorrhagic diathesis, carcinoma of the breast, pregnancy, undiagnosed abnormal uterine or genital bleeding, history of idiopathic intracranial hypertension, congenital or acquired uterine abnormality, acute pelvic inflammatory disease, postpartum endometritis or infected abortion in the past 3 months, uterine or cervical neoplasia, genital infections.

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022501

28.06B Progestins

29036 B / Infant risk is

ENDOMETRIN* 100mg vaginal tablet 安度孕陰道錠100毫克

Progesterone 100mg vaginal tab

Dosage: 1常備品 29036

Adult
·Assisted Reproductive Technology treatment for infertility : 100 mg vaginal insert vaginally 2 to 3 times a day starting the day after oocyte retrieval and continuing for up to 10 weeks (or up to 12 weeks of gestation).

Pediatric
·Safety and effectiveness not established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Vag tab: 100mg(29036); Cap: 100mg(25673); Vag gel: 8% 1.125g/tube(29018); Inj: 50mg/mL Amp(35270)

ADR:

COMMON
Abdominal pain, Constipation, Nausea, Swollen abdomen, Viral disease, Cramp, Musculoskeletal pain, Dizziness, Headache, Sleep disorder, Somnolence, Depression, Mood swings, Nocturia, Breast tenderness, Large breast, Post-oocyte

retrieval Pain, Pain of breast, Perineal pain, Vaginal discharge, Fatigue.
SERIOUS
Shock, Breast cancer, Cholecystectomy, acute Pancreatitis, Deep venous thrombosis, Venous thromboembolism, Cholestasis, Cholestatic hepatitis, Cholestatic jaundice syndrome, Hepatic necrosis, Hepatitis, Jaundice, Liver failure, Anaphylactoid reaction, Anaphylaxis, Cerebrovascular accident, Ischemic stroke, Transient ischemic attack, Thrombosis of retinal artery, Dementia, Suicidal thoughts, Endometrial carcinoma, Pulmonary embolism, Breast cancer, Endometrial carcinoma.

NOTE: 室溫儲存

·禁忌(仿單2019年9月)
有下列任一症狀的患者不應使用：
· 對「成分」中所列之有效成分或任一賦形劑過敏者
· 不明原因之陰道出血
· 已知過期流產或子宮外孕
· 重度肝功能不全或相關疾病
· 已知或疑似罹患乳癌或生殖道癌
· 主動脈或靜脈血栓栓塞或重度血栓性靜脈炎，或曾有發生這些事件的病史
· 紫質症

藥名相似:

外觀相似:

外觀描述: 白色至灰白橢圓凸形錠，1面有 FPI 字樣，1面有 100 字樣

28.06B Progestins

35271 **B / Caution**

PROGESTERONE* INJECTION "CHI SHENG" "濟生"黃體素注射液

Progesterone inj 25mg/1mL amp

Dosage: 1常備品 35271

Adult
·Amenorrhea: 5-10mg in oil IM daily for 6-8 days
·Functional Uterine bleeding: 5-10mg in oil IM daily for 6 doses
·Habitual abortion: IM, 25-100mg twice weekly, from day 15 of pregnancy until 8-16 wks
.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap:100mg(25673); Vag gel: 8% 1.125g/tube(29018); Inj: 125mg/5ml Amp(35271)

ADR:

COMMON
Abdominal cramping, breast enlargement, breast pain, constipation, dizziness, emotional lability, headache
SERIOUS
ectopic pregnancy (IUD), pulmonary embolism, retinal thrombosis (rare), thrombophlebitis, cerebrovascular disorders (rare)

NOTE: 室溫儲存

Contraindications: allergy to progesterone products, peanut oil, breast/genital cancer, liver disease, missed abortion, pregnancy, undiagnosed abnormal vaginal bleeding, thromboembolic disorders

藥名相似:

外觀相似:

外觀描述: 1mL淡黃色透明油狀注射液，『棕』色安瓿頸部有白點，白底黑字標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1057889

28.06B Progestins

35274 **B / Caution**

PROGESTON DEPOT INTRAMUSCULAR 125MG 普寶胎注射液125毫克/毫升

Hydroxyprogesterone caproate inj 125mg/1mL amp

Dosage: 1常備品 35274

Adult
·To reduce the risk of preterm birth: IM, 250 mg once weekly, Treatment may begin between 16 weeks 0 days and 20 weeks 6 days of gestation; continue weekly administration until 37 weeks gestation or delivery.
·Amenorrhea, functional uterine bleeding, habitual abortion: IM, 65-125mg once weekly.

Pediatric
·Safety and efficacy have not been established in patients less than 16 years old

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 125mg/1mL amp(35274); 25mg/1mL amp(35271);Cap:100mg(25673)

ADR:

COMMON
Injection site pain, injection site pruritus, injection site reaction, pruritus, swelling at injection site, urticaria, diarrhea, nausea
SERIOUS
Thromboembolic disorder

NOTE: 室溫避光儲存

藥名相似:

外觀相似:

外觀描述: 1mL淺黃色油性澄明注射液，透明安瓿頸部有『藍』點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1025803

28.06C Estrogen-Progestin Combination

25657 X / Unsafe

Venina Tablets 維妮娜 錠

Estradiol valerate 1mg & medroxyprogesterone acetate 2.5mg tab

Dosage: 1常備品 25657

Adult

·Menopausal symptoms: PO, 1 tab daily without interruption; the dosage can be adjusted according to response

Dosing adjustments in hepatic impairment:

Contraindicated in liver disease

Dosing adjustments in renal impairment:

Use with caution

P: Tab: Indivina* 28tab/pk(25657); Divina* 21tab/pk(25672); Covina* 28tab/pk(25671)

ADR:

Nausea, vomiting, dyspepsia, abdominal pain, flatulence, gallbladder disease/gall stones, alopecia, hirsutism, rash, itching, headache, dizziness, migraine, uterine bleeding, increase in size of uterine fibroids, vaginal candidiasis, increase in blood pressure, venous thromboembolism, weight change, edema, breast tenderness, breast enlargement, anxiety, depressive, changes in libido, leg cramps

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有1+及2.5字樣，另一面中央有刻痕及SY字樣。

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048181

28.06C Estrogen-Progestin Combination

25667 X / Caution

GYNERA 祈麗安錠

Ethinyl estradiol 0.03mg & Gestodene 0.075mg tab

Dosage: 1常備品 25667

Adult

·Contraception: PO, 1 tab qd, starting on day 1 of menstrual cycle for 21 consecutive days, then discontinue for 7 days; repeat cycle

Dosing adjustments in hepatic impairment:

Contraindicated in hepatic impairment

Dosing adjustments in renal impairment:

Use with caution

P:

ADR:

COMMON

Abdominal cramps, bloating, nausea, vomiting, amenorrhea, breakthrough bleeding, change in menstrual flow, spotting,
breast changes (enlargement, tenderness, secretion), headache, mood changes, weight increase or decrease.

SERIOUS

Arterial thromboembolism, thrombophlebitis, cerebral hemorrhage, cerebral thrombosis, gallbladder disease, hepatic adenomas or benign liver tumors, hypertension, mycardial infarction, pulmonary embolism.

NOTE: 室溫儲存25 °C以下

Contraindications: past history of deep-vein thrombophlebitis or thromboembolic disorders, carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia, cerebral-vascular or coronary artery disease, cholestatic jaundice of pregnancy or jaundice with prior pill use, diabetes with vascular involvement, headaches with focal neurological symptoms, hepatic adenomas or carcinomas or active liver disease, known or suspected carcinoma of the breast, known or suspected pregnancy, thrombogenic rhythm disorders, thrombogenic valvulopathies, thrombophlebitis or thromboembolic disorders, uncontrolled hypertension, undiagnosed abnormal genital bleeding.

藥名相似:

外觀相似:

外觀描述: 白色圓錠，每片21粒

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2017244

28.06C Estrogen-Progestin Combination

25671 X / Caution

COVINA F.C. TABLETS 康樂娜膜衣錠

Estradiol 2mg & norethisterone acetate 1mg FC tab

Dosage: 1常備品 25671

Adult:

·The symptoms of estrogen deficiency, prevention of postmenopausal osteoporosis: PO,1 tab daily without interruption.

NDA

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P: Tab: Divina* 21tab/pk (25672); Covina* 28tab/pk (25671)

ADR:

N/V, vaginal bleeding, venous thromboembolism, breast tenderness, headache, depression, weight changes

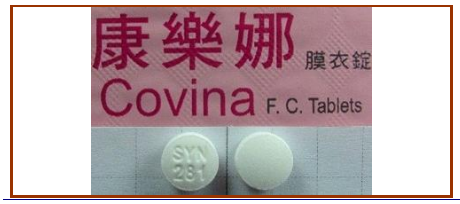
NOTE: 室溫儲存

1. It should preferably be initiated not earlier than one year after the menopause.
2. It's better to take the tablet in the night. If you miss the tablet, take this tablet in the next morning. If you miss the tablet within 24hrs, discard this tablet and take the next tablet. But vaginal bleeding/spotting may happen.

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，有SYN 281字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1042026

28.06C Estrogen-Progestin Combination

25672 X / Caution

TENGEN* TABLETS "MACRO" "瑪科隆" 婷晴錠

White tab: estradiol valerate [X] 2mg; Blue tab: estradiol valerate 2mg & medroxyprogesterone acetate [X]10mg

Dosage: 1常備品 25672

Adult
·Estrogen deficiency, treatment of symptoms of climacterium, amenorrhea, oligomenorrhea, sex hormone replacement therapy(e.g. after ovariectomy):
take the first tablet on cycle day five, 1 tab qd, the white tablets first then the blue tablets. Thereafter you have a 7 interval. During this menstruation-like withdrawal bleeding will appear in most women. (Divina is not a contraceptive)

Dosing adjustments in hepatic impairment:

Contraindicated in hepatic dysfunction

Dosing adjustments in renal impairment:

Use with caution

P: Tab: Divina 21tab/pk(25672); Covina 28tab/pk(25671)

ADR:

Nausea, feeling of tension in the breasts, headache, migraine, visual disturbances, fatigue, sense of weight, changes in libido and mood, mid-cycle bleeding and changes in normal clinico-chemical parameters.

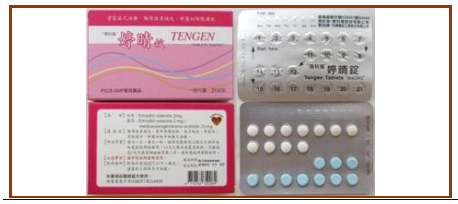
NOTE: 室溫儲存

It is preferable to take the tablet in the evening. If forgotten, take it immediately the following morning. Then take in the evening normally the tablet you were actually supposed to take that day.

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠；淺藍色圓扁錠，一面中央有刻痕



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1038091

28.06C Estrogen-Progestin Combination

25677 X / Unsafe

DIANE-35 S.C. TABLETS 黛麗安糖衣錠

Cyproterone acetate 2mg & Ethinyl estradiol 0.035mg tab

Dosage: 1常備品 25677

Adult (females)
·Acne, androgenetic alopecia, mild forms of hirsutism, and contraception: PO, 1 tablet daily starting on the 1st day of menstrual flow for 21 days, followed by 7 days off. After this 7-day interval, resume next cycle. Discontinue therapy 3-4 cycles after symptoms have resolved.

Dosing adjustments in hepatic impairment:

Contraindicated in hepatic impairment or active liver disease

Dosing adjustments in renal impairment:

Use with caution

P:

ADR:

headaches, gastric upsets, nausea, tension in the breasts, changes in body weight and libido, depressive moods, arterial thromboembolism

NOTE: 室溫儲存

Diane-35 is not for use in men

藥名相似:

外觀相似:

外觀描述: 黃色圓錠

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022877

28.06C Estrogen-Progestin Combination

25678 X / Unsafe

YASMIN 悅己膜衣錠

Ethinylestradiol 0.03mg & Drospirenone 3mg tab

Dosage: 1常備品 25678

Adult
·Contraception: PO, 1 tab qd for 21 consecutive days; then discontinue for 7 days; repeat cycle. Start on day 1 of menstrual cycle or on the first Sunday after the onset of menstruation

Dosing adjustments in hepatic impairment:
Contraindicated in hepatic impairment or active liver disease

Dosing adjustments in renal impairment:
Contraindicated in severe renal impairment or acute renal failure

P: Tab: Yasmin* 21tab/pk(25678), Diane-35* 21tab/pk(25677); TTS: Evra* TTS(29014)

ADR:
COMMON
Weight changes, bloating symptom, nausea, stomach cramps, vomiting, migraine, depression, amenorrhea, break-through bleeding, breast tenderness, discharge from nipple, disorder of menstruation, swelling of breast
SERIOUS
Arterial thromboembolism, hypertension, myocardial infarction, thrombophlebitis, disorder of gallbladder, neoplasm of liver, cerebral hemorrhage, cerebral thrombosis, pulmonary embolism

NOTE: 室溫儲存
·Nonhormonal contraception should be used if initiates therapy later than the first day of menstruation or if patient has intercourse in the 7 days after missing pills

藥名相似:

外觀相似:

外觀描述: 淡黃圓扁錠，有DO字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023338

28.06D Estrogen-Androgen Combination

35263 X / Unsafe

TEATODIOL DEPOT INJECTION "T.F." 得速脫疚得保注射液

Estradiol valerate [X] 4mg & Testosterone enanthate [X] 90.3mg/1mL amp

Dosage: 1常備品 35263

Adult
·The symptoms of menopause in men and women: IM, 1ml every 2-4 wks.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:
Use with caution

Dosing adjustments in renal impairment:
Use with caution

P: Tab: 2mg(25674), Covina(25671), Divina (25672); Gel: 0.06% 30g(29023); Inj:Testodiol* Depot(35263)

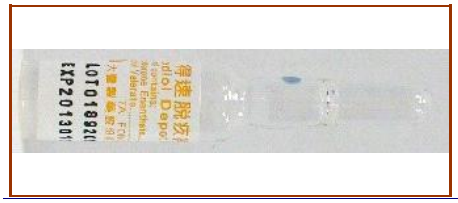
ADR:
N/V, vaginal bleeding, venous thromboembolism, breast tenderness, headache, depression, weight changes

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液，透明安瓿頸部有藍點



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1033994

28.06E SERM

27198 X / Unsafe

EVISTA 60MG FILM COATED TABLETS "西班牙禮來" 鈣穩膜衣錠60公絲

Raloxifene 60 mg tab

Dosage: 1常備品 27198

Adult
·Postmenopausal osteoporosis: PO, 60mg qd

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Tab: 60mg (27198)

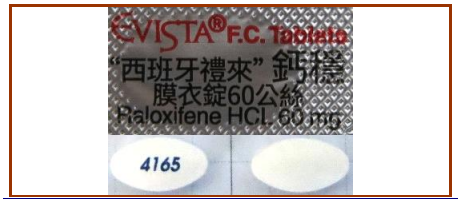
ADR:
hot flush, leg cramp, retinal vascular occlusion

NOTE: 室溫儲存
1. May be administered any time of day without regard to meals
2. Supplemental calcium and/or vitamin D should be added to the diet if daily intake is inadequate

藥名相似:

外觀相似:

外觀描述: 白色長橢圓錠,有4165字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024023

28.06E SERM

27199 X / Unsafe

CLOMIPHENE TABLET 50MG "YUNG SHIN" "永信"喜妊錠 5 0 公絲（可洛米分）

Clomifene citrate 50mg tab

Dosage: 1常備品 27199

Adult
·Female infertility due to ovulatory disorder: PO, 50mg qd for 5 days started on the 5th day of the cycle; if no ovulation after the first course, 100mg qd for 5 days, starting as early as 30 days after the previous course; Max 200mg/day
·Male infertility: PO, 25-50mg qd for 25 days followed by 5 drug-free days; repeat cycle

NDA

Dosing adjustments in hepatic impairment:

Contraindicated in patients with hepatic dysfunction .

Dosing adjustments in renal impairment:

No dosage adiustment needed

P: Tab:50mg (27199)

ADR:

COMMON
Abdominal discomfort, blurred vision, insomnia, nervousness, ovarian cysts, ovarian enlargement , vasomotor flushing.
SERIOUS
Thromboembolism.

NOTE: 室溫儲存

Contraindications:
1.Pregnancy
2.Liver disease/dysfunction
3.Endometrial carcinoma
4.Abnormal uterine bleeding
5.Organic intracranial lesion such as a pituitary tumor
6.Uncontrolled thyroid or adrenal dysfunction
7.Hypersensitivity to clomiphene

藥名相似:

外觀相似:

外觀描述: 黃色圓扁錠，一面刻有商標圖案

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=127338

28.06G Miscellaneous

25676 / Caution

LIVIAL "歐加儂 " 利飛亞錠

Tibolone 2.5mg tab

Dosage: 1常備品 25676

Adult
·Menopausal symptoms: PO, 2.5mg once daily.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed in GFR greater than 12.7ml/min/1.73m2.

P: Tab: 2.5mg(25676)

ADR:

Headache, dizziness, edema, weight gain, gastrointestinal disturbances, vaginal bleeding, potentially deleterious decreases in HDL cholesterol and apolipoprotein A1 levels.

NOTE: 室溫儲存

1.Swallow whole; do not crush or chew.
2.Tibolone is a synthetic steroidal agent with estrogenic, progestogenic, and androgenic activity.

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，有MK 2及ORGANON字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021683

28.08 Gonadotropins

35295 X / Unsafe

Elonva Solution for Injection 100ug/0.5ml 伊諾娃注射液 100 微克/0.5 毫升

■Corifollitropin alfa 100mcg/0.5mL prefilled syringe

Dosage: 1常備品 35295

Adult
·Assisted reproductive technologies: SC,<=60kg 100mcg single dose, >60kg 150mcg single dose.Treatment should be started during the early follicular phase of the menstrual cycle.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA, renal insufficiency is not recommended

P: Inj: 100mcg/0.5mL(35295)

ADR:

Headache, nausea, pelvic pain and discomfort, breast complaints, fatigue, headache, ovarian hyperstimulation syndrome

NOTE: 冰箱冷藏，不可冷凍

1.Corifollitropin alfa has prolonged duration of follicle-stimulating activity for single dose use.
2. The recommended doses of ELONVA* have only been established in a treatment regimen with a gonadotrophin releasing hormone antagonist.

藥名相似:

外觀相似:

外觀描述: 0.5mL含藥透明溶液注射器，附一支黃色標籤注射針頭

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000904

28.08 Gonadotropins

35296 X / Unsafe

Elonva Solution for Injection 150ug/0.5ml 伊諾娃注射液 150 微克/0.5 毫升

■Corifollitropin alfa inj 150mcg/0.5mL prefilled syringe

Dosage: 1常備品 35296

Adult
·Assisted reproductive technologies: SC,<=60kg 100mcg single dose, >60kg 150mcg single dose.Treatment should be started during the early follicular phase of the menstrual cycle.

·safety and effectiveness is not established

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Inj: 100mcg/0.5mL(35295), 150mcg/0.5mL(35296)

ADR:

COMMON
·Gastrointestinal: Nausea (2.3%)
·Musculoskeletal: Discomfort, In pelvis (6%), Pain in pelvis (2.9%)
·Neurologic: Headache (4%)
·Reproductive: Breast tenderness (1.3%)
·Other: Fatigue (1.5%)
SERIOUS
·Reproductive: Ovarian hyperstimulation syndrome (4.3%), Torsion of ovary (0.1% to less than 1%)

NOTE: 冰箱冷藏2°C-8°C，不可冷凍。

1.Corifollitropin alfa has prolonged duration of follicle-stimulating activity for single dose use.
2. The recommended doses of ELONVA* have only been established in a treatment regimen with a gonadotrophin releasing hormone antagonist.

藥名相似:

外觀相似:

外觀描述: 0.5mL含藥透明溶液注射器，附一支黃色標籤注射針頭

28.08 Gonadotropins

35297 X /

Pergoveris 倍孕力凍晶注射劑

■r-hFSH 150IU(12mcg) & r-hLH 75IU(3.7mcg) vial

Dosage: 1常備品 35297

Adult
·Induction of ovulation and pregnancy: SC, 1 vial daily for 7-12 days followed by hCG 5000-10,000 IU one day after the last dose of menotropins

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: r-hFSH 150 IU & r-hLH 75 IU pow in vial with 1mL solvent (PERGOVERIS* 35297), FSH 75 IU & LH 75 IU pow in vial with 1mL solvent (MENOPUR* 35299)

ADR:

COMMON
Tachyarrhythmia, rash, swelling at injection site, gynecomastia (men), abdominal pain, bloating symptom, diarrhea, nausea, vomiting, dizziness, pain, cyst of ovary, hypertrophy of ovary, dyspnea, tachypnea
SERIOUS
Occlusion of artery, venous thrombophlebitis, ectopic pregnancy, ovarian hyperstimulation syndrome, acute respiratory distress syndrome, atelectasis, pulmonary embolism, pulmonary infarction, congenital disease

NOTE: 冰箱保存

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『透明』蓋玻璃小瓶，附1mL稀釋液『粉紅』蓋玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000915

28.08 Gonadotropins

35299 X / Unsafe

Menopur Powder for Injection 美諾孕注射劑

■Human Menopausal Gonadotropin (hMG, Menotropins) 75 int unit vial

Dosage: 1常備品 35299

Adult
·Induction of ovulation and pregnancy: SC, IM, 1-2 vial (75-150 IU)daily for 7-12 days followed by hCG 5000-10,000 IU one day after the last dose of menotropins
·Male infertility: SC, IM, 1-2 vial(75-150 IU) BIW-TIW with hCG for 90 days.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: FSH 75 IU & LH 75 IU pow in vial with 1mL solvent

ADR:

COMMON
Tachyarrhythmia, rash, swelling at injection site, gynecomastia (men), abdominal pain, bloating symptom, diarrhea, nausea, vomiting, dizziness, pain, cyst of ovary, hypertrophy of ovary, dyspnea, tachypnea
SERIOUS
Occlusion of artery, venous thrombophlebitis, ectopic pregnancy, ovarian hyperstimulation syndrome, acute respiratory distress syndrome, atelectasis, pulmonary embolism, pulmonary infarction, congenital disease

NOTE: 冰箱保存

·只能使用藥盒中提供的溶劑調配，藥粉溶解成透明藥液。可將藥瓶放在雙手間輕輕地轉動，不可用力搖晃。3瓶凍晶藥粉可溶於1 毫升的溶劑。
·女性有以下情況禁用：腦下垂體或下視丘腫瘤、卵巢、子宮或乳房癌、懷孕和授乳婦女、原因不明的婦科出血、對本製劑的活性成分或任何賦型劑過敏、非多囊性卵巢症所引起的卵巢囊腫或卵巢增大者。
·男性有以下情況禁用：對本製劑的活性成分或任何賦型劑過敏、睪丸腫瘤、物理性不孕、腦下垂體或下視丘腫瘤。

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『藍』蓋透明玻璃小瓶蓋上有FLIP及OFF字樣，附1ml稀釋液透明安瓿頸部有1條藍色線條和1條紅色線條

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024424

28.08 Gonadotropins

35303 X /

GONAL-F 75IU(5.5MCG) 果納芬75國際單位(5.5微克)

■Follitropin alfa (r-hFSH) 75 int unit amp

Dosage: 1常備品 35303

Adult
· Induction of ovulation: SC, initial 75 IU daily; may adjust dose in 37.5 IU increments after 14 days, additional adjustments, if needed, every 7 days; Max. 300 IU/day, duration: 35 days; administer hCG 1 day after last dose
· Assisted reproductive technologies: SC, 150-225 IU/day on the 2nd or 3rd day of the cycle, until sufficient follicular development is attained; administer hCG once follicular development is evident

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Inj: 75 IU pow in amp with 1mL solvent (35303); Inj: 450IU prefilled pen with 7 needles (35308); Inj: 300IU prefilled pen with 5 needles(35310)

ADR:

Headache, ovarian cysts, OHSS, N/V

NOTE:

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『灰』蓋透明玻璃小瓶，蓋上有FLIP及OFF字樣，附一支預先充填好1mL賦形劑溶液的針筒 ，1支標示『粉紅』色記號針頭、1支標示『灰』色記號針頭

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000763

28.08 Gonadotropins

35308 X / Unsafe

GONAL-F 450IU/0.75ML (33MICROGRAMS/0.75ML) 果納芬注射筆450國際單位/0.75公撮(33微克/0.75公撮)

■Follitropin alfa (r-hFSH) 450 int unit(33mcg) prefilled pen

Dosage: 1常備品 35308

Adult
·Anovulation: SC, 75-150 IU daily, increased by 37.5 or 75 IU at 7 or 14 days intervals if necessary. Max. 225 IU/day; administer hCG 1 day after last dose.
·Assisted reproductive technologies: SC, 150-225 IU daily on the 2nd or 3rd day of the cycle. Max. 450 IU/day; administer hCG once follicular development is evident.
·Male hypogonadotropic hypogonadism, primary and secondary, in whom the cause of infertility is not due to primary testicular failure - Spermatogenesis induction: following hCG pretreatment, SC, 150 IU 3 times/wk up to 18 mon; dose may be increased to Max. 300 IU 3 times/wk; administer with hCG.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Inj: 75 IU pow in amp with 1mL solvent (35303); Inj: 450IU prefilled pen with 7 needles (35308); Inj: 300IU prefilled pen with 5 needles (35310)

ADR:

ovarian cysts, injection site reactions, headache, ovarian hyperstimulation syndrome , N/V

NOTE: 冰箱儲存

After opening, store the pre-filled pen below 25 ℃ (or refrigerate at 2-8 ℃) and used within 28 days.

藥名相似:

外觀相似:

外觀描述: 白色筆型注射器附7個注射針頭

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000802

28.08 Gonadotropins

35310 X /

GONAL-F 300IU/0.5ML (22MICROGRAMS/0.5ML) 果納芬注射筆300國際單位/0.5公撮(22微克/0.5公撮)

■Follitropin alfa (r-hFSH) 300 int unit (22mcg) prefilled pen

Dosage: 1常備品 35310

Adult
·Anovulation: SC, 75-150 IU daily, increased by 37.5 or 75 IU at 7 or 14 days intervals if necessary. Max. 225 IU/day; administer hCG 1 day after last dose
·Assisted reproductive technologies: SC, 150-225 IU daily on the 2nd or 3rd day of the cycle. Max. 450 IU/day; administer hCG once follicular development is evident.
·Male hypogonadotropic hypogonadism, primary and secondary, in whom the cause of infertility is not due to primary testicular failure - Spermatogenesis induction: following hCG pretreatment, SC, 150 IU 3 times/wk up to 18 mon; dose may be increased to Max. 300 IU 3 times/wk; administer with hCG.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 75 IU pow in amp with 1mL solvent(35303); Inj: 450IU prefilled pen with 7 needles(35308); Inj: 300IU prefilled pen with 5 needles(35310)

ADR:

COMMON
Abdominal pain, nausea, headache, upper respiratory infection
SERIOUS
Arterial thromboembolism, cyst of ovary, hypertrophy of ovary, ovarian hyperstimulation syndrome, acute respiratory distress syndrome, atelectasis

NOTE: 冰箱儲存

藥名相似:

外觀相似:

外觀描述: 白色筆型注射器附5個注射針頭

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000801

28.08 Gonadotropins

35312 X / Unknown(有

OVIDREL 250 MICROGRAMS SOLUTION FOR INJECTION 克得諾注射液250微克

■ChorioGonadotropin Alfa 250mcg/0.5mL syringe

Dosage: 1常備品 35312

ADULT
·Assisted reproductive technologies(ART) and ovulation induction : SC, 250 mcg given 1 day following the last dose of follicle stimulating agent.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj : 250mcg(35312)

ADR:

Injection site pain, gynecomastia, precocious puberty, thromboembolic disorder, headache, irritability

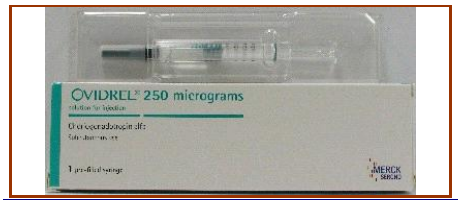
NOTE: Refrigerate

1.For SC use only
2.250mcg=6500IU

藥名相似:

外觀相似:

外觀描述: 0.5mL含藥透明溶液注射器，灰色蓋頭



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000799

28.10A Biguanide

25703 B / Unsafe

UFORMIN TABLETS 500MG 克醣錠500公絲

■Metformin HCl 500mg tab

Dosage: 1常備品 25703

Adult
·Diabetes mellitus: PO, 500mg bid-tid, Max. 2500mg/day

Pediatric
·Diabetes mellitus: 10-16 yr, PO, 500mg bid, Max. 2000mg/day

Dosing adjustments in hepatic impairment:

Hepatic insufficiency: avoid use

Dosing adjustments in renal impairment:

1) eGFR < 30 mL/min/1.73 m2: contraindicated .
2) eGFR 30 ~ 45 mL/min/1.73 m2: not recommended.
3) eGFR falls below 45 mL/min/1.73 m2 after initiation: Assess the benefits and risks of continuing treatment
4) eGFR falls below 30 mL/min/1.73 m2 after initiation: Discontinue treatment .
5) Iodinated Contrast Imaging Procedure: eGFR 30~60 mL/min/1.73 m2: Discontinue metformin at the time of or before procedure. Evaluate eGFR 48 hours after the imaging procedure; restart metformin if renal function is stable .

P: Tab: Avandamet*(25716), Metformin 500mg(25703), Amaryl M*(25719)

ADR:

Asthenia, flatulence, nausea/vomiting, diarrhea, vitamin B12 deficiency, lactic acidosis

NOTE:

藥名相似: Tab: Avandamet*(25716), Metformin 500mg(

外觀相似:

外觀描述: 白色長橢圓形扁錠，一面中央有一刻痕並有"MF"及"1"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1036349

28.10B Insulins

35335 ɔt be ruled out / Infant risk can

Tresiba FlexTouch 諾胰保 諾特筆

■▼Insulin degludec inj 300 unit/3mL pen

Dosage: 1常備品 35335

Adult
·Diabetes (Insulin-naive): SC, Initial dose, type 1: one-third to one-half the total daily insulin dose (general rule for total daily dose, 0.2 to 0.4 units/kg) subQ; remainder of total daily dose given as a short-acting insulin and divided between each daily meal. / type 2: 10 units subQ once daily. Maintenance dose: titrate to clinical effect with dose increases every 3 to 4 days as needed.
·Diabetes (Insulin-experienced): SC, Initiate with same unit dose as the total daily long or intermediate-acting insulin unit dose, once daily at any time of the day; titrate to clinical effect with dose increases every 3 to 4 days as needed.

Pediatric
·Diabetes type 1(1 year or older): SC, once daily at the same time each day .Initial dose: Insulin-naive: one-third to one-half the total daily insulin dose (general rule for total daily dose, 0.2 to 0.4 units/kg); remainder of total daily dose given as a short-acting insulin and divided between each daily meal./ Insulin-experienced: 80% of the total daily long or intermediate-acting insulin unit dose. Individualize dose based on patient needs and titrate to clinical effect with dose increases every 3 to 4 days as needed.
·Diabetes type 2 (1 year or older):SC, once daily at the same time each day .Insulin-experienced: Initiate at 80% of the total daily long or intermediate-acting insulin unit dose; titrate to clinical effect with dose increases every 3 to 4 days as needed.

Dosing adjustments in hepatic impairment:

Use care during dose adjustments monitor glucose closely

Dosing adjustments in renal impairment:

Use care during dose adjustments monitor glucose closely

P: Inj: 100U/mL, 3mL/pen(35335)

ADR:

COMMON
Injection site reaction, pruritus, rash, hypoglycemia, allergic reaction

NOTE: 冰箱冷藏，不可冷凍。

·It should not be mixed or diluted with any other insulin preparations
·When switching patients from NPH insulin, higher doses of insulin detemir will be required for similar hypoglycemic activity
·併用Thiazolidinediones(TZD)類藥品時，特別具潛在鬱血性心臟衰竭危險因子病人，應觀察患者鬱血性心臟衰竭、體重增加及水腫徵兆及症狀。如有發生心臟惡化症狀時，應停用TZD。
·胰島素抗體-使用胰島素可能有抗體形成，在發生案例中，可能需要調整劑量以避免高血糖或低血糖發生。
·已知很多物質會影響葡萄糖代謝：
-下列會減少胰島素需求量：Oral antidiabetic products, monoamine oxidase inhibitors(MAOIs), beta-blockers, angiotensin converting enzyme(ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.
-下列會增加胰島素需求量：Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.
-Beta-blocking agents 會遮蔽低血糖症狀。
-Octreotide/lanreotide 可能都會增加或是減少胰島素的需求量。
-酒精可能會加強或減少胰島素的降血糖作用。

藥名相似:

外觀相似:

外觀描述: 3mL 澄清注射液，『芥末綠』色標籤,深藍色注射筆

28.10B Insulins

35336 C /

Insulatard 因速來達胰島素注射液

■Insulin isophane(NPH) inj 1000 interUnit /10mL vial

Dosage: 1常備品 35336

Adult
·Diabetes mellitus:SC, individualized per patient needs.Usual total daily dose is 0.5-1.2U/kg/day.

Pediatric(≧ 1yrs)
·Diabetes mellitus:SC, individualized per patient needs.Usual total daily dose is 0.5-1.2U/kg/day.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Insulin dose will require adjustment based on patient response and blood glucose monitoring. For patients with a glomerular filtration rate (GFR) between 10 and 50 milliliters/minute (Ml/min), a dosage reduction of approximately 25% may be indicated. Since renal metabolism of insulin decreases during azotemia, a dosage reduction of approximately 50% may be indicated in patients with a GFR less than 10 Ml/min .

P: Inj: 1000IU/10mL vial(35340); 1000IU/10mLvial(35336); 300IU/3mL penfill(35352); Mixtard 1000IU/10mL Vial (35346)

ADR:

COMMON
allergic skin reactions
hypoglycemia
injection site pain
lipodystrophy
rash
SERIOUS
diabetic ketoacidosis
severe hypoglycemic episodes

NOTE: 冰箱冷藏，不可冷凍

avoid using during hypoglycemia
·併用Thiazolidinediones(TZD)類藥品時，特別具潛在鬱血性心臟衰竭危險因子病人，應觀察患者鬱血性心臟衰竭、體重增加及水腫徵兆及症狀。如有發生心臟惡化症狀時，應停用TZD。
·胰島素抗體-使用胰島素可能有抗體形成，在發生案例中，可能需要調整劑量以避免高血糖或低血糖發生。
·已知很多物質會影響葡萄糖代謝：
-下列會減少胰島素需求量：Oral antidiabetic products, monoamine oxidase inhibitors(MAOIs), beta-blockers, angiotensin converting enzyme(ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.
-下列會增加胰島素需求量：Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.
-Beta-blocking agents 會遮蔽低血糖症狀。
-Octreotide/lanreotide 可能都會增加或是減少胰島素的需求量。
-酒精可能會加強或減少胰島素的降血糖作用。

藥名相似:

外觀相似:

外觀描述: 10mL 白色懸浮注射液『綠』蓋透明玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000760

28.10B Insulins

35341 B / Infant risk is

ACTRAPID 100 IU/ML 愛速基因人體胰島素

■Insulin human rDNA 100 IU/mL 10mL vial

Dosage: 1常備品 35341

Adult
·Diabetes mellitus:SC, individualized per patient needs.Usual total daily dose is 0.5-1.2U/kg/day.

Pediatric(≧ 1yrs)
·Diabetes mellitus:SC, individualized per patient needs.Usual total daily dose is 0.5-1.2U/kg/day.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Insulin dose will require adjustment based on patient response and blood glucose monitoring. For patients with a glomerular filtration rate (GFR) between 10 and 50 milliliters/minute (Ml/min), a dosage reduction of approximately 25% may be indicated. Since renal metabolism of insulin decreases during azotemia, a dosage reduction of approximately 50% may be indicated in patients with a GFR less than 10 Ml/min .

P: Inj: 1000IU/10mL Vial(35339, Humilin) (35343, 急診及TPN調劑換算用) (35341, Actrapid); Mixtard 1000IU/10mL Vial (35346)

ADR:

COMMON
allergic skin reactions, hypoglycemia, injection site pain, lipodystrophy, rash
SERIOUS
diabetic ketoacidosis, severe hypoglycemic episodes

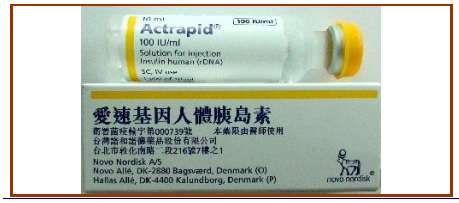
NOTE: 冰箱冷藏，不可冷凍

avoid using during hypoglycemia
·併用Thiazolidinediones(TZD)類藥品時，特別具潛在鬱血性心臟衰竭危險因子病人，應觀察患者鬱血性心臟衰竭、體重增加及水腫徵兆及症狀。如有發生心臟惡化症狀時，應停用TZD。
·胰島素抗體-使用胰島素可能有抗體形成，在發生案例中，可能需要調整劑量以避免高血糖或低血糖發生。
·已知很多物質會影響葡萄糖代謝：
-下列會減少胰島素需求量：Oral antidiabetic products, monoamine oxidase inhibitors(MAOIs), beta-blockers, angiotensin converting enzyme(ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.
-下列會增加胰島素需求量：Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.
-Beta-blocking agents 會遮蔽低血糖症狀。
-Octreotide/lanreotide 可能都會增加或是減少胰島素的需求量。
-酒精可能會加強或減少胰島素的降血糖作用。

藥名相似:

外觀相似:

外觀描述: 10mL 澄清注射液『黃』蓋玻璃瓶



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000739

28.10B Insulins

35344 B /

Humalog Mix 25 100U/ml KwikPen 優泌樂筆-混合型 25 100 單位/毫升

■Insulin lispro 25%, Insulin lispro protamine 75%, 300 int unit/3mL KwikPen

Dosage: 1常備品 35344

Adult
·Diabetes mellitus:SC, within 15 min before meals. The dosage of insulin (Fixed ratio insulin lispro and insulin lispro protamine) should be individualized for each patient depending on eating habits, metabolic needs, and lifestyle.

Pediatric(≧ 1yrs)
·<12 years should be considered only in case of an expected benefit when compared to regular insulin.

Dosing adjustments in hepatic impairment:

careful monitoring of blood glucose is necessary, and adjustment of the fixed ratio insulin lispro dose may be necessary

Dosing adjustments in renal impairment:

careful monitoring of blood glucose is necessary, and adjustment of the fixed ratio insulin lispro dose may be necessary

P: Inj: Humalog* Mix50 KwikPen(35345) ; Humalog* Mix25 KwikPen(35344); NovoMix 30 penfill (35348); Insulin aspart 300IU/3mL penfill(35354);

ADR:

COMMON
Cutaneous hypersensitivity, injection site pain, rash, hypoglycemia, lipodystrophy
SERIOUS
Immune hypersensitivity reaction

NOTE: 冰箱冷藏，不可冷凍。

1.Insulin lispro is a fast-acting insulin analogue; Insulin lispro protamine is a intermediate-acting insulin analogue.
2.Contraindications:current hypoglycemic episode, hypersensitivity to insulin lispro or to any component of the formulation
·併用Thiazolidinediones(TZD)類藥品時，特別具潛在鬱血性心臟衰竭危險因子病人，應觀察患者鬱血性心臟衰竭、體重增加及水腫徵兆及症狀。如有發生心臟惡化症狀時，應停用TZD。
·胰島素抗體-使用胰島素可能有抗體形成，在發生案例中，可能需要調整劑量以避免高血糖或低血糖發生。
·已知很多物質會影響葡萄糖代謝：
-下列會減少胰島素需求量：Oral antidiabetic products, monoamine oxidase inhibitors(MAOIs), beta-blockers, angiotensin converting enzyme(ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.
-下列會增加胰島素需求量：Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.
-Beta-blocking agents 會遮蔽低血糖症狀。
-Octreotide/lanreotide 可能都會增加或是減少胰島素的需求量。
-酒精可能會加強或減少胰島素的降血糖作用。

藥名相似: Inj: Humalog* Mix50 KwikPen(35345) ; Huma

外觀相似: Humalog* Mix50 cartridge

外觀描述: 鐵灰色注射筆內含 3mL 澄清注射液，『黃』色劑量旋鈕

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000898

28.10B Insulins

35345 B /

Humalog Mix 50 100U/ml KwikPen 優泌樂筆-混合型 50 100單位/毫升

■Insulin lispro 50%, Insulin lispro protamine 50%, 300 int unit/3mL KwikPen

Dosage: 1常備品 35345

Adult
·Diabetes mellitus:SC, within 15 min before meals. The dosage of insulin (Fixed ratio insulin lispro and insulin lispro protamine) should be individualized for each patient depending on eating habits, metabolic needs, and lifestyle.

Pediatric(≧ 1yrs)
·<12 years should be considered only in case of an expected benefit when compared to regular insulin.

Dosing adjustments in hepatic impairment:

careful monitoring of blood glucose is necessary, and adjustment of the fixed ratio insulin lispro dose may be necessary

Dosing adjustments in renal impairment:

careful monitoring of blood glucose is necessary, and adjustment of the fixed ratio insulin lispro dose may be necessary

P: Inj: Humalog* Mix50 cartridge(35345) ; Humalog* Mix25 cartridge(35344); NovoMix 30 penfill (35348); Insulin aspart 300IU/3mL penfill(35354);

ADR:

COMMON
Cutaneous hypersensitivity, injection site pain, rash, hypoglycemia, lipodystrophy
SERIOUS
Immune hypersensitivity reaction

NOTE: 冰箱冷藏，不可冷凍

1.Insulin lispro is a fast-acting insulin analogue; Insulin lispro protamine is a intermediate-acting insulin analogue.
2.Contraindications:current hypoglycemic episode,

hypersensitivity to insulin lispro or to any component of the formulation
·併用Thiazolidinediones(TZD)類藥品時，特別具潛在鬱血性心臟衰竭危險因子病人，應觀察患者鬱血性心臟衰竭、體重增加及水腫徵兆及症狀。如有發生心臟惡化症狀時，應停用TZD。
·胰島素抗體-使用胰島素可能有抗體形成，在發生案例中，可能需要調整劑量以避免高血糖或低血糖發生。
·已知很多物質會影響葡萄糖代謝：
-下列會減少胰島素需求量：Oral antidiabetic products, monoamine oxidase inhibitors(MAOIs), beta-blockers, angiotensin converting enzyme(ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.
-下列會增加胰島素需求量：Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.
-Beta-blocking agents 會遮蔽低血糖症狀。
-Octreotide/lanreotide 可能都會增加或是減少胰島素的需求量。
-酒精可能會加強或減少胰島素的降血糖作用。

藥名相似: Inj: Humalog* Mix50 cartridge(35345)；Hum

外觀相似: Humalog* Mix25 Catridge

外觀描述: 鐵灰色注射筆內含 3mL 澄清注射液，『紅』色劑量旋鈕

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000899

28.10B Insulins

35348 B /

NovoMix 30 FlexPen 諾和密斯 30諾易筆 注射劑

■Insulin aspart 30%, Insulin aspart protamine 70% 300 int unit/3mL FlexPen

Dosage: 1常備品 35348

Adult
·Diabetes mellitus: The dosage of insulin aspart should be individualized for each patient depending on eating habits, metabolic needs, and lifestyle. SC, usually between 0.5 to 1 unit/kg/day

Pediatric(≧ 1yrs)
·<10 years should be considered only in case of an expected benefit when compared to regular insulin.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: NovoMix 30 FlexPen (35348); Insulin aspart 300IU/3mL FlexPen(35354)

ADR:

Hypokalemia, injection site reactions and lipodystrophy

NOTE: 冰箱冷藏，不可冷凍。

Insulin aspart is a rapid-acting insulin analogue.
·併用Thiazolidinediones(TZD)類藥品時，特別具潛在鬱血性心臟衰竭危險因子病人，應觀察患者鬱血性心臟衰竭、體重增加及水腫徵兆及症狀。如有發生心臟惡化症狀時，應停用TZD。
·胰島素抗體-使用胰島素可能有抗體形成，在發生案例中，可能需要調整劑量以避免高血糖或低血糖發生。
·已知很多物質會影響葡萄糖代謝：
-下列會減少胰島素需求量：Oral antidiabetic products, monoamine oxidase inhibitors(MAOIs), beta-blockers, angiotensin converting enzyme(ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.
-下列會增加胰島素需求量：Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.
-Beta-blocking agents 會遮蔽低血糖症狀。
-Octreotide/lanreotide 可能都會增加或是減少胰島素的需求量。
-酒精可能會加強或減少胰島素的降血糖作用。

藥名相似:

外觀相似:

外觀描述: 3mL 懸浮注射液，『藍』色注射筆，深藍色標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000820

28.10B Insulins

35349 ɔt be ruled out / Infant risk can

NOVOMIX* 50 FlexPen 諾和密斯50諾易筆

■Insulin aspart 50%, Insulin aspart protamine 50% 300 int unit/3mL FlexPen

Dosage: 1常備品 35349

Adult
·Diabetes mellitus: The dosage of insulin aspart should be individualized for each patient depending on eating habits, metabolic needs, and lifestyle. SC, usually between 0.5 to 1 unit/kg/day

Pediatric(<18 years)
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: I Inj: NovoMix*50 FlexPen(35349); NovoMix*30 FlexPen(35348); Insulin aspart 300IU/3mL penfill(35354)

ADR:

Common
Hypoglycemia, Abdominal pain, Diarrhea, Indigestion, Backache, Musculoskeletal pain, Headache, Neuropathy, Pharyngitis, Rhinitis, Upper respiratory infection, Influenza-like symptoms.
Serious
Hypoglycemia, Hypokalemia, Hypersensitivity reaction

NOTE: 冰箱冷藏，不可冷凍。

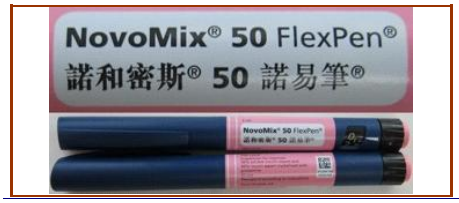
Insulin aspart is a rapid-acting insulin analogue.

·併用Thiazolidinediones(TZD)類藥品時，特別具潛在鬱血性心臟衰竭危險因子病人，應觀察患者鬱血性心臟衰竭、體重增加及水腫徵兆及症狀。如有發生心臟惡化症狀時，應停用TZD。
·胰島素抗體-使用胰島素可能有抗體形成，在發生案例中，可能需要調整劑量以避免高血糖或低血糖發生。
·已知很多物質會影響葡萄糖代謝：
-下列會減少胰島素需求量：Oral antidiabetic products, monoamine oxidase inhibitors(MAOIs), beta-blockers, angiotensin converting enzyme(ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.
-下列會增加胰島素需求量：Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.
-Beta-blocking agents 會遮蔽低血糖症狀。
-Octreotide/lanreotide 可能都會增加或是減少胰島素的需求量。
-酒精可能會加強或減少胰島素的降血糖作用。

藥名相似:

外觀相似:

外觀描述: 3mL懸浮注射液，『粉紅』色標籤,深藍色注射筆



28.10B Insulins

35350 ɔt be ruled out / Infant risk can

LANTUS 100 U/ML, SOLUTION FOR INJECTION 蘭德仕注射劑

■Insulin glargine inj 300 int unit/3mL SoloStar pen

Dosage: 1常備品 35350

Adult
·Diabetes Type 1: SC, individualized dose once daily
·Diabetes Type 2 (insulin-na?ve): SC, Initial 10 IU once daily ; MD, 2-100 IU once daily

Pediatric(6 yrs and older)
·Diabetes Type 1: SC, individualized dose once daily.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 300IU/3mL SoloStar pen(35350)；450IU/1.5mL SoloStar pen(35351)

ADR:

COMMON
Cutaneous hypersensitivity, injection site pain, rash, hypoglycemia, lipodystrophy
SERIOUS
Diabetic ketoacidosis, hypoglycemia (severe)

NOTE: 冰箱冷藏，不可冷凍。

1. Lantus*, a long-acting insulin, cannot be diluted or mixed any other insulin or solution; should be adminstered S.C. only ; use only if solution is clear and colorless.
2. Lantus* should not be used to treat diabetic ketoacidosis
·併用Thiazolidinediones(TZD)類藥品時，特別具潛在鬱血性心臟衰竭危險因子病人，應觀察患者鬱血性心臟衰竭、體重增加及水腫徵兆及症狀。如有發生心臟惡化症狀時，應停用TZD。
·胰島素抗體-使用胰島素可能有抗體形成，在發生案例中，可能需要調整劑量以避免高血糖或低血糖發生。
·已知很多物質會影響葡萄糖代謝：
-下列會減少胰島素需求量：Oral antidiabetic products, monoamine oxidase inhibitors(MAOIs), beta-blockers, angiotensin converting enzyme(ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.
-下列會增加胰島素需求量：Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.
-Beta-blocking agents 會遮蔽低血糖症狀。
-Octreotide/lanreotide 可能都會增加或是減少胰島素的需求量。
-酒精可能會加強或減少胰島素的降血糖作用。

藥名相似:

外觀相似:

外觀描述: 灰色注射筆, 3mL 澄清注射液

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000728

28.10B Insulins

35351 ɔt be ruled out / Infant risk can

Toujeo 300 units/mL solution for injection 糖德仕注射劑

■Insulin glargine inj 450 int unit/1.5mL SoloStar pen

Dosage: 1常備品 35351

Adult
·Diabetes Type 1: SC, individualized dose once daily
·Diabetes Type 2 (insulin-nave): SC, Initial 0.2 units/kg once daily ; MD, 1-80 IU once daily

Pediatric(≧ 1yrs)
·efficacy and safety not established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 450IU/1.5mL SoloStar pen(35351)；300IU/3mL SoloStar pen(35350)

ADR:

COMMON
Cutaneous hypersensitivity, injection site pain, rash, hypoglycemia, lipodystrophy
SERIOUS
Diabetic ketoacidosis, hypoglycemia (severe)

NOTE: 冰箱冷藏，不可冷凍。

1. TOUJEO*, a long-acting insulin, cannot be diluted or mixed any other insulin or solution; should be adminstered S.C. only ; use only if solution is clear and colorless.
2. TOUJEO* should not be used to treat diabetic

ketoacidosis
3.於室溫(不超過30℃)，最長可達6星期
·併用Thiazolidinediones(TZD)類藥品時，特別具潛在鬱血性心臟衰竭危險因子病人，應觀察患者鬱血性心臟衰竭、體重增加及水腫徵兆及症狀。如有發生心臟惡化症狀時，應停用TZD。
·胰島素抗體-使用胰島素可能有抗體形成，在發生案例中，可能需要調整劑量以避免高血糖或低血糖發生。
·已知很多物質會影響葡萄糖代謝：
-下列會減少胰島素需求量：Oral antidiabetic products, monoamine oxidase inhibitors(MAOIs), beta-blockers, angiotensin converting enzyme(ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.
-下列會增加胰島素需求量：Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.
-Beta-blocking agents 會遮蔽低血糖症狀。
-Octreotide/lanreotide 可能都會增加或是減少胰島素的需求量。
-酒精可能會加強或減少胰島素的降血糖作用。

藥名相似:

外觀相似:

外觀描述: 白色注射筆淺綠色標籤，1.5mL 澄清注射液

28.10B Insulins

35354 **B / Unknown(有**

NovoRapid FlexPen 諾和瑞 諾易筆

■Insulin Aspart 300 unit/3mL FlexPen

Dosage: 1常備品 35354

Adult
·Diabetes: SC, within 5-10 min before a meal, individualized per patient needs.Usual total daily dose is 0.5-1U/kg/day.

Pediatric
·Diabetes(>2yrs): SC, within 5-10 min before a meal, individualized per patient needs.Usual total daily dose is 0.5-1U/kg/day.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Use with caution

P: Inj: 300IU/3mL FlexPen(35354); NovoMix 30 FlexPen(35348)

ADR:

COMMON
allergic skin reactions, hypoglycemia, lipodystrophy, transient injection site reaction
SERIOUS
diabetic ketoacidosis, severe hypoglycemic episodes

NOTE: 冰箱冷藏，不可冷凍。

1.Insulin aspart compared to regular human insulin, has more rapid onset and shorter duration of action
2. Contraindications: Hypoglycemia
·併用Thiazolidinediones(TZD)類藥品時，特別具潛在鬱血性心臟衰竭危險因子病人，應觀察患者鬱血性心臟衰竭、體重增加及水腫徵兆及症狀。如有發生心臟惡化症狀時，應停用TZD。
·胰島素抗體-使用胰島素可能有抗體形成，在發生案例中，可能需要調整劑量以避免高血糖或低血糖發生。
·已知很多物質會影響葡萄糖代謝：
-下列會減少胰島素需求量：Oral antidiabetic products, monoamine oxidase inhibitors(MAOIs), beta-blockers, angiotensin converting enzyme(ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.
-下列會增加胰島素需求量：Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.
-Beta-blocking agents 會遮蔽低血糖症狀。
-Octreotide/lanreotide 可能都會增加或是減少胰島素的需求量。
-酒精可能會加強或減少胰島素的降血糖作用。

藥名相似:

外觀相似:

外觀描述: 3mL 澄清注射液，橘色注射筆

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000823

28.10B Insulins

35355 **B / Infant risk can**

LEVEMIR FLEX PEN 瑞和密爾諾易筆

■Insulin detemir 300 unit/3mL pen

Dosage: 1常備品 35355

Adult
·Diabetes type 1 or type 2 on basal-bolus or basal insulin treatment: SC, once or twice daily, change the basal insulin to insulin detemir can be done on a unit-to-unit basis; adjust dose to achieve glycemic targets
·Diabetes type 2(insulin-na?ve): SC, 0.1-0.2U/kg once daily in the evening or 10 units once or twice daily, adjust dose to achieve glycemic targets

Pediatric(≧ 1yrs)
·Diabetes type 1 on basal-bolus or basal insulin treatment: SC, once or twice daily, change the basal insulin to insulin detemir can be done on a unit-to-unit basis; adjust dose to achieve glycemic targets

Dosing adjustments in hepatic impairment:

Use care during dose adjustments monitor glucose closely

Dosing adjustments in renal impairment:

Use care during dose adjustments monitor glucose closely

P: Inj: 100U/mL, 3mL/pen(35355)

ADR:

COMMON
Injection site reaction, pruritus, rash, hypoglycemia, allergic reaction

NOTE: 冰箱冷藏，不可冷凍。

·It should not be mixed or diluted with any other insulin preparations
·When switching patients from NPH insulin, higher doses of insulin detemir will be required for similar hypoglycemic activity
·併用Thiazolidinediones(TZD)類藥品時，特別具潛在鬱血性心臟衰竭危險因子病人，應觀察患者鬱血性心臟衰竭、體重增加及水腫徵兆及症狀。如有發生心臟惡化症狀時，應停用TZD。
·胰島素抗體-使用胰島素可能有抗體形成，在發生案例中，可能需要調整劑量以避免高血糖或低血糖發生。
·已知很多物質會影響葡萄糖代謝：
-下列會減少胰島素需求量：Oral antidiabetic products, monoamine oxidase inhibitors(MAOIs), beta-blockers, angiotensin converting enzyme(ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.
-下列會增加胰島素需求量：Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.
-Beta-blocking agents 會遮蔽低血糖症狀。
-Octreotide/lanreotide 可能都會增加或是減少胰島素的需求量。
-酒精可能會加強或減少胰島素的降血糖作用。

藥名相似:

外觀相似:

外觀描述: 3mL澄清注射液，『綠』色標籤,深藍色注射筆

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000810

28.10B Insulins

35358 B /

Humalog 100U/ml KwikPen 優泌樂筆注射劑 100單位/毫升

■Insulin lispro 300 unit/3mL KwikPen

Dosage: 1常備品 35358

Adult
·Diabetes mellitus: SC, within 15 min before meals. Individualize per patient needs. Usual total daily insulin requirement is 0.5 to 1 unit/kg/day

Pediatric(≧ 1yrs)
·Diabetes mellitus: SC, within 15 min before meals. Individualize per patient needs. Usual total daily insulin requirement is 0.5 to 1 unit/kg/day

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P: Inj: Humalog* Mix50 KwikPen(35345); Humalog* Mix25 KwikPen(35344); Humalog* KwikPen(35358)

ADR:

COMMON
Minor injection site reactions, hypoglycemia, hypokalemia, lipodystrophy

SERIOUS
Immune hypersensitivity reaction, anaphylaxis

NOTE: 冰箱冷藏，不可冷凍

1.Insulin lispro is a rapid-acting biosynthetic human insulin analog
2. Contraindications: Hypoglycemia
·併用Thiazolidinediones(TZD)類藥品時，特別具潛在鬱血性心臟衰竭危險因子病人，應觀察患者鬱血性心臟衰竭、體重增加及水腫徵兆及症狀。如有發生心臟惡化症狀時，應停用TZD。
·胰島素抗體-使用胰島素可能有抗體形成，在發生案例中，可能需要調整劑量以避免高血糖或低血糖發生。
·已知很多物質會影響葡萄糖代謝：
-下列會減少胰島素需求量：Oral antidiabetic products, monoamine oxidase inhibitors(MAOIs), beta-blockers, angiotensin converting enzyme(ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.
-下列會增加胰島素需求量：Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.
-Beta-blocking agents 會遮蔽低血糖症狀。
-Octreotide/lanreotide 可能都會增加或是減少胰島素的需求量。
-酒精可能會加強或減少胰島素的降血糖作用。

藥名相似:

外觀相似:

外觀描述: 藍色注射筆，3mL澄清注射液，『咖啡』色劑量旋鈕

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000900

28.10B Insulins

35359 B / Unknown(有

NOVORAPID PENFILL 3ML, 100 U/ML 諾和瑞 諾芯管

■Insulin Aspart 300 unit/3mL penfill

Dosage: 1常備品 35359

Adult
·Diabetes: SC, within 5-10 min before a meal, individualized per patient needs.Usual total daily dose is 0.5-1U/kg/day.

Pediatric
·Diabetes(>2yrs): SC, within 5-10 min before a meal, individualized per patient needs.Usual total daily dose is 0.5-1U/kg/day.

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P: Inj: 300IU/3mL penfill(35354), 300IU/3mL penfill(35359); NovoMix 30 penfill(35348)

ADR:

COMMON
allergic skin reactions, hypoglycemia, lipodystrophy, transient injection site reaction

SERIOUS
diabetic ketoacidosis, severe hypoglycemic episodes

NOTE: 冰箱冷藏，不可冷凍。

1.Insulin aspart compared to regular human insulin, has more rapid onset and shorter duration of action
2.Contraindications: Hypoglycemia
3.孩童使用時須注意使用的胰島素劑量(特別是基礎-餐前胰島素組合)符合進食、體能活動及當下血糖值，使低血糖的風險降至最低。
4.避免出現意外地混合或用藥錯誤-必須在每一次注射前一定要確認胰島素的標籤，以避免意外發生本藥和其他胰島素產品混合的事
件。
·併用Thiazolidinediones(TZD)類藥品時，特別具潛在鬱血性心臟衰竭危險因子病人，應觀察患者鬱血性心臟衰竭、體重增加及水腫徵兆及症狀。如有發生心臟惡化症狀時，應停用TZD。
·胰島素抗體-使用胰島素可能有抗體形成，在發生案例中，可能需要調整劑量以避免高血糖或低血糖發生。
·已知很多物質會影響葡萄糖代謝：
-下列會減少胰島素需求量：Oral antidiabetic products, monoamine oxidase inhibitors(MAOIs), beta-blockers, angiotensin converting enzyme(ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.
-下列會增加胰島素需求量：Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.
-Beta-blocking agents 會遮蔽低血糖症狀。
-Octreotide/lanreotide 可能都會增加或是減少胰島素的需求量。
-酒精可能會加強或減少胰島素的降血糖作用。

藥名相似:

外觀相似:

外觀描述: (3mL 澄清注射液『橘』蓋卡式管)

28.10C Sulfonylureas

25709 C / Caution

GRUMED TABLETS 2MG "STANDARD" "生達" 達醣定錠2毫克

■Glimepiride 2mg tab

Dosage: 1常備品 25709

Adult
·Diabetes mellitus: PO, initial, 1-2mg once daily immediately before the first main meal. MD 1-4mg once daily, Max. 8mg/day

PEDIATRIC
·因為體重及低血糖的副作用不建議使用(仿單)

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Clcr <22mL/min: Inintial 1mg, and dose titration based on fasting blood glucose

P: Tab: 2mg(25709)

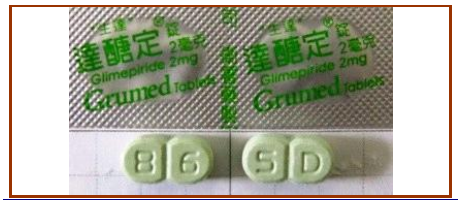
ADR:

NOTE: 室溫儲存

藥名相似: Tab: 2mg(25709), Amaryl M* Tab (25719), A

外觀相似:

外觀描述: 綠色橢圓形錠，中間有刻痕，一面有"S D"，另一面有" B 6"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046640

28.10C Sulfonylureas

25713 C /

DIAMIN MR TABLETS 30MG (GLICLAZIDE) "信東"代蜜持續性藥效錠30毫克

■Gliclazide MR 30mg tab

Dosage: 1常備品 25713

Adult
·Diabetes mellitus: PO, initial 30mg qd, MD 30-120 mg qd, Max.120mg/day.

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Severe renal insufficiency: Not recommended

P: MR tab:30mg(25713)

ADR:

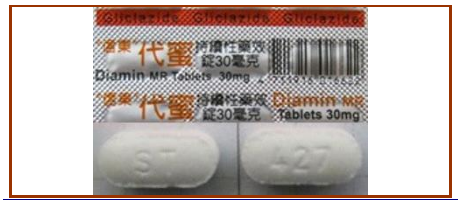
NOTE: 室溫儲存

1. Swallow whole; do not crush or chew
2. Gliclazide MR(Modified Release) 30mg = Gliclazide (Regular release) 80mg

藥名相似: MR tab:30mg(25713), Gliben* 5mg Tab (2570

外觀相似: Acertil* PLUS Tab(22489),

外觀描述: 白色橢圓扁錠，一面印有"ST"，另一面印有"427"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048089

28.10C Sulfonylureas

25719 UK / Unsafe

■Glimet F.C. Tablets 2/500mg "信東"利控糖膜衣錠2/500毫克

■Glimepiride 2mg[C], Metformin 500mg[B] tab

Dosage: 1常備品 25719

Adult
·Type 2 diabetes mellitus: PO, 1 tab qd-bid before or

with meal; Max. 4 tab/day div bid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Avoid use

Dosing adjustments in renal impairment:

1) eGFR < 30 mL/min/1.73 m2: contraindicated .
2) eGFR 30 ~ 45 mL/min/1.73 m2: not recommended.

P: Tab: Glimepiride 2mg(25709), Metformin 500mg(25703), Avandamet*(25716), Amaryl M*(25719)

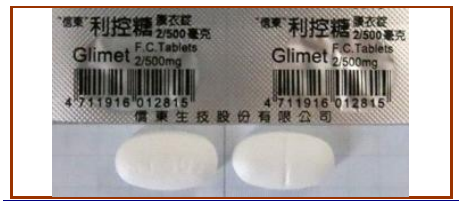
ADR:

NOTE: 室溫儲存

藥名相似: Tab: Glimepiride 2mg(25709), Metformin 500

外觀相似:

外觀描述: 白色長橢圓形錠,一面中央有刻痕,另一面有"ST 502"字樣



28.10D Meglitinide

25701 **C / Unsafe**

Repaglinide Tablets 1mg "CYH" 柔醣錠1毫克

■Repaglinide 1mg tab

Dosage: 1常備品 25701

Adult
·Diabetes mellitus: PO, ac(1-30 min), 0.5mg (HbA1c<8%) or 1-2mg (HbA1c>8%), MD 0.5-4mg bid-qid depending on meal patterns. Max.16mg/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

1.Clcr 20-40mL/min: starting from 0.5 mg; titrate doses carefully
2.Mild-to-moderate renal insufficiency: Dosage adjustment needed

P: Tab:1mg(25701)

ADR:

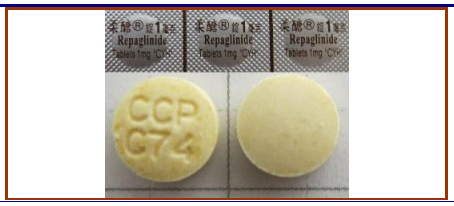
Arthralgia, diarrhea, hypoglycemia, URI

NOTE: 室溫儲存

藥名相似:

外觀相似: CARLATREN* 6.25mg Tab (22409)

外觀描述: 淡黃色圓扁錠，一面有"CCP"及"C74"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1057225

28.10E Alpha-glucosidase Inhibitor

25721 **B / Unsafe**

Litacarbose Tablets 100mg" LITA " "利達" 衛醣錠 100 毫克

■Acarbose 100mg tab

Dosage: 1常備品 25721

Adult
·Diabetes mellitus: PO, initial 25 mg tid with the first bite of each meal, adjusted at 4-8wks intervals; MD 50-100mg tid. Max.<=60kg: 50mg tid, >60kg: 100mg tid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Severe renal impairment(CrCl <25 mL/min): Use is contraindicated

P: Tab: 100mg(25721)

ADR:

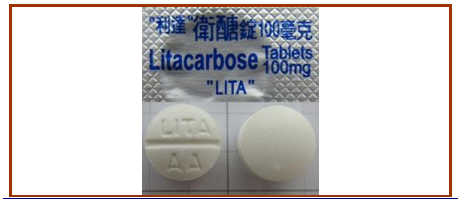
Fatulence, diarrhea, abdominal pain

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面中央有刻痕及"LITA｜AA"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049204

28.10F Thiazolidinediones

25722 **C / Unsafe**

DIAZONE* TABLETS 15MG "C.H" "正和" 糖立敏錠15毫克

■Pioglitazone 15mg tab

Dosage: 1常備品 25722

Adult
·Diabetes mellitus type 2: PO, initial 15-30mg once daily; Max.45mg daily as monotherapy or in combination with a sulfonylurea, metformin, or insulin.

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Severe hepatic impairment (ALT>=2.5 times upper limit of normal, or active liver disease): not recommended

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 15mg(25722)

ADR:

Common
Edema, weight increased, anemia, fracture of bone , Myalgia, headache, pharyngitis, sinusitis, upper respiratory infection
Serious
Congestive heart failure, ALT/SGPT level raised, liver failure, diabetic macular edema, malignant tumor of urinary bladder, pneumonia

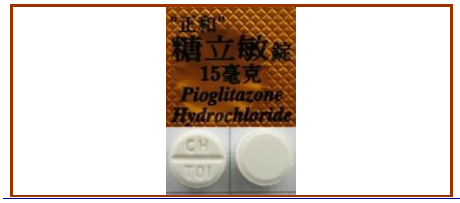
NOTE: 室溫保存25℃以下

第三級或第四級心臟衰竭病人為ACTOS使用禁忌之確立，是為紐約心臟協會所訂定的。

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面中央刻痕及"CH | T 01"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048602

28.10G Dipeptidyl Peptidase-4 (DPP-4) Inhibitor

25718 B /

JANUVIA 100 mg F.C. Tablets 佳糖維100 毫克 膜衣錠

■Sitagliptin 100mg tab

Dosage: 1常備品 25718

Adult
·Diabetes mellitus: PO, 100mg qd as monotherapy or in combination with metformin, a sulfonylurea or a PPARγ agonist (e.g. thiazolidinedione)

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Mild to moderate hepatic impairment (Child-Pugh score 7-9): No dosage adjustment required
Severe hepatic impairment (Child-Pugh score>9): Not studied

Dosing adjustments in renal impairment:

eGFR ≧ 45mL/min/1.73 m2: No dosage adjustment required.
eGFR 30-45mL/min/1.73 m2: 50mg qd
eGFR < 30mL/min/1.73 m2: 25mg qd

P: Tab: 100mg(25718)

ADR:

COMMON
Hypoglycemia, Headache, Nasopharyngitis, Upper respiratory infection.
SERIOUS
Pancreatic cancer, Pancreatitis, Anaphylaxis, Angioedema, Erythroderma, Hypersensitivity reaction, Rash, Stevens-Johnson syndrome, Urticaria, Arthralgia, Abnormal renal function, Acute renal failure.

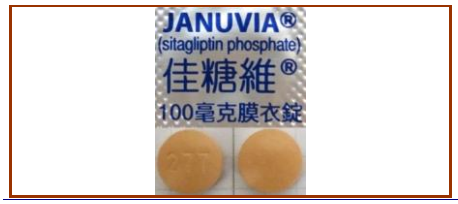
NOTE: 室溫儲存

·When administered with a sulfonylurea, a lower dose of sulfonylurea may be required to reduce the risk of hypoglycemia

藥名相似:

外觀相似:

外觀描述: 土黃色圓扁錠,一面有277字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024668

28.10G Dipeptidyl Peptidase-4 (DPP-4) Inhibitor

25724 UK /

GALVUS TABLETS 50MG 高糖優適錠50毫克

■Vildagliptin 50mg tab

Dosage: 1常備品 25724

Adult
·Diabetes mellitus: PO, 50mg qd-bid

Pediatric
.

Dosing adjustments in hepatic impairment:

Not recommended

Dosing adjustments in renal impairment:

Clcr >50mL/min: No dosage adjustment required
Clcr <50mL/min: 50mg qd

P: Tab: 50mg(25724),GALVUS MET* FC tab(25726)

ADR:

COMMON
Hypoglycemia, headache, dizziness, tremor, nausea, nasopharyngitis, upper respiratory infection, hypertension, peripheral edema
SERIOUS
Urticaria

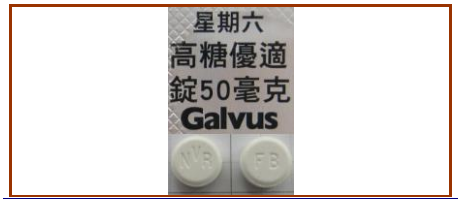
NOTE: 室溫儲存

·When administered with a sulfonylurea, a lower dose of sulfonylurea may be required to reduce the risk of hypoglycemia

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有NVR、另一印有FB字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025306

28.10G Dipeptidyl Peptidase-4 (DPP-4) Inhibitor

25726 UK /

Galvus Met 50/1000 film-coated tablets 高糖優美膜衣錠 50/1000毫克

■Vildagliptin 50mg, metformin 1000mg tab

Dosage: 1常備品 25726

Adult
·Diabetes mellitus: PO, 1 tab bid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Not recommended

Dosing adjustments in renal impairment:

eGFR < 30 mL/min/1.73 m(2): Use contraindicated
eGFR 30 to 60 mL/min/1.73 m(2): 1 tab (Max. daily dose)

P: Tab: GALVUS*(25724),GALVUS MET*(25726)

ADR:

COMMON
Hypoglycemia, headache, nasopharyngitis, upper respiratory infection
SERIOUS
Anaphylaxis, angioedema, generalized exfoliative dermatitis, hypersensitivity reaction, rash, Stevens-Johnson syndrome, urticaria

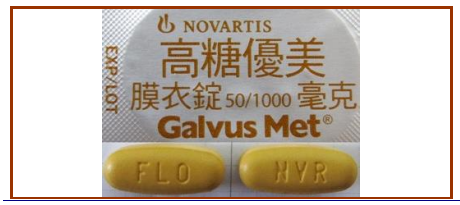
NOTE: 室溫儲存

·When administered with a sulfonylurea, a lower dose of sulfonylurea may be required to reduce the risk of hypoglycemia

藥名相似:

外觀相似:

外觀描述: 土黃色長橢圓形錠，一面有NVR、另一面有FLO字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025482

28.10G Dipeptidyl Peptidase-4 (DPP-4) Inhibitor

25727 ɔt be ruled out / Infant risk can

Trajenta 5mg Film-Coated Tablets 糖漸平膜衣錠 5毫克

■Linagliptin 5mg FC tab

Dosage: 1常備品 25727

Adult
·Diabetes mellitus: PO, 5 mg qd with or without food, when administered with a sulfonylurea or insulin, a lower dose of the sulfonylurea or insulin may be required

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P:

ADR:

COMMON
Hypoglycemia, Diarrhea, Cough, Nasopharyngitis.
SERIOUS
Heart failure, Bullous pemphigoid, Pancreatitis, Anaphylaxis, Hypersensitivity reaction, Arthralgia, Angioedema.

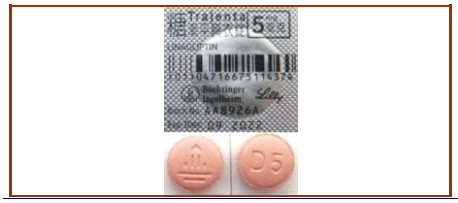
NOTE: 室溫保存

·《Contraindications》History of hypersensitivity to linagliptin, or any component of the product (eg, anaphylaxis, angioedema, exfoliative skin conditions, urticaria, or bronchial hyperreactivity)；
·When administered with a sulfonylurea, a lower dose of sulfonylurea may be required to reduce the risk of hypoglycemia
·心臟衰竭-心臟衰竭風險高的病人在開始治療前，應考慮本藥的風險與效益，如過去有心臟衰竭病史及腎功能不全病史者，在治療期間，觀察這些病人是否出現心臟衰竭的症狀。應告知病人心臟衰竭的特殊症狀，出現這些症狀，立即就醫。如發生心臟衰竭，應依照現行標準照護治療法評估與治療，並考慮停用本藥。
·大皰性類天?瘡-請告知病人，使用此類藥物時可能發生大皰性類天?瘡，出現水泡或糜爛時應就醫。

藥名相似:

外觀相似:

外觀描述: 淺紅色圓扁錠，一面有"D5"字樣，另一面有商標圖樣



28.10G Dipeptidyl Peptidase-4 (DPP-4) Inhibitor

25728 ɔt be ruled out / Infant risk can

TRAJENTA Duo* 2.5/850mg Film-Coated Tablets 糖倍平 膜衣錠 2.5/850 毫克

■Linagliptin 2.5mg & metformin 850mg tab

Dosage: 1常備品 25728

Adult
·Diabetes mellitus: PO, 1 tab bid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Use cautiously in patients at risk for lactic acidosis

Dosing adjustments in renal impairment:

1) eGFR >45 mL/min/1.73 m2: No dosage adjustment necessary.
2) eGFR 30 to 45 mL/min/1.73 m2: Use is not recommended for initiation of therapy; if eGFR falls to <45 mL/min/1.73 m2 during therapy, consider benefits/risks of continuing therapy. If continuing therapy, a metformin dosage reduction of 50% (maximum: 1 g/day) and monitoring of renal function every 3 months is recommended.
3) eGFR <30 mL/min/1.73 m2: Use is contraindicated.

P: P Tab:TRAJENTA(25727),TRAJENTA Duo*(25728)

ADR:

COMMON
Hypoglycemia, Diarrhea, Cough, Nasopharyngitis.
SERIOUS
Heart failure, Bullous pemphigoid, Pancreatitis,

Anaphylaxis, Hypersensitivity reaction, Arthralgia, Angioedema.

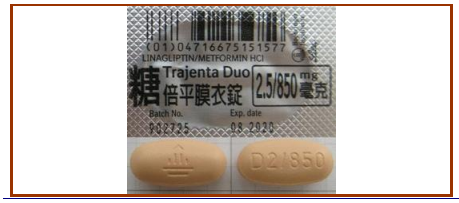
NOTE: 室溫保存

·《Contraindications》History of hypersensitivity to linagliptin, or any component of the product (eg, anaphylaxis, angioedema, exfoliative skin conditions, urticaria, or bronchial hyperreactivity)；
·When administered with a sulfonylurea, a lower dose of sulfonylurea may be required to reduce the risk of hypoglycemia
·心臟衰竭-心臟衰竭風險高的病人在開始治療前，應考慮本藥的風險與效益，如過去有心臟衰竭病史及腎功能不全病史者，在治療期間，觀察這些病人是否出現心臟衰竭的症狀。應告知病人心臟衰竭的特殊症狀，出現這些症狀，立即就醫。如發生心臟衰竭，應依照現行標準照護治療法評估與治療，並考慮停用本藥。
·大皰性類天?瘡-請告知病人，使用此類藥物時可能發生大皰性類天?瘡，出現水泡或糜爛時應就醫。
·監測腎功能。

藥名相似:

外觀相似:

外觀描述: 淡橘色橢圓形雙凸錠，一面有"D2/850'字樣，另一面有商標刻圖



ADR:

COMMON:
Headache, Nasopharyngitis, Upper respiratory infection.
SERIOUS:
Congestive heart failure, Stevens-Johnson syndrome, Pancreatitis, Fulminant hepatic failure, Anaphylaxis, Arthralgia, Angioedema.

上市後不良反應案例(仿單)：
·在上市後案例有使用DPP-4 抑制劑後出現需要住院的大皰性類天皰瘡(Bullous Pemphigoid)報告。報告案例中，病人接受局部或全身性免疫抑制治療並停用DPP-4 抑制劑後可得到恢復。若有疑似症狀，應停用ESINA，並轉介皮膚科診置。

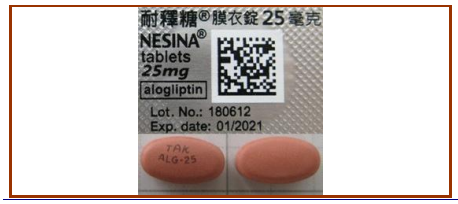
NOTE: 室溫儲存

·When administered with a sulfonylurea, a lower dose of sulfonylurea may be required to reduce the risk of hypoglycemia

藥名相似:

外觀相似:

外觀描述: 淺紅色卵圓形雙凸膜衣錠，一面有" TAK ALG-25" 字樣



28.10G Dipeptidyl Peptidase-4 (DPP-4) Inhibitor

25729 ɔt be ruled out / Infant risk can

NESINA* Tablets 25mg 耐釋糖膜衣錠25毫克

■Alogliptin 25mg tab

Dosage: 1常備品 25729

Adult
·Diabetes mellitus: PO, 25 mg qd with or without food, when administered with a sulfonylurea or insulin, a lower dose of the sulfonylurea or insulin may be required

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

·hepatic insufficiency, mild to moderate: no dose adjustment needed.
·hepatic impairment, use caution; if liver injury occurs, interrupt therapy and assess for cause; do not restart therapy if cause is not identified.

Dosing adjustments in renal impairment:

·CrCl≧60 mL/min: no dose adjustment needed
·CrCl≧30 mL/min or < 60 mL/min: 12.5 mg ORALLY once daily
·CrCl≧15 mL/min or < 30 mL/min: 6.25 mg ORALLY once daily
·ESRD (CrCl < 15 mL/min or requiring hemodialysis): 6.25 mg ORALLY once daily, administered regardless of the timing of hemodialysis.

P: Tab: 25mg(25729)

28.10H Glucagon-like Peptide-1 (GLP-1) receptor agonist

35372 X / Infant risk can

Victoza 胰妥善注射液

■Liraglutide inj 18mg/3mL prefilled pen

Dosage: 1常備品 35372

Adult
·Type 2 diabetes mellitus:SC, Initial 0.6 mg once daily for 1 week; Maintenance:1.2 mg once daily; may increase to 1.8 mg/day if needed; MAX.1.8 mg/day

Pediatric
·Safety and effectiveness have not been established in pediatric patients.

Dosing adjustments in hepatic impairment:

Use with caution in patients with hepatic impairment.

Dosing adjustments in renal impairment:

No dose adjustment is recommended.

P: P Inj: 18mg/3mL pen(35372)

ADR:

COMMON
Hypoglycemia, constipation, decrease in appetite, diarrhea, indigestion, nausea, vomiting, headache, Upper respiratory infection.
SERIOUS
Breast cancer, C-cell hyperplasia of thyroid, medullary thyroid carcinoma, papillary thyroid carcinoma, cholecystitis, cholelithiasis, colorectal

cancer, pancreatic cancer, pancreatitis, anaphylaxis, suicidal thoughts, acute renal failure, angioedema, Breast cancer, Pancreatic cancer.

NOTE: 冰箱冷藏，不可冷凍。

·並非 insulin 的替代品。不可用於第 1 型糖尿病患者，或用於治療糖尿病酮酸血症，因為對這些並無治療效益。

·由控制飲食和運動，血糖控制仍不佳者，不建議將本藥當作第一線治療藥物。

·基於排除半衰期，如果在最近一次注射後已超過 3 日，應建議患者重新以 0.6 mg 劑量開始投予，如此可以減緩因為重新開始療程所造成的胃腸道症狀。

藥名相似:

外觀相似:

外觀描述: 淺藍色藥注射筆，含 3mL澄清注射液

28.10H Glucagon-like Peptide-1 (GLP-1) receptor agonist

35373 **C / Infant risk can**

TRULICITY* injection 1.5mg/0.5mL 易週糖 注射劑 1.5毫克/0.5毫升

■Dulaglutide inj 1.5mg/0.5mL prefilled pen

Dosage: 1常備品 35373

Adult
·Type 2 diabetes mellitus: SC, Initial 0.75 mg once weekly; may be increased to MAX of 1.5 mg once weekly any time of day, with or without food.

Pediatric
·Safety and efficacy have not been established in pediatric patients

Dosing adjustments in hepatic impairment:

Use with caution in patients with hepatic impairment.

Dosing adjustments in renal impairment:

No dose adjustment is recommended in patients with renal impairment, including ESRD; however, use caution when initiating therapy or titrating dose upward

P: P Inj: 1.5mg/0.5mL pen(35373)

ADR:

COMMON
Abdominal pain, Decrease in appetite, Diarrhea, Nausea, Vomiting
SERIOUS
AV block, Hypoglycemia, Malignant tumor of thyroid gland, Pancreatitis, Hypersensitivity reaction, Renal failure.

NOTE: 避光冷藏2~8℃，不可冷凍。

藥名相似:

外觀相似:

外觀描述: 藍/紫色條紋注射筆，內含 0.5mL澄清注射液，『綠』色劑量按鈕

28.10I Sodium-glucose co-transporter 2 (SGLT2) Inhibitor

25740 **ɔt be ruled out / Infant risk can**

Jardiance 25mg Film-Coated Tablets 恩排糖膜衣錠25毫克

■ Empagliflozin 25mg FC tab

Dosage: 1常備品 25740

Adult:
·Diabetes mellitus: PO, 10 mg qd; may increase to 25 mg qd; Max. 25mg/day

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

No dosage adjustment necessary

Dosing adjustments in renal impairment:

eGFR 30 mL/min/1.73m(2) or greater: No dosage adjustment necessary
eGFR (eGFR) less than 30 mL/min/1.73m(2): Do not initiate therapy; discontinue use if eGFR drops and remains below 30 mL/min/1.73m(2)
Severe renal impairment, ESRD, or receiving dialysis: Use contraindicated

P: Tab: JARDIANCE*(25740), GLYXAMBI*(25741)

ADR:

COMMON
Overall Hypoglycemia, Increased frequency of urination, Urinary tract infectious disease, Female genital infection.
SERIOUS
Diabetic ketoacidosis, Severe Hypoglycemia, Acute injury of kidney, Pyelonephritis, Sepsis due to urinary tract infection, Necrotizing fasciitis, Perineum.

NOTE: 儲存30℃以下

·When administered with a sulfonylurea, a lower dose of sulfonylurea may be required to reduce the risk of hypoglycemia
·接受 JARDIANCE 治療的病人如果有出現重度代謝性酸中毒的徵象和症狀(包括噁心、嘔吐、腹痛、全身不適，以及呼吸急促)，無論其血糖濃度多高，即使血糖濃度低於 250 mg/dL，均應評估是否發生酮酸中毒，因為仍可能發生 JARDIANCE 相關酮酸中毒。已知較可能發生酮酸中毒的臨床情形下，如：胰臟胰島素不足、熱量攝取限制(例如，因急性疾病或手術而長時間禁食時)，以及酗酒，考慮監測酮酸中毒，並暫時停用JARDIANCE。
·泌尿與生殖器感染：可能進而引發腎盂腎炎、外陰部及會陰部壞死性筋膜炎(Fournier氏壞疽)等嚴重感染。如出現生殖器或會陰區域疼痛或壓痛、紅斑或腫脹並伴隨發

燒或身體不適者，應評估是否發生壞死性筋膜炎。如有懷疑，應立即以廣效性抗生素進行治療，如有必要，可進行手術清創，停用本藥，並提供適當血糖控制替代療法。告知病人如果生殖器或其後至直腸區域出現疼痛或壓痛、發紅或腫脹並伴隨發燒超過38°C或身體不適，應立即就醫。

·酮酸中毒：若有疑似症狀(噁心、嘔吐、食慾減退、腹痛、過度口渴、倦怠感、呼吸困難、意識不清等)，應立即就醫。即使血糖值不高，依然可能發生酮酸中毒。

·泌尿與生殖器感染：可能進而引發腎盂腎炎、外陰部及會陰部壞死性筋膜炎(Fournier氏壞疽)等嚴重感染。如出現生殖器或會陰區域疼痛或壓痛、紅斑或腫脹並伴隨發燒或身體不適者，應評估是否發生壞死性筋膜炎。如有懷疑，應立即以廣效性抗生素進行治療，如有必要，可進行手術清創，停用本藥，並提供適當血糖控制替代療法。告知病人如果生殖器或其後至直腸區域出現疼痛或壓痛、發紅或腫脹並伴隨發燒超過38°C或身體不適，應立即就醫。

·酮酸中毒：若有疑似症狀(噁心、嘔吐、食慾減退、腹痛、過度口渴、倦怠感、呼吸困難、意識不清等)，應立即就醫。即使血糖值不高，依然可能發生酮酸中毒。

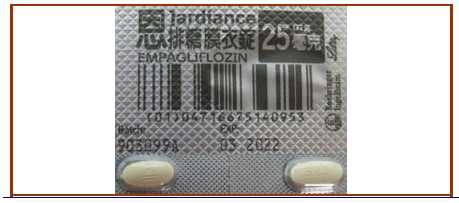
·急性腎損傷：當攝食量減少(例如急性疾病或禁食)或體液流失(例如嘔吐、腹瀉或處於過度熱暴露的環境)時，應立即就醫，並可能需暫停用藥。

·過敏反應：包括蕁麻疹及血管性水腫。若病人出現反應時應立即通報，並且在諮詢醫師前先停用藥。

藥名相似:

外觀相似:

外觀描述: 淺黃色橢圓形錠,一面有S25字樣,一面有廠商標誌



28.10I Sodium-glucose co-transporter 2 (SGLT2) Inhibitor

25741 **ɔt be ruled out / Infant risk can**

GLYXAMBI* Film-Coated Tablets 25/5 mg 糖順平膜衣錠 25/5毫克

■Empagliflozin 25mg & Linagliptin 5mg tab

Dosage: 1常備品 25741

Adult

·Diabetes mellitus: PO, 1 tab qd

Pediatric

·Safety and efficacy not established in pediatric patients

Dosing adjustments in hepatic impairment:

No dosage adjustment necessary

Dosing adjustments in renal impairment:

·ESRD, or receiving dialysis: Use contraindicated

·eGFR < 45 mL/min/1.73 m(2): Do not initiate; discontinue if eGFR is persistently less than 45 mL/min/1.73 m(2) during therapy.

·eGFR≧45 mL/min/1.73 m(2): No dosage adjustment necessary

P: Tab:GLYXAMBI*(25741), JARDIANCE*(25740)

ADR:

COMMON

Urinary tract infectious disease, Nasopharyngitis, Upper respiratory infection.

SERIOUS

Heart failure, Hypotension, Diabetic ketoacidosis, Hypoglycemia, Pancreatitis, Hypersensitivity reaction, Arthralgia, Creatinine clearance-glomerular filtration abnormal, Decreased, Pyelonephritis, Sepsis due to urinary tract infection, Serum creatinine raised, Necrotizing fasciitis, Perineum, Angioedema.

NOTE: 室溫保存

·《Contraindications》Severe renal impairment, dialysis, or end-stage renal disease; Hypersensitivity reaction to empagliflozin, linagliptin, or any of the excipients; anaphylaxis, angioedema, exfoliative skin conditions, urticaria, or bronchial hyperreactivity have occurred；

·Linaglipting上市後報告有急性胰臟炎病例及致死病例，若懷疑出現胰臟炎症狀，請立即停用並開始給予適當治療。

·Linaglipting上市後報告有大皰性類天皰瘡病例，若出現水泡或糜爛懷疑有大皰性類天皰瘡，請立即停用並開始會診皮膚科給予適當診治。

·本藥與胰島素促泌劑或胰島素併用時，可能須降低胰島素促泌劑或胰島素的劑量，以減少低血糖症的風險。

·泌尿與生殖器感染：可能進而引發腎盂腎炎、外陰部及會陰部壞死性筋膜炎(Fournier氏壞疽)等嚴重感染。如出現生殖器或會陰區域疼痛或壓痛、紅斑或腫脹並伴隨發燒或身體不適者，應評估是否發生壞死性筋膜炎。如有懷疑，應立即以廣效性抗生素進行治療，如有必要，可進行手術清創，停用本藥，並提供適當血糖控制替代療法。告知病人如果生殖器或其後至直腸區域出現疼痛或壓痛、發紅或腫脹並伴隨發燒超過38°C或身體不適，應立即就醫。

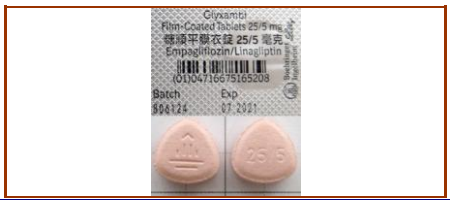
·會陰部壞死性筋膜炎(弗尼爾氏壞疽)-如有出現生殖器或會陰區域疼痛或壓痛、紅斑或腫脹並伴隨發燒或身體不適的病人，皆應評估是否發生壞死性筋膜炎。如有懷疑，應立即以廣效性抗生素進行治療，如有必要，可進行手術清創，停用本藥，密切測血糖濃度，並提供適當的血糖控制替代療法。

·心臟衰竭-告知病人心臟衰竭的症狀。使用本藥前，應詢問病人有關心臟衰竭之病史或其他危險因子包括中度或重度腎功能不全。如果發生心臟衰竭的症狀，請病人立即與醫師聯繫，包含呼吸短促、體重快速增加或腿部水腫。

藥名相似:

外觀相似:

外觀描述: 淺粉紅色圓弧三角形膜衣錠，一面印有廠商標誌一面印有25/5



28.10I Sodium-glucose co-transporter 2 (SGLT2) Inhibitor

25744 **C / Infant risk can**

CANAGLU* Tablets 100mg 可拿糖膜衣錠100毫克

■Canagliflozin 100mg FC tab

Dosage: 1常備品 25744

Adult
·Diabetes mellitus: PO, 100 mg qd; may increase to 300 mg qd; Max. 300 mg/day。本藥品核准之用法用量為100 mg/日(仿單)。

Pediatric
·Safety and effectiveness have not been established.

Dosing adjustments in hepatic impairment:

·Hepatic impairment, mild or moderate (Child-Pugh class A or B): No dose adjustment necessary
·Hepatic impairment, severe (Child-Pugh class C): Use not recommended

Dosing adjustments in renal impairment:

·eGFR≧60 mL/min/1.73 m2: No dosage adjustment necessary.
·eGFR 45 to <60 mL/min/1.73 m2: Maximum dose: 100 mg once daily. If Concomitant administration with a UGT enzyme inducer (eg, rifampin, phenytoin, phenobarbital, ritonavir) and eGFR 45 to <60 mL/min/1.73 m2 at baseline, consider the use of another antidiabetic agent.
·eGFR≧30 to <45 mL/min/1.73 m2: Use not recommended for initiation of therapy or when eGFR is persistently <45 mL/min/1.73 m2.
·eGFR <30 mL/min/1.73 m2、ESRD、Hemodialysis: Use is contraindicated.

P:

ADR:

COMMON
Micturition frequency and polyuria, Urinary tract infectious disease, Female genital Mycosis.
SERIOUS
Hypovolemia, Diabetic ketoacidosis, Severe Hypoglycemia, Ketoacidosis, Pancreatitis, Anaphylaxis, Hypersensitivity reaction, Fracture of bone, Injury of kidney, Pyelonephritis, Renal impairment, Sepsis due to urinary tract infection, Male genital Mycosis, Perineum Necrotizing fasciitis, Angioedema, Limb loss(Leg and Foot).

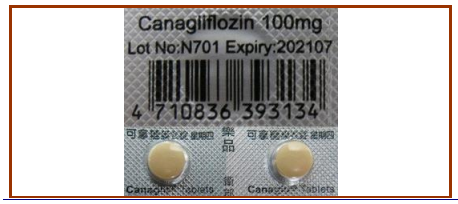
NOTE: 室溫儲存

·【健保給付】每日最多處方1粒。(5.1.5)(107/3/1)
·未核准用於治療第一型糖尿病。
·【禁忌】(勿對以下病人投藥)
(1)酮酸中毒：因必須輸注胰島素以迅速矯治高血糖，故不適合投予本藥品。
(2)嚴重泌尿道感染及生殖器感染：建議以胰島素注射劑控制血糖，故不適合投予本藥品。
·泌尿與生殖器感染：可能進而引發腎盂腎炎、外陰部及會陰部壞死性筋膜炎(Fournier氏壞疽)等嚴重感染。如出現生殖器或會陰區域疼痛或壓痛、紅斑或腫脹並伴隨發燒或身體不適者，應評估是否發生壞死性筋膜炎。如有懷疑，應立即以廣效性抗生素進行治療，如有必要，可進行手術清創，停用本藥，並提供適當血糖控制替代療法。告知病人如果生殖器或其後至直腸區域出現疼痛或壓痛、發紅或腫脹並伴隨發燒超過38°C或身體不適，應立即就醫。
·酮酸中毒：若有疑似症狀(噁心、嘔吐、食慾減退、腹痛、過度口渴、倦怠感、呼吸困難、意識不清等)，應立即就醫。即使血糖值不高，依然可能發生酮酸中毒。

藥名相似:

外觀相似:

外觀描述: 淡黃色圓形膜衣錠



28.12 Pituitary and Hypothalamic Hormones

32802 ɔt be ruled out / Infant risk can

GENOTROPIN 5.3MG 增若托平注射劑5.3毫克

Somatropin inj 5.3mg(16 IU)/1mL cartridge

Dosage: 1常備品 32802

Adult
·Growth-hormone deficiency in adults : SC, 0.018-0.036 IU/kg/day (0.006-0.012 mg/kg/day), Max. 0.036 IU/kg/day

Pediatric
·Growth-hormone deficiency in children : SC, 0.07-0.1 IU/kg/day (0.025-0.035mg/kg/day) or 2.1-3.0 IU/m2/day (0.1-1.0mg/m2/day)
·Gonadal dysgensis (Turner's Syndrom) and growth disturbance in chronic renal insufficiency : SC, 0.14 IU/kg/day (0.045-0.050mg/kg/day) or 4.3 IU/m2/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 12mg(36 IU) /1.5mL (32805), 5.3mg(16 IU)/1mL (32802), 10mg/1.5mL (35367), 10mg(30 IU)/1.5mL(35369)

ADR:

COMMON
Edema of lower extremity, Peripheral edema, Injection site reaction, Lipoatrophy, Eosinophil count raised, Hematoma, Arthralgia, Myalgia, Headache, Paresthesia, Pharyngitis, Rhinitis, Upper respiratory infection, Influenza-like symptoms.
SERIOUS
Disorder of cardiovascular system, In patients with Turner syndrome, Edema, Diabetes mellitus, Hypothyroidism, Impaired glucose tolerance, Pancreatitis, Hypersensitivity reaction, Scoliosis deformity of spine, Progression, Slipped upper femoral epiphysis, Intracranial tumor, Pseudotumor cerebri, Otitis media, In pediatric patients.

NOTE: 冰箱保存

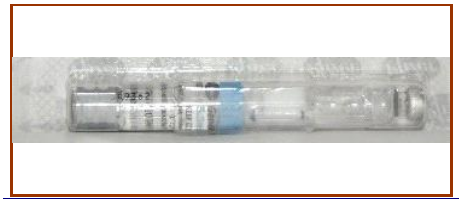
·《Contraindications》Acute critical illness due to complications following open heart surgery, abdominal surgery, or multiple accidental trauma; increased mortality has been reported with pharmacologic doses; Acute respiratory failure; increased mortality has been reported with pharmacologic doses; Active malignancy; Active proliferative or severe non-proliferative diabetic retinopathy; Closed epiphyses in pediatric patients;

Hypersensitivity to somatropin, Escherichia coli, or any of its excipients or diluents; Hypersensitivity to benzyl alcohol containing diluent; Hypersensitivity to metacresol-containing diluent; Prader-Willi syndrome, in pediatric patients who are severely obese or with severe respiratory impairment or have a history of upper airway obstruction or sleep apnea; Progression or recurrence of underlying intracranial tumor ;
·The solution is prepared by screwing the reconstitution device together so that the solvent will be mixed with the powder in the two chamber cartridge.
·每日維持劑量很少需要超過每天1.0 mg。
·每六個月核對一次生長激素的劑量。因為正常的生理性生長激素製造通常隨著年齡的增加而減少，所以可能需要降低劑量。應以最低有效劑量為目標。
·接受口服雌激素補充治療的女性可能需要更高劑量的生長激素才可達到治療目標。

藥名相似:

外觀相似:

外觀描述: 乾粉附注射用水。玻璃雙室藥筒前室裝有白色粉末，後室裝有澄清溶液



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000683

28.12A Pituitary Hormones

25608 ɔt be ruled out / Infant risk can

MINIRIN* Melt 60 μg 迷你寧 凍晶口溶錠 60 μg

Desmopressin(DDAVP) 60ug MELT tab

Dosage: 1常備品 25608

Adult
·Primary nocturnal enuresis : SL, initial 120ug hs, Max. 240ug
·Central diabetes insipidus : SL, initial 60ug tid, MD 60-120ug tid(Max.720ug/day)

Pediatric
·Primary nocturnal enuresis:>6 yrs,SL,initial 120ug hs, Max.240ug
·Central diabetes insipidus:>4 yrs,SL,initial 60ug tid, MD 60-120ug tid(Max.720ug/day)

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

eGFR<50 mL/min/1.73m(2)) is contraindicated

P: Tab: 60ug(25608); 0.1mg(25606); Nasal spray: 10mcg/puff, 25puff/B(29067); Inj: 4mcg/1mL Amp(35363)

ADR:

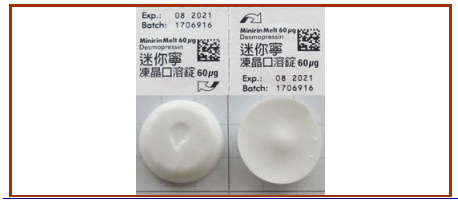
COMMON
Hypertension, Xerostomia, Backache, Dizziness, Fatigue, Bronchitis, Nasal Discomfort, Epistaxis, Nasal congestion, Nasopharyngitis, Rhinitis, Sneezing.
SERIOUS
Atrial fibrillation, Myocardial infarction, Body fluid retention, Hyponatremia, Hyposmolality, Water intoxication syndrome, Anaphylaxis, Seizure.

NOTE: 室溫儲存25°C以下
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面中央有水滴狀刻痕，另一面中央有圓凸起



28.12A Pituitary Hormones

32805 ɔt be ruled out / Infant risk can

Saizen 12 mg solution for injection 帥健 注射劑 12 毫克

Somatropin inj 12mg(36IU)/cartridge

Dosage: 1常備品 32805

Adult
·Growth hormone deficiency: SC, 0.15-0.3mg/day (0.45-0.9IU/day) daily at bedtime
·Cachexia, AIDS-related: SC,
<35 kg: 0.1 mg/kg daily at bedtime
35-45 kg: 4 mg daily at bedtime
45-55 kg: 5 mg daily at bedtime
> 55 kg: 6 mg daily at bedtime
·Short bowel syndrome: SC, 0.1mg/kg daily(Max. 8 mg/day) for 4 wks

Pediatric
·Growth-hormone deficiency in children: SC, 0.025-0.035mg/kg/day or 0.7-1.0mg/m2/day at bedtime
·Turner's Syndrom, growth failure due to chronic renal insufficiency: SC, 0.045-0.05mg/kg/day or 1.4mg/m2/day at bedtime

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P: Inj: 12mg(36 IU) /1.5mL (32805), 5.3mg(16 IU)/1mL (32802), 10mg/1.5mL (35367), 10mg(30 IU)/1.5mL(35369)

ADR:

COMMON
injection site reactions (numbness, pain, redness, swelling), musculoskeletal discomfort, increase tissue turgor (peripheral swelling)
SERIOUS
hyperglycemia (infrequent), hypothyroidism (infrequent), intracranial hypertension (rare), leukemia (rare), pancreatitis (rare)

NOTE: 冰箱冷藏，不可冷凍。

·《Contraindications》Acute critical illness due to complications following open heart surgery, abdominal surgery, or multiple accidental trauma; Acute respiratory failure; Prader-Willi syndrome, in patients who are severely obese, have a history of

upper airway obstruction or sleep apnea, or have severe respiratory impairment; sudden death has been reported; Active malignancy; Active proliferative or severe non-proliferative diabetic retinopathy; Closed epiphyses in pediatric patients; Hypersensitivity to mammalian-derived somatropin or any excipient; Hypersensitivity to benzyl alcohol-containing diluent ;
·脊椎側彎-本藥並未顯示會增加脊椎側彎的風險或嚴重性。在治療期間應監控脊椎側彎的徵狀。
·與口服oestrogen併用-如果女性病人在本藥治療時開始口服oestrogen，可能需要增加本藥的劑量以維持血液中IGF-1的濃度在正常的適齡範圍內。相對來說，當女性在本藥治療時停止使用oestrogen，則可能需要降低本藥的劑量以避免產生過量的生長激素及/或副作用。

藥名相似:

外觀相似:

外觀描述: 1.5mL 澄清注射液，『灰』蓋管式藥匣

28.12A Pituitary Hormones

35367 **C / Unknown(有**

Norditropin NordiFlex 10mg/1.5ml 諾德欣 諾易筆10公絲/1.5公撮

Somatropin inj 10mg/1.5mL cartridge

Dosage: 1常備品 35367

Adult
·Growth hormone deficiency: SC, 0.15-0.3mg/day (0.45-0.9IU/day) daily in the evening

Pediatric
·Growth-hormone deficiency in children: SC, 0.025-0.035mg/kg/day or 0.7-1.0mg/m2/day in the evening
·Turner's Syndrom, growth failure due to chronic renal insufficiency: SC, 0.045-0.05mg/kg/day or 1.4mg/m2/day in the evening

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P: Inj: 12mg(36 IU) /1.5mL (32805), 5.3mg(16 IU)/1mL (32802), 10mg/1.5mL (35367), 10mg(30 IU)/1.5mL(35369)

ADR:

COMMON
Injection site reactions (numbness, pain, redness, swelling), musculoskeletal discomfort, increase tissue turgor (peripheral swelling)
SERIOUS
Hyperglycemia (infrequent), hypothyroidism (infrequent), intracranial hypertension (rare), leukemia (rare), pancreatitis (rare)

NOTE: 儲存 2-8℃

·《仿單禁忌》：急重症、兒童普瑞德威利氏症候群(Prader-Willi Syndrome)、活性惡性腫瘤、糖尿病視網膜病變、生長板已閉合及已知對 somatropin 或其任何賦形劑過敏的患者。

·Must be stored in the refrigerator and used within 4 wks once inserted into pen.

藥名相似:

外觀相似:

外觀描述: 藍色注射筆內含1.5mL 澄清注射液，『藍』色劑量旋鈕

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000677

28.12A Pituitary Hormones

35368 **C / Caution**

Humatrope for injection 12 mg 優猛茁 注射劑 12 毫克

Somatropin 12mg/3mL cartridge

Dosage: 1常備品 35368

Adult
·Growth hormone deficiency: SC,
(1)Weight-based dosing: Not more than 0.006mg/kg/day, dose may be increased up to Max. 0.0125mg/kg/day
(2)Non-weight based dosing: Initial 0.2mg(0.15-0.3mg)/day, dose may increase by 0.1-0.2mg/day every 1-2 mons

Pediatric
·Growth-hormone deficiency in children: SC, 0.026-0.043mg/kg/day (0.18-0.3mg/kg/wk)
·Turner's syndrome: SC, up to 0.054mg/kg/day (0.375mg/kg/wk)
·Small for gestational age: SC, Initial 0.035mg/kg/day
·Short stature homeobox (SHOX)-containing gene deficiency: SC, 0.05mg/kg/day (0.35mg/kg/wk)

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: P Inj: 12mg(36 IU) cartridge with solvent(35368), 8mg(24 IU) with solvent ,cartridge(32803), 5.3mg(16IU) /1mL cartridge(32802), 10mg/1.5mL cartridge(35367), 3.33mg(10 IU) pow in vial(32804)

ADR:

COMMON
Edema of leg, peripheral edema, injection site reactions, lipoatrophy, eosinophil count raised, hematoma, arthralgia, myalgia, headache, paresthesia, rhinitis, influenza-like symptoms
SERIOUS
Disorder of cardiovascular system (In patients with Turner syndrome), edema, diabetes mellitus, hypothyroidism, impaired glucose tolerance, pancreatitis, progression of scoliosis deformity of spine, slipped upper femoral epiphysis, intracranial

tumor, pseudotumor cerebri, otitis media (in pediatric patients)

NOTE: 冰箱冷藏，不可冷凍。

·《Contraindications》Acute critical illness due to complications following open heart surgery, abdominal surgery, or multiple accidental trauma; increased mortality has been reported with pharmacologic doses; Acute respiratory failure; increased mortality has been reported with pharmacologic doses; Active malignancy; Active proliferative or severe non-proliferative diabetic retinopathy; Closed epiphyses in pediatric patients; Hypersensitivity to somatropin, Escherichia coli, or any of its excipients or diluents; Hypersensitivity to benzyl alcohol containing diluent; Hypersensitivity to metacresol-containing diluent; Prader-Willi syndrome, in pediatric patients who are severely obese or with severe respiratory impairment or have a history of upper airway obstruction or sleep apnea; Progression or recurrence of underlying intracranial tumor；
After reconstitution with provided diluent, refrigerate between 2-8℃ for up to 28 days.

藥名相似:

外觀相似:

外觀描述: 筆式小管附稀釋劑針筒

28.12A Pituitary Hormones

35369 **ɔt be ruled out / Infant risk can**

Omnitrope 10mg/1.5mL Solution for Injection 歐密拓“山德士”注射液10毫克/1.5毫升

Somatropin inj 10mg/1.5mL cartridge

Dosage: 1常備品 35369

Adult
·Growth hormone deficiency: SC,
(1)Weight-based dosing: Not more than 0.006 mg/kg/day, dose may be increased up to Max. 0.0125 mg/kg/day.
(2)Non-weight based dosing: Initial 0.2mg(0.15-0.3mg)/day, dose may increase by 0.1-0.2mg/day every 1-2 mons

Pediatric
·Growth-hormone deficiency in children: SC, 0.026-0.043mg/kg/day
·Turner's syndrome: SC, 0.045-0.054mg/kg/day
·Small for gestational age: SC, 0.035mg/kg/day
·Prader-Willi syndrome: SC, 0.035mg/kg/day, max. 2.7mg/day

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Inj: 12mg(36 IU) /1.5mL (32805), 5.3mg(16 IU)/1mL (32802), 10mg/1.5mL (35367), 10mg(30 IU)/1.5mL(35369)

ADR:

COMMON
Peripheral edema, Injection site reaction, Gynecomastia, Arthralgia, Arthritis/arthrosis, Myalgia, Headache, Hypesthesia, Paresthesia.
SERIOUS
Edema, Diabetes mellitus, Hyperglycemia, Hypothyroidism, Impaired glucose tolerance, Pancreatitis, Hypersensitivity reaction, Carpal tunnel syndrome, Scoliosis deformity of spine, Intracranial hypertension, Intracranial tumor, Neoplastic disease of uncertain behavior.

NOTE: 冰箱冷藏，不可冷凍。

·《Contraindications》Acute critical illness due to complications following open heart surgery, abdominal surgery, or multiple accidental trauma; increased mortality has been reported with pharmacologic doses; Acute respiratory failure; increased mortality has been reported with pharmacologic doses; Active malignancy; Active proliferative or severe non-proliferative diabetic retinopathy; Closed epiphyses in pediatric patients; Hypersensitivity to somatropin, Escherichia coli, or any of its excipients or diluents; Hypersensitivity to benzyl alcohol containing diluent; Hypersensitivity to metacresol-containing diluent; Prader-Willi syndrome, in pediatric patients who are severely obese or with severe respiratory impairment or have a history of upper airway obstruction or sleep apnea; Progression or recurrence of underlying intracranial tumor；
·After used, refrigerate between 2-8℃ for up to 28 days.

藥名相似:

外觀相似:

外觀描述: 1.5mL 澄清注射液，透明玻璃卡匣

28.12C Gonadotropin-Releasing Hormone (GnRH) Antagonists

35298 **UK /**

Decapeptyl Solution for injection 0.1mg/ml 弟凱得注射液 0.1毫克/毫升

Triptorelin acetate 105mcg/1mL (=95.6mcg triptorelin) syringe

Dosage: 1常備品 35298

Adult
·Infertility: SC, 0.1mg qd starts 5-7 days prior to menses and continue up to the day of ovulation induction with human chorionic gonadotropin

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 105mcg/1mL (=95.6mcg triptorelin)
Syringe(35298)

ADR:

Hot flushes, impotence, loss of libido, gynecomastia, vaginal dryness and/or dyspareunia, spotting

NOTE: 冰箱儲存

藥名相似:

外觀相似:

外觀描述: 1mL含藥透明溶液注射器，灰色蓋頭，白色推進器

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024602

28.14A Bisphosphonates

25756 C / Infant risk can

Reosteo 35mg Tablets 瑞骨卓35毫克膜衣錠

Risedronate sodium 35mg tab

Dosage: 1常備品 25756

Adult
·Osteoporosis in postmenopausal women and men: PO, ac, 35mg once weekly

Pediatric
·safety and effectiveness not established in children

Dosing adjustments in hepatic impairment:

No dosage adjustment need

Dosing adjustments in renal impairment:

Clcr≧30mL/min: No dosage adjustment need.
Clcr<30mL/min: Not recommended

P:

ADR:

COMMON
Decreased calcium level, decreased phosphate level, abdominal pain, constipation, flatulence, indigestion, nausea, headache
SERIOUS
Skin reaction, duodenal ulcer disease, esophageal erosions, esophageal perforation, esophageal stricture(rare), esophagitis(rare), gastric ulcer, acute ulcerative pharyngitis, ulcer of esophagus, hypersensitivity reaction, aseptic necrosis of bone(rare), musculoskeletal pain, scleritis, uveitis

NOTE: 室溫儲存

Contraindication: esophageal abnormalities, hypocalcemia, inability to stand or sit upright for 30 minutes

藥名相似:

外觀相似:

外觀描述: 橘色橢圓型錠，一面刻 RS，另一面刻 35。

28.14A Bisphosphonates

25757 ɔt be ruled out / Infant risk can

Reosteo 150mg Tablets 瑞骨卓150毫克膜衣錠

Risedronate sodium 150mg tab

Dosage: 1常備品 25757

Adult
·Postmenopausal osteoporosis; treatment and/or prophylaxis: PO, ac, 150mg Q1M

PEDATIRC
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

·No dosage adjustment needed

Dosing adjustments in renal impairment:

·CrCl ≧30mL/min: No dosage adjustment needed
·CrCl <30mL/min: Use not recommended

P: P Tab: 150mg(25757), 35mg(25756)

ADR:

COMMON
Rash, abdominal pain, constipation, diarrhea, indigestion, nausea, backache, urinary tract infectious disease, influenza-like illness
SERIOUS
Cardiac dysrhythmia, peripheral edema, hypersensitivity reaction, arthralgia, bone pain, myalgia, osteonecrosis of jaw, iritis, uveitis, nephrolithiasis, benign prostatic hyperplasia

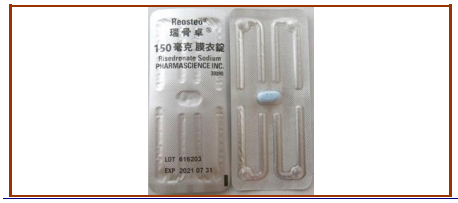
NOTE: 室溫儲存

·Contraindications: Esophageal abnormalities (eg, stricture or achalasia) that delay esophageal emptying, hypocalcemia, inability to sit or stand upright for at least 30 minutes

藥名相似:

外觀相似:

外觀描述: 藍色橢圓形錠，一面刻 RS，另一面刻 150



28.14A Bisphosphonates

25758 C / Unknown(有

FOSAMAX* PLUS TABLETS 70MG/5600 IU 福善美保骨錠 70毫克/5600國際單位

Alendronate 70mg & Colecalciferol 5600IU tab

Dosage: 1常備品 25758

Adult
·Osteoporosis in postmenopausal women and men:

PO, ac, 70mg once weekly

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr>35mL/min: No dosage adjustment needed
Clcr<35mL/min: Not recommended

P: Tab: 70mg/5600 IU(25758)

ADR:

COMMON
Decreased calcium level, decreased phosphate level, abdominal pain, constipation, flatulence, indigestion, nausea, headache
SERIOUS
Skin reaction, duodenal ulcer disease, esophageal erosions, esophageal perforation, esophageal stricture(rare), esophagitis(rare), gastric ulcer, acute ulcerative pharyngitis, ulcer of esophagus, hypersensitivity reaction, aseptic necrosis of bone(rare), musculoskeletal pain, scleritis, uveitis

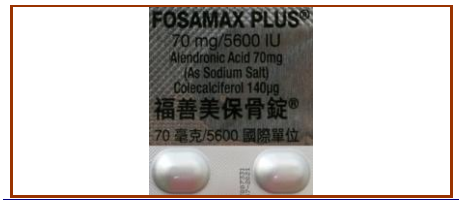
NOTE: 儲存30℃以下

Contraindication: esophageal abnormalities, hypocalcemia, inability to stand or sit upright for 30 minutes

藥名相似:

外觀相似:

外觀描述: 白色長橢圓扁錠，有270字樣



28.14A Bisphosphonates

27211 **D / Unsafe**

Sinclote Capsules "Sinphar" 400mg "杏輝" 杏骨樂膠囊400毫克

Clodronate disodium 400mg cap

Dosage: 1常備品 27211

Adult
·Hypercalcemia of malignacy and osteolysis of malignancy: PO, 1 hr ac, 1.6g/day.

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 50-80mL/min: 1600mg/day,
Clcr 30-50mL/min: 1200mg/day,
Clcr <30mL/min: 800mg/day

P: Cap: 400mg(27211), Inj: 300mg/5ml(37608)

ADR:

Leukemia, hypocalcemia, hyperkalemia, hyperparathyroidema, gastrointestinal disturbances, including nausea, dyspepsia, and diarrhea, nephrotoxicity, uveitis, rash, skeletal abnormalities.

NOTE: 室溫儲存

Should not take with milk, food or drugs containing calcium or other divalent cations because they impair the absorption of clodronate.

藥名相似:

外觀相似:

外觀描述: 淡黃色膠囊，有"SP614"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1047874

28.14A Bisphosphonates

36807 **D /**

Aclasta 5mg/100ml Solution for infusion 骨力強注射液5毫克/100毫升

Zoledronic Acid inj 5mg/100mL bot

Dosage: 1常備品 36807

Adult
·Paget's disease of bone & Postmenopausal osteoporosis: IV infusion over at least 15 minutes, 5 mg every 12 months. All patients should also receive 1500 mg elemental calcium daily in divided doses and 800 IU of vitamin D daily, particularly during the 2 weeks following administration

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr ? 35 mL/minute: No adjustment required.
Clcr < 35 mL/minute: Use is not recommended.

P: Inj: 4mg Vial (with 5mL SWI)(37868), 5mg/100mL Bot(36807)

ADR:

COMMON
Peripheral edema, weight decreased, abdominal pain, constipation, diarrhea, loss of appetite, nausea, vomiting, arthralgia, backache, asthenia, dizziness, headache, insomnia, paresthesia, nephrotoxicity, fatigue, fever
SERIOUS
Atrial fibrillation, cerebrovascular accident, aseptic necrosis of bone of jaw, bone pain, myalgia, dyspnea

NOTE: 儲存15-30℃

藥名相似:

外觀相似:

外觀描述: 100mL透明注射液『黃』蓋透明玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024692

28.14A Bisphosphonates

37610 **D / Unknown(有**

PAMISOL CONCENTRATED INJECTION 3MG/ML 裴米索注射液 3 公絲 / 公撮

Pamidronate disodium inj 15mg/5mL vial

Dosage: 1常備品 37610

Adult:
·Hypercalcemia of malignancy : IV infusion, 60-90mg dil. In 1000ml of IV fluid, over at least 2 to 24 hours ; a minimum of 7 days elapse is recommended before a second course of therapy
Initial serum Ca < 3 mmol/L or 12.0 mg%: 15-30mg
Initial serum Ca < 3-3.5 mmol/L or 12-14 mg%: 30-60mg
Initial serum Ca < 3.5-4 mmol/L or 14-16 mg%: 60-90mg
Initial serum Ca >4 mmol/L: 90mg
·Osteolytic bone metastases of breast cancer : IV infusion, 90mg dil. In 250ml of IV fluid as a 2-hour infusion , q3-4wk
·Osteolytic bone metastases of multiple myeloma : IV infusion, 90mg dil. In 500ml of IV fluid as a 4-hour infusion, q4wk
·Paget's disease : IV infusion, 30mg dil. In 500ml of IV fluid as a 4-hour infusion 3 days

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adstment needed.
Renal impairment: Infusion rate < 20mg/hr

P: Inj: 15mg/5mL Vial(37610)

ADR:

COMMON
anorexia,nausea,vomiting, fever, hypocalcemia, hypokalemia, hypomagnesemia, hypophosphatemia, infusion site reaction
SERIOUS
anemia, hypertension, seizures, worsening renal function

NOTE: 室溫儲存

1. Do not IV push
2. Aredia should be diluted in a calcium-free infusion solusion.

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液，『黃』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023633

28.14A Bisphosphonates

37868 **D /**

Zobonic lyophilized powder for solution for I.V. infusion 4mg 抑骨凍晶靜脈注射劑 4 毫克

Zoledronic Acid 4mg vial (with 5mL SWI)

Dosage: 1常備品 37868

Adult
·Bone metastasis(multiple myeloma & solid tumor configuration): IV infusion, 4mg every 3-4 wk; administer with an oral calcium supplement of 500mg and a multiple vitamin containing 400IU of vitamin D
·Malignant hypercalcemia: IV infusion, 4mg as a single dose; may repeat after a minimum of 7 days if serum calcium does not return to normal or remain normal after initial treatment

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 50-60mL/min: 3.5mg
Clcr 40-49mL/min: 3.3mg
Clcr 30-39mL/min: 3.0mg
Clcr<30mL/min: Not recommended

P: Inj: 4mg Vial (with 5mL SWI)(37868), 5mg/100mL Bot(36807)

ADR:

COMMON
Peripheral edema, weight decreased, abdominal pain, constipation, diarrhea, loss of appetite, nausea, vomiting, arthralgia, backache, asthenia, dizziness, headache, insomnia, paresthesia, nephrotoxicity, fatigue, fever
SERIOUS
Atrial fibrillation, cerebrovascular accident, aseptic necrosis of bone of jaw, bone pain, myalgia, dyspnea

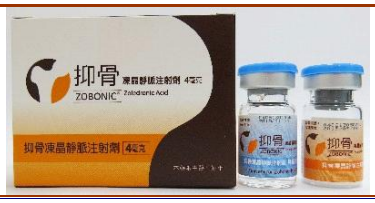
NOTE: 室溫儲存

·Single dose should not exceed 4mg and infusion over no less than 15 minutes
·Do not mix with Ca-containing solutions such as Lactated Ringers solution

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『藍』蓋透明玻璃小瓶，附5mL稀釋液『藍』蓋透明玻璃小瓶



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=155020

28.14B Parathyroid Agents

36806 **C /**

FORTEO FOR INJECTION 骨穩 注射液

Teriparatide 250mcg/mL, 2.4mL Prefilled Pen

Dosage: 1常備品 36806

Adult
·Postmenopausal osteoporosis, primary or hypogonadal osteoporosis in men: SC, 20mcg qd

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Mild to moderate renal impairment: No dosage adjustment needed

P: Inj: 250mcg/mL, 2.4mL Prefilled Pen(36806)

ADR:

COMMON
Hypotension, syncope, rash, sweating symptom, hyperuricemia, constipation, diarrhea, indigestion, nausea, vomiting, arthralgia, leg cramp, asthenia, dizziness, increasing frequency of cough, pharyngitis, rhinitis
SERIOUS
Angina

NOTE: 冰箱儲存

·Discard pen 28 days after first injection

藥名相似:

外觀相似:

外觀描述: 藍色注射筆，2.4mL澄清注射液

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000787

28.14B Parathyroid Agents

37611 **ɔt be ruled out / Infant risk can**

MIACALCIC SOLUTION FOR INJECTION 100 I.U./ML 密鈣息注射液１００國際單位／毫升

Calcitonin salmon 100 IU/1mL amp

Dosage: 1常備品 37611

衛生福利部(102.10.01)公告:適應症修訂為：「高血鈣危象、骨骼的帕哲特氏病(僅適合對替代療法無效或不適合這類療法的病人，如腎功能嚴重受損者)」

Adult
·Paget's disease : IM, SC, 100 IU/day, MD 50 IU qd or 50-100 IU qod
·Postmenopausal osteoporosis: IM, SC, 100 IU/day
·Hypercalcemia : IM, SC, initial 4 IU/kg q12h; after 1-2 days, may increase to 8 IU/kg q12h; after another 2 days, may increase to 8 IU/kg q6h

Pediatric
.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Nasal spray: 200IU/puff, 14puff/set (29058); Inj: 100IU/Amp (37611)

ADR:

COMMON
flushing of face or hands, inflammatory reactions at injection site, nausea, vomiting
SERIOUS
anaphylaxis, bronchospasm(few cases), anemia, cerebrovascular accident, thrombophlebitis, myocardial infarction.

NOTE: 冰箱保存

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液透明安瓿，頸部有藍點 及1條紅色線條

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2015478

28.14C Miscellaneous

36808 **demonstrated / Infant risk can**

Prolia 保骼麗注射液

Denosumab 60mg/1mL syringe

Dosage: 1常備品 36808

Adult
·Postmenopausal osteoporosis: SC,60 mg once every 6 months. All patients should also receive 1000 mg elemental calcium daily in divided doses and 400 IU of vitamin D daily.

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dose adjustments are needed

P: Inj: 60mg/1mL syringe(36808)

ADR:

COMMON
Hypercholesterolemia, Diarrhea, Nausea, Vomiting, Anemia, Arthralgia, Backache, Pain in limb, Asthenia, Headache, Cystitis, Nasopharyngitis, Upper respiratory infection, Fatigue.
SERIOUS
Endocarditis, Cellulitis, Dermatitis, Erysipelas, Rash, Hypercalcemia, Hypocalcemia, Hypophosphatemia, Pancreatitis, Anaphylaxis, Hypersensitivity reaction, Serious Infectious disease, Fracture of femur, Atypical, Osteonecrosis of jaw, Polymyalgia rheumatica, Worsening, Dyspnea, Cancer, Drug

withdrawal, Rebound effect.

·不良反應：上市後的使用經驗-增列皮膚與黏膜苔蘚樣藥疹(如類似扁平苔蘚的皮膚反應)及掉髮。

NOTE: 冰箱冷藏，不可冷凍

·《Contraindications》Hypersensitivity to any component of the product; Hypocalcemia; correct before initiating therapy; Pregnancy; may cause fetal harm. Perform pregnancy test prior to therapy initiation; adequate contraception required in women of reproductive potential during treatment and for at least 5 months after discontinuation ;
·施打本藥前必須排除懷孕情形。
·在治療期間直到最後一劑施打後至少5個月內，都需要採取有效的避孕法。
·嚴重腎功能不全者，新增合併使用擬鈣藥物可能加重低血鈣症風險且應嚴密監控血鈣。

藥名相似:

外觀相似:

外觀描述: 單次使用型預充針筒附『綠』色安全裝置

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000918

28.14C Miscellaneous

37776 **D / Unsafe**

XGEVA 癌骨瓦 注射液

Denosumab inj 120mg/1.7mL vial

Dosage: 1常備品 37776

Adult
·Prevention of skeletal events associated with bone metastases from solid tumors: SC, 120mg every 4 weeks

Pediatric
·Safety and efficacy have not been established.
·Giant cell tumor of bone: adolescents (skeletally mature) 13-17 years: SubQ: 120 mg once every 4 weeks; during the first month, give an additional 120 mg on days 8 and 15

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 120mg/1.7mL vial(37776), 60mg/1mL syringe(36808)

ADR:

COMMON
Hypercholesterolemia, diarrhea, nausea, vomiting, arthralgia, backache, pain in limb, asthenia, headache, cystitis, nasopharyngitis, upper respiratory infection, fatigue
SERIOUS
Endocarditis, cellulitis, dermatitis, erysipelas, rash, hypocalcemia, hypophosphatemia, pancreatitis, serious infectious disease, aseptic necrosis of bone of jaw, dyspnea, cancer

NOTE: 冷藏避光，不可冷凍

·It is not indicated for the prevention of skeletal-related events in patients with multiple myeloma.
·Administer Ca and vitamin D as needed for the treatment or prevention of hypocalcemia.
·停止使用本藥治療後，可能發生非因骨轉移之多發性脊椎骨折(MVF)，特別是有風險因子(如骨質疏鬆或之前有骨折病史)的病人。

藥名相似:

外觀相似:

外觀描述: 1.7mL透明注射液，『橘』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000924

28.16A Thyroid Agents

25730 **risk is minimal / Infant risk is**

THYROID-S TABLETS 100UG "JOHNSON "強生" 活甲錠 100微克

Levothyroxine sodium (T4) 100mcg tab

Dosage: 1常備品 25730

Adult
·Hypothyroidism: PO, 1.7mcg/kg/day (MD, 100-200mcg/day).
·Pituitary TSH suppression: PO, >2mcg/kg/day are usually required to suppress TSH < 0.1mU/L .

Pediatric
·Hypothyroidism

Age	Daily dose/kg or Dose/day
0-3 mon:	10-15mcg/kg
3-6 mon:	8-10mcg/kg or 25-50mcg
6-12 mon:	6-8mcg/kg or 50-75mcg
1-5 yrs:	5-6mcg/kg or 75-100mcg
6-12 yrs:	4-5mcg/kg or 100-150mcg
>12 yrs:	2-3mcg/kg
Growth & puberty complete:	1.6mcg/kg

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab:100mcg(25730)

ADR:

COMMON
Palpitations, Sweating, Weight loss, Diarrhea, Insomnia, Anxiety, Fatigue
SERIOUS
Tachycardia, Hyperthyroidism, Decreased bone mineral density, Hip fracture, Seizure,Dyspnea

NOTE: 避光儲存

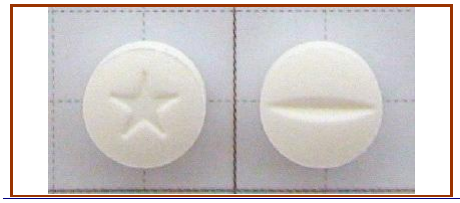
1.Contraindications: acute MI, hypersensitivity to thyroid hormone, treatment of obesity, uncorrected adrenal, cortical insufficiency, untreated angina, untreated hypertension, untreated thyrotoxicosis.
2.For patients> 50 yrs or younger patients with cardiovascular disease, starting dose 25-

50mcg/day, with adjustments of 12.5-25 mcg/day at 6-8 week intervals

藥名相似:

外觀相似: Metisone* Methylprednisolone (25601),

外觀描述: 白色圓扁錠，一面有刻痕，另一面有星星圖案



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048191

28.16B Antithyroid Agents

25761 D / Caution

LICA* TABLETS 利甲錠

Methimazole 5mg tab

Dosage: 1常備品 25761

Adult
·Hyperthyroidism: initial PO, 15-60mg/day in 3 divided doses q8hr apart; MD 5-15mg/day.
·Thyrotoxicosis: PO, 60-120mg/day in divided doses.

Pediatric
·Hyperthyroidism: initial PO, 0.4-0.7mg/kg/day in 3 divided doses q8hr apart; MD 1/2 of the initial dose. Max: 30mg/24 hrs

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adiustment needed

P: Tab: 5mg(25761)

ADR:

Myelosuppression, N/V, rash/urticaria, epigastric distress, arthralgias, paresthesia, aplastic anemia

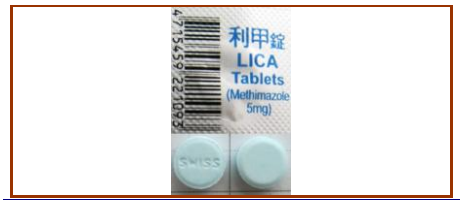
NOTE: 室溫儲存

Contraindications: breast feeding , hypersensitivity to methimazole products

藥名相似: Tab: 5mg(25761)

外觀相似:

外觀描述: 『淡藍』色圓扁錠，一面有"SWISS"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1004221

28.16B Antithyroid Agents

25762 D / Caution

POLUPI TABLET 50MG "PANBIOTIC" "汎生"僕樂彼錠 5 0毫克

Propylthiouracil 50mg tab

Dosage: 1常備品 25762

Adult
·Hyperthyroidism: initial 300-400mg/day div doses q8h (occasionally initial doses as high as 600-900mg/day are necessary), MD 100-150mg/day div doses q8-12h

Pediatric
·Hyperthyroidism:
6-10yrs: PO, initial 50-150mg/day or 5-7mg/kg/day, div doses q6-8hr
>10yrs: PO, initial 150-300mg/day or 5-7mg/kg/day div doses q6-8h
·Hyperthyroidism: MD 50mg bid or 1/3-2/3 of the initial dose

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

GFR 10-50 mL/min, reduce usual dose by 25%
GFR < 10 mL/min, reduce usual dose by 50%

P: Tab: 50mg(25762)

ADR:

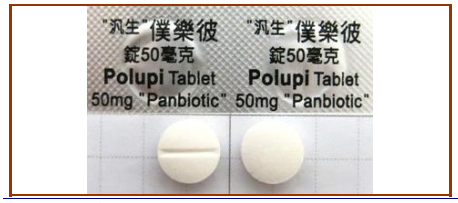
Myelosuppression, lupus-like syndrome, drug fever, N/V, epigastric distress, hepatotoxicity, rash

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠,一面有中央刻痕。包裝效期："E"+月份2碼+西元年後2碼



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043335

28.18 Miscellaneous

35413 ɔt be ruled out / Infant risk can

SOMATULINE AUTOGEL 120MG PROLONGED RELEASE SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE 舒得寧長效型注射凝膠劑120公絲

急用Lanreotide acetate 120mg/0.5mL syringe

Dosage: 2急用藥 35413

Adult
·Acromegaly: SC, 60-120mg q28 days
·Carcinoid tumours: SC, 120mg q28 days
·Neuroendocrine tumor, Gastroenteropancreatic: SC, 120mg q28 days

Pediatric
·Safety and effectiveness in pediatric patients have not been established

Dosing adjustments in hepatic impairment:

No dosage adjustment necessary.

Dosing adjustments in renal impairment:

No dosage adjustment necessary.

P: Inj: 120mg/0.5mL syringe(35413)

ADR:

COMMOM

Decreased heart rate, Hypertension, Sinus bradycardia, Injection site reaction, Abdominal pain, Constipation, Diarrhea, Flatulence, Loose stool, Nausea, Vomiting, Musculoskeletal pain, Dizziness, Headache.
SERIOUS
Bradyarrhythmia, Hyperglycemia, Hypoglycemia, Hypothyroidism, Cholangitis, Cholecystitis, Cholelithiasis, Pancreatitis, Anaphylaxis, Angioedema.

NOTE: 冰箱冷藏，不可冷凍。

·從冰箱取出後，若產品仍放在密封袋內且置放溫度低於40℃且不超過24小時，則本品仍可放回冰箱(從冰箱取出次數不得超過3次)及於之後使用。
·此藥為單次使用，第一次開封後應立即使用。若鋁箔袋已破損或開封，則請勿使用。
·若發生疑似膽結石併發症，應停止使用本藥。
·使用時及最後一次給藥後6個月內不要哺乳。

藥名相似:

外觀相似:

外觀描述: 預先充填注射針

28.18 Miscellaneous

37614 **B / Caution**

SANDOSTATIN LAR MICROSPHERES FOR INJECTION 30MG 善得定長效緩釋注射劑 3 0 毫克

急用Octreotide acetate LAR 30mg vial

Dosage: 2急用藥 37614

Adult
·Acromegaly: IM, intragluteally; initial 20mg at 4-wk intervals for 3 mons
if GH≦2.5ng/mL, continue 20mg every 4 weeks
if GH> 2.5ng/mL, increase to 30mg every 4 weeks
if GH≦1ng/mL, decrease to 10mg every 4 weeks
·Diarrhea and flushing associated with carcinoid tumors or diarrhea associated with vasoactive intestinal peptide tumors (VIPomas): IM, intragluteally; initial 20mg at 4-wk intervals for 2 mons; continue subcutaneous octreotide for at least 2 weeks before switching to the long-acting depot; then 10-30mg every 4 weeks, depending on the symptoms

Dosing adjustments in hepatic impairment:
Liver cirrhosis: Initial 10mg every 4 weeks

Dosing adjustments in renal impairment:
No dosage adjustment needed

P: Inj: 0.1mg/1mL Amp (37616), 20mg Vial (37615), 30mg Vial (37614, 急用藥)

ADR:
COMMON
Injection site pain, hyperglycemia, hypoglycemia, hypothyroidism, abdominal discomfort, cholelithiasis, constipation, diarrhea, flatulence, nausea, pancreatitis, disorder of biliary tract, dizziness, headache
SERIOUS
Cardiac dysrhythmia, worsening of congestive heart failure, sinus bradycardia

NOTE: Refrigerate, Protect from light

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『紅』蓋透明玻璃小瓶

28.18 Miscellaneous

37615 **B / Unsafe**

SANDOSTATIN LAR MICROSPHERES FOR INJECTION 20MG 善得定長效緩釋注射劑 2 0 毫克

Octreotide acetate LAR 20mg vial

Dosage: 1常備品 37615

Adult
·Acromegaly: IM, intragluteally; initial 20mg at 4-wk intervals for 3 mon
if GH< 2.5ng/mL, continue 20 mg every 4 weeks
if GH> 2.5ng/mL, increase to 30 mg every 4 weeks
if GH<1ng/mL, decrease to 10 mg every 4 weeks
·Diarrhea and flushing associated with carcinoid tumors or diarrhea associated with vasoactive intestinal peptide tumors (VIPomas): IM, intragluteally; initial 20mg at 4-wk intervals for 2 mon; then 10-30mg every 4 weeks, depending on the symptoms

Dosing adjustments in hepatic impairment:
Dosage adjustment required

Dosing adjustments in renal impairment:
Dosage adjustment required

P: Inj: 0.1mg/1mL Amp (37616), 20mg Vial (37615)

ADR:
COMMON
Abdominal discomfort, constipation, diarrhea, flatulence, nausea, biliary tract abnormalities, dizziness, headache, hyperglycemia, hypoglycemia, hypothyroidism , pain on injection, pancreatitis
SERIOUS
Arrhythmias, conduction abnormalities, sinus bradycardia, worsening of CHF

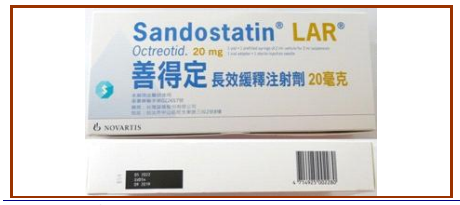
NOTE: 冰箱儲存

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『橙』蓋透明玻璃小瓶蓋上有FLIP及OFF字樣，附一支預先充填好賦形劑溶液的針筒

及兩支針頭



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022657

28.18 Miscellaneous

37616 **B / Caution**

SANDOSTATIN AMPOULES 0.1MG/ML 善得定注射液 0．1 毫克 / 毫升

Octreotide acetate inj 0.1mg/1mL amp

Dosage: 1常備品 37616

Adult
·Acromegaly: SC, IV, initial 50mcg tid, MD 100-500mcg tid
·Diarrhea and flushing associated with carcinoid tumors: SC, IV, initial 100-600mcg/day div. Into 2-4 doses for 2 weeks; MD 450 mcg/day (range 50-1500mcg/day, experience with doses above 750 mcg/day is limite)
·Diarrhea associated with vasoactive intestinal peptide tumors (VIPomas): SC, IV, initial, 200-300mcg div. Into 2-4 doses for 2 weeks(range 150-750mcg), MD, adjust to achieve therapeutic response (usually not more than 450mcg/day is required)

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

Dosage adjustment required

P: Inj: 0.1mg/1mL Amp (37616), 20mg Vial (37615)

ADR:

COMMON
Abdominal discomfort, constipation, diarrhea, flatulence, nausea, biliary tract abnormalities, dizziness, headache, hyperglycemia, hypoglycemia, hypothyroidism , pain on injection, pancreatitis
SERIOUS
Arrhythmias, conduction abnormalities, sinus bradycardia, worsening of CHF

NOTE: 冰箱冷藏，不可冷凍

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液透明安瓿，頸部有藍點及1條藍色線條和1條綠色線條

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2017873

30.02 Uterine Stimulants

26000 / Unsafe

ERGOMETRINE MALEATE TABLETS 0.2MG "JOHNSON" "強生"縮水蘋果酸麥角新鹼膜衣錠0．2毫克

Ergonovine maleate 0.2mg tab

Dosage: 1常備品 26000

Adult
·Postpartum/postabortal hemorrhage: PO, 0.2-0.4mg bid-qid for until the danger of uterine atony has passed, usually 48 hours

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Tab: 0.2mg(26000)

ADR:
COMMON
Hypertension, nausea, vomiting, dizziness, headache, nasal congestion
SERIOUS
Angina, MI, arrhythmia, hypertensive episode

NOTE: 室溫避光
Contraindications: induction of labor, threatened spontaneous abortion, pregnancy

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有JCP，另一面中央有溝痕及H、I字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12001749

30.02 Uterine Stimulants

27301 X / Unsafe

APANO TABLETS 200MG "L.O." "美時"保諾錠200公絲

Mifepristone 200mg tab

Dosage: 1常備品 27301

Adult
· Termination of intrauterine pregnancy through 49 days' pregnancy: PO, 600mg as a single dose. Two days after mifepristone, misoprostol 400mcg is administered unless a complete abortion has been confirmed

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Tab: 200mg(27301)

ADR:
COMMON
Rash, abdominal pain, diarrhea, nausea, vomiting, cramp, headache, abnormal vaginal bleeding
SERIOUS
Blood coagulation disorder with prolonged bleeding time, sepsis, toxic shock syndrome, abortion-related Clostridial Infection

NOTE: 室溫儲存
· It should be administered under physician supervision.
· Use with caution in women over age 35 who smoke 10 or more cigarettes daily.
· 14 days after administration of mifepristone, patient must return for a follow-up clinical examination or ultrasound for verification complete termination of pregnancy.

藥名相似:

外觀相似:

外觀描述: 淡黃色圓扁錠，一面有十字刻痕，另一面有LO 08字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044476

30.02 Uterine Stimulants

29030 C / Unknown(有

PROSTIN E2 VAGINAL TABLETS 普洛舒定 - 益二型陰道錠

Dinoprostone Vag. tab 3mg

Dosage: 1常備品 29030

Adult
·Elective labor induction: Intravaginally, one tablet(3 mg) to be inserted high into the posterior fornix. A second tablet may be inserted after 6-8 hrs if labor is not established. The maximum is 6 mg. Continuous administration of the drug for more than 2 days is not recommended.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Tab: 0.5mg(25664); VT: 3mg(29030)

ADR:
ADR:
COMMON
diarrhea, nausea, vomiting, backache, headache, irregular uterine contractions, fever, shivering
SERIOUS
Abnormal fetal heart rate, decreased diastolic arterial pressure, fetal heart deceleration, late fetal heart deceleration, myocardial infarction, disseminated intravascular coagulation, amniotic fluid embolism, hypertonic uterine dysfunction, infection of amniotic cavity, intrauterine sepsis of

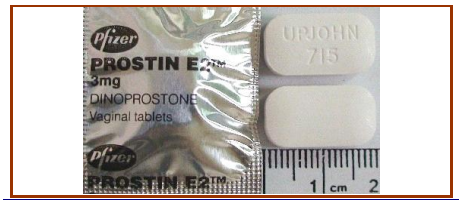
fetus, premature rupture of membranes, rupture of uterus, vaginospasm, fetal distress

NOTE: 冰箱保存

藥名相似:

外觀相似:

外觀描述: 白色方形扁錠，1面無字樣，1面"UPJOHN""715"



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2018215

30.02 Uterine Stimulants

35600 C / Caution

METHERGIN (R) AMPOULES 0.2MG/1ML 美腧琴注射液 0 · 2 毫克/毫升

Methylergometrine hydrogen maleate 0.2 mg/1mL amp

Dosage: 1常備品 35600

Adult
·Uterine atony/hemorrhage: IM, 0.2 mg; slowly IV, 0.1-0.2mg, may be repeated every 2 to 4 hrs as needed; up to 5 doses within 24 hrs

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 0.2mg/1mL amp(35600)

ADR:

COMMON
tinnitus, dizziness, hypertension, nausea, vomiting, sweating
SERIOUS
severe hypertension, cardiovascular events/angina, myocardial infarction

NOTE: 冰箱儲存

IV doses should be given over a period of not less than 1 minute

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液透明安瓿，頸部有藍點及1條藍色線條和1條紅色線條

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2013159

30.02 Uterine Stimulants

35601 a / Caution

OXOCIN INJECTION 10IU/ML "T.F." (OXYTOCIN) "大豐 " 諾速生注射液 1 0 國際單位 / 公撮 (催產素)

■Oxytocin inj 10 unit/1mL amp

Dosage: 1常備品 35601

Adult
·Induction of labor: IV infusion at conc of 10U/1000mL(10mU/mL), initial 0.5-1mU/min, increase every 30-60 min in increments of 1-2 mU/min until the desired contraction pattern has been established
·Postpartum uterine bleeding : IV infusion at conc of 10U/500mL(20mU/mL), 10-40 units may be infused at a rate of 20-40 mU/min; adjust infusion rate to sustain uterine contractions and control uterine atony
· Adjunctive treatment of abortion: IV infusion at conc of 10U/500mL(20mU/mL), 10-20mU/min; Max total dose 30 U/12h

--

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

COMMON
Nausea, vomiting
SERIOUS
Mother : Cardiac dysrhythmia, hypertensive episode, ventricular premature beats, water intoxication syndrome, afibrinogenemia, fatal, anaphylaxis, brain damage, CNS deficit, coma, subarachnoid hemorrhage, pelvic hematoma, postpartum hemorrhage, rupture of uterus
Fetus: Cardiac dysrhythmia, fetal bradycardia, ventricular premature beats, neonatal jaundice, newborn convulsions, neonatal retinal hemorrhage

NOTE: 室溫保存

Must be diluted before IV administration (eg, 10 U diluted in 500mL D5W or NS to yield 20mU/mL)

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液，透明安瓿頸部有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1033873

30.02 Uterine Stimulants

35605 X / Infant risk is

Duratocin Injection 100mcg/ml 巧特欣注射劑

■Carbetocin inj 100mcg/1mL vial

Dosage: 1常備品 35605

Adult
·Prevention of uterine atony after caesarean section under epidural or spinal anaesthesia: Slow IV over 1 min, 100mcg as a single dose given as soon as

possible after delivery of the infant, preferably before removal of the placenta

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Inj: 100mcg/1mL amp(35605)

ADR:

Flushing, hypotension, chest pain, tachycardia, headache, anxiety, chills, dizziness, pruritus, abdominal pain, nausea, vomiting, metallic taste, tremor, back pain, anemia, dyspnea, feeling of warmth, diaphoresis

NOTE: 室溫儲存30℃以下

·禁忌症
- 嬰兒出生前之懷孕和生產陣痛。
- Carbetocin不可用於引產（induction of labor）。
- 對carbetocin、oxytocin或任一賦形劑過敏。
- 肝臟疾病或腎臟疾病。
- 嚴重心血管疾病。
- 癲癇。

·〔警告〕在嬰兒出生前任何一產程都不適宜使用carbetocin。
·不建議同時服用本藥與prostaglandins。如需併用，須對患者小心監測。

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液，透明玻璃小瓶黑體字樣，『綠』色塑膠蓋

30.04 Uterine Relaxants

26408 **B / Unknown(有**

ANPO TABLETS 10MG "信東"安寶錠１０毫克

Ritodrine HCl 10mg tab

Dosage: 1常備品 26408

Adult
·Premature labor: PO,10 mg q2h for the first day, MD 10-20 mg q4-6h (Oral treatment is given 30 min before termination of IV therapy), Max. 120 mg/day

Pediatric

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 10mg (26408); Inj: 50mg/5mL Amp (36401)

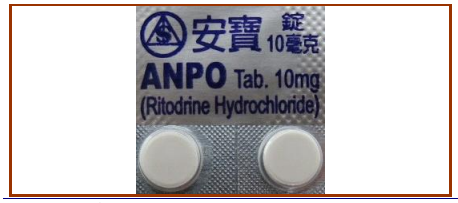
ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1037196

30.04 Uterine Relaxants

36401 **B / Unknown(有**

ANPO INJECTION 10MG/ML "信東"安寶注射液10毫克/毫升

Ritodrine HCl inj 50mg/5mL amp

Dosage: 1常備品 36401

Adult
·Premature labor: IV infusion, initial 50 mcg/min, increase every 10-15 min as necessary in increments of 50 mcg/min to the effective dose Max. 350mcg/min ; The infusion should be continued for 12-24 hrs after uterine contractions cease

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 10mg (26408); Inj: 50mg/5mL Amp (36401)

ADR:

tachycardia, pulmonary edema, tremor, nausea, vomiting, headache, erythema, nervousness, restlessness, jitteriness, emotional upset, anxiety or malaise, chest pain or tightness, cardiac arrhythmias, hepatic impairment

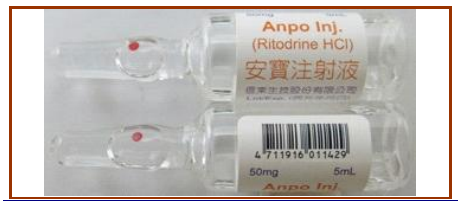
NOTE: 室溫儲存

Oral ritodrine may be administered 30 min before the termination of IV infusion

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液，透明安瓿頸部有紅點，白底橘/紫色字標籤



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1037126

30.04 Uterine Relaxants

36402 **UK /**

Tractocile concentrate for solution for infusion 7.5mg/ml 孕保寧濃縮輸注液

Atosiban 37.5mg/5mL vial

Dosage: 1常備品 36402

Adult
·Preterm labor: IV, initial 6.75mg bolus followed by infusion of 0.3mg/min for 3 hours and then 0.1mg/min up to 45 hours

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 6.75mg/0.9mL Vial(36403), 37.5mg/5mL Vial(36402)

ADR:

Nausea, headache, dizziness, hot flushes, vomiting, tachycardia, hypotension, injection site reaction, hyperglycemia

NOTE: 冰箱儲存

·The duration of the treatment should not exceed 48 hours; total dose should preferably not exceed 330mg

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液『藍』蓋透明玻璃瓶，蓋上有FLIP及OFF字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024561

32.02 Serums

36000 / Unknown(有

ANTIVENIN OF TR. MUCROSQUAMATUS AND TR. GRAMINEUS (LYOPHILIZED) 抗龜殼花及赤尾鮐蛇毒血清凍晶注射劑

Hemorrhagic antivenin single dose package (with 10mL solvent)

Dosage: 1常備品 36000

Adult
·1 package; A small portion SC around the wound, all the left IV at rate < 1ml/min, repeated q 0.5-2 hrs as needed.

Pediatric
·Children < 10 yrs: Double the dose.
·Children >= 10 yrs: 1 package

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: inj: Single dose package (36000)

ADR:

urticaria, fever, arthralgia, lymphadenopathy, shock, dyspnea, cyanosis, Arthus reaction

NOTE: 冰箱冷藏，不可冷凍

1.Each 10ml contains : Antivenin of tr. Mucrosquamatus & tr. Gramineus lyophilized ; 1000 or more Tanaka units.
2.Should be used within 2 hrs after reconstitution.

藥名相似:

外觀相似:

外觀描述: 白色乾粉、透明玻璃小瓶銀色鐵鋁瓶口，附10mL稀釋液透明玻璃小瓶銀色鐵鋁瓶口

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=9000006

32.02 Serums

36001 / Unknown(有

Antivenin of B. multicinctus and N. naja atra (Lyophilized) 抗雨傘節及飯匙倩蛇毒血清凍晶注射劑

Neurotropic antivenin single dose package (with 10 mL solvent)

Dosage: 1常備品 36001

ADULT
·1 package; A small portion SC around the wound, all the left IV at rate < 1ml/min, repeated q 0.5-2 hrs as needed.

Pediatric
·Children < 10 yrs: Double the dose.
·Children >= 10 yrs: 1 package.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: inj: Single dose package (36001)

ADR:

urticaria, fever, arthralgia, lymphadenopathy, shock, dyspnea, cyanosis, Arthus reaction

NOTE: 冰箱冷藏，不可冷凍。

1.Each 10ml contains : Antivenin of B. multicintus & N. naja atra lyophilized; 1000 or more Tanaka units.
2.Should be used within 2 hrs after reconstitution.

藥名相似:

外觀相似:

外觀描述: 白色乾粉、透明玻璃小瓶銀色鐵鋁瓶口，附10mL稀釋液透明玻璃小瓶銀色鐵鋁瓶口

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=9000009

32.02 Serums

36002 UK / Unknown(有

ANTIVENIN OF D. ACUTUS (LYOPHILIZED) 抗百步蛇毒血清凍晶注射劑

Antivenin of D. Acutus 1000 or more Tanaka units (with solvent)

Dosage: 1常備品 36002

Adult
·Snake bite by Deinagkistrodon acutus: initial 1 dose (1000 Tanaka units); if the local or systemic symptoms increase in severity, may repeat dose every 0.5-2 hrs until symptoms improve
The route of administration is based on elapsed time after the bite:
(1) within 2 hrs and without systemic symptoms: 1/2 of the dose injected SC around the bite area, the other 1/2 dose administered by IM
(2) 2 hrs later or have systemic symptoms: most of the dose administered by IV infusion, the residual dose administered by SC around the bite area

Pediatric
·Snake bite by Deinagkistrodon acutus:
<10 yrs: Double the adult dose. If the local or systemic symptoms increase in severity, may repeat dose every 0.5-2 hrs until symptoms improve
≧10 yrs: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 1000 or more Tanaka units vial with solvent(36002)

ADR:

Serum shock, chillness, fever, serum sickness, Arthus reaction

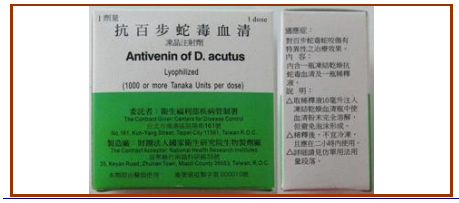
NOTE: 冰箱冷藏，不可冷凍。

·IV rate: the first 1mL should be administered over at least 5 mins, there after must not exceed 1mL/min

藥名相似:

外觀相似:

外觀描述: 白色乾粉、透明玻璃小瓶銀色鐵鋁瓶口，附10mL稀釋液透明玻璃小瓶銀色鐵鋁瓶口



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=9000010

32.02 Serums

36005 **C / Unknown(有**

HEPATITIS B IMMUNE GLOBULIN (HUMAN), HYPERHEP B S/D B型肝炎免疫人血球蛋白注射液

Hepatitis B Immune Globulin (HBIG) 0.5mL prefilled syringes

Dosage: 1常備品 36005

Adult

˙ Postexposure prophylaxis: IM, 0.06mL/kg, one dose within 24hrs after exposure & the second 1 month later

˙ Prophylaxis for sexual or intimate contacts of HBsAg-positive individuals: IM, single dose with 0.06mL/kg, within 14 days of the last sexual or intimate exposure

Pediatric

˙ Neonates born to HBsAg-positive women: IM, 0.5mL within 12hrs after birth

˙ Children exposed to individuals with acute HBV infection (for unvaccinated infants< 12 months) : IM, 0.5mL

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 0.5mL prefilled syringe(36005), 500IU/10mL Vial(37874, 急用藥-IV), 1100IU/5mL Vial(37790, 急用藥-IM), 健診(39316)

ADR:

COMMON
erythema at injection site, pain at injection site, headache, myalgias, malaise, nausea, vomiting, joint stiffness, leukopenia, elevated alkaline phosphatase, elevated AST, elevated creatinine, ecchymosis

NOTE: 冰箱冷藏，不可冷凍。

1.BayHep B should not be administered intravenously.
2.HBIG is most effective when administered as soon as possible after exposure (preferably within 24 hours) and may be ineffective if administered 7 days after a percutaneous exposure or 14 days after a sexual exposure.

藥名相似:

外觀相似:

外觀描述: 0.5mL透明注射液含藥注射器外包『紫』色針筒套 ，灰色蓋頭

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000452

32.02 Serums

36014 **C / Infant risk can**

Thymoglobuline 25mg (ATG) 兔抗胸腺細胞免疫球蛋白急用Antithymocyte globulin

Dosage: 2急用藥 36014

Adult
IV infusion over 4 hrs.
· Prophylaxis of heart transplant rejection: 4 mg/kg IV as 6 hr infusion on days 1-5 posttransplant combined with conventional immunosuppression therapy
· Prophylaxis of renal transplant rejection: initial 1-2 mg/kg daily as 4-24 hr infusion via central venous catheter/brachial arteriovenous fistula with dose adjustments 3 times weekly for 10-14 days posttransplant; maintain sheep-erythrocyte-rosette level of circulating mononucleated cells less than 10%
· Treatment of rejection in heart transplant:125 mg daily for 3 days has been administered (infused over 8-hour period)
· Aplastic anemia: 2.5-3.5 mg/kg/day for 5 days

--

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: rabbit ATG 25mg (36014)

ADR:

COMMON
abdominal pain, diarrhea, nausea, vomiting, dizziness, headache, dyspnea, myalgia
SERIOUS
shivering, fever, hyperkalemia, hypertension, peripheral edema, tachycardia, infection (including cytomegalovirus infection)
leukopenia, thrombocytopenia, sepsis

NOTE: 冰箱儲存

藥名相似:

外觀相似:

外觀描述: 白色注射凍晶,『深綠』色蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000308

32.02 Serums

36017 C / Infant risk is

HyperRHO* S/D full dose inj 抗RH因子球蛋白注射液

Rho(D) immune globulin(Human) 1500 int unit(300mcg)/1mL prefilled syringe

Dosage: 1常備品 36017

Adult

·Dosing adjustment: 1 prefilled syringe (1500 int unit) prevents maternal sensitization if fetal packed red blood cell volume that has entered the circulation is <15mL (or 30 Ml whole blood); if it is more, give additional vials. The number of vials = RBC volume of the calculated fetomaternal hemorrhage divided by 15.

·Postpartum prophylaxis: IM, 1 prefilled syringe (1500 int unit) to Rh(-) woman following delivery of a full-term Rh(+) infant within 72 hrs (if dosage results in a fraction of a single-dose prefilled syringe, the total dose can be given in divided doses at different sites at one time or intervals, provided the entire dose within 72 hrs.)

·Antepartum prophylaxis: IM, 1 prefilled syringe at 26~28 wks of gestation; If the infant is Rh(+), the second single-dose administered within 72 hrs after delivery (If delivery occurs within 3 wks after antepartum dose, the postpartum dose withheld, but a test for fetal-maternal hemorrhage should be performed.)

·Following amniocentesis, percutaneous umbilical blood sampling, chorionic villus sampling, threatened abortion at any stage of gestation with continuation of pregnancy, or other abdominal trauma during pregnancy: IM, 1 prefilled syringe (If required at 13~18 wks gestation, an additional single-dose should be given at 26~28 wks; If required in the early pregnancy, additional antepartum doses should be administered, e.g., at 12-week intervals)；following miscarriage, abortion, or termination of ectopic pregnancy ≦13 wks of gestation: IM, 250 int unit as soon as possible；13 wks of gestation: IM, 1 prefilled syringe (1500 int unit)；following transfusion of Rh(+) blood to an unsensitized, Rh(-) individual: the number of prefilled syringes is determined by dividing the volume of Rh(+) packed red cells transfused by 15; if the calculated dose results in a fraction, the next whole number of single-dose prefilled syringes should be administered (eg, if 1.4, give 2 syringes). It should be administered wit

.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 1500 int unit(300mcg)/1mL prefilled syringe(36017)

ADR:

COMMON

Rho(D) positive patients with ITP: chills, fever, headache, backache, intravascular hemolysis(mean decrease in hemoglobin of 1.7 g/dL at full initial dose and 0.81 g/dL at reduced dose)

SERIOUS

Rho(D) positive patients with ITP: Acute renal failure

NOTE: 儲存2-8℃

Contraindications: Neonates, IgA deficiency

本藥只能肌肉注射，絕不可靜脈注射

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液含藥注射器外包『粉紅』色針筒套，灰色蓋頭

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000462

32.02 Serums

36020 ɔt be ruled out / Infant risk can

■▼PRIVIGEN* solution for infusion "貝靈"瑞利勁人體免疫球蛋白靜脈注射液10%

■▼Human Immunoglobulin (IVIG) inj 5g/50mL bot

Dosage: 1常備品 36020

ADULT

˙ Primary immunodeficiency diseases: IV, initial 0.4~0.8g/kg, followed by 0.2g/kg every 3 wks

˙ Secondary immunodeficiency diseases: IV, 0.2~0.4g/kg every 3~4 wks

˙ Idiopathic thrombocytopenic purpura(acute): IV, 0.8~1.0g/kg on 1st day, repeated on 3rd day (or 0.4g/kg/day on 2nd~5th day)

˙ Bone marrow transplantation: IV, 0.5g/kg once daily beginning days 7 and 2 prior to transplantation (or at the time conditioning therapy for transplantation is begun); then once weekly through day 90 posttransplant.

˙ Toxic shock syndrome (staphylococcal or streptococcal): 0.15~0.4 g/kg once daily for 5 days (or single dose of 1-2 g/kg)

˙ Prevent bacterial infections in allogeneic hematopoietic stem cell transplant (HSCT) recipients(IgG < 400mg/dL)

Adults & adolescents: 0.5 g/kg once weekly

˙ Bacterial infections, secondary to B-cell chronic lymphocytic leukemia (CLL) patient: 0.4 g/kg given once every 3~4 wks

PEDIATRIC

˙ Primary immunodeficiency diseases: IV, started with 0.4~0.8g/kg, followed by 0.2g/kg every 3 wks

˙ Secondary immunodeficiency diseases: IV, 0.2~0.4g/kg every 3~4 wks

˙ Idiopathic thrombocytopenic purpura(acute): IV, 0.8~1.0g/kg on 1st day, repeated on 3rd day (or 0.4g/kg/day on 2nd~5th day)

˙ Kawasaki disease: IV, 1.6~2.0g/kg in divided doses over 2~5 days (initiated within the first 10 days of fever; therapy should be combinated with aspirin: PO, initial 80~100 mg/kg/day div in 4 equally doses; when fever subsides, decreased to 3~5 mg/kg once daily for 6-8 weeks or longer)

˙ Toxic shock syndrome (staphylococcal or streptococcal): 0.15~0.4 g/kg once daily for 5 days (or single dose of 1-2 g/kg)

˙ Prevent bacterial infections in allogeneic Hematopoietic stem cell transplant (HSCT)

recipients(IgG< 400mg/dL): 0.4 g/kg once monthly
· Prevent serious bacterial infections in HIV-infected infants & children (IgG< 400mg/dL): 0.4 g/kg once every 2~4 wks

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

COMMON
Heart murmur, Hypertension, Hypotension, Increased heart rate, Increased systolic arterial pressure, Peripheral edema, Injection site reaction, Pruritus, Rash, Urticaria, Increased body temperature, Aphthous ulcer of mouth, Diarrhea, Nausea, Upper abdominal pain, Vomiting, Complication of infusion, Arthralgia, Muscle weakness, Myalgia, Pain in limb, Spasm, Asthenia, Dizziness, Headache, Lethargy, Migraine, Otalgia, Asthma, Cough, Nasal congestion, Pain in throat, Pharyngitis, Pharyngolaryngitis, Sinusitis, Wheezing, Dehydration, Fatigue, Fever, Pain, Rigor, Shivering

SERIOUS
Chest discomfort, Chest pain, Myocardial infarction, Tachycardia, Hyponatremia, Hemolysis, Hemolytic anemia, Thrombosis(Primary humoral immunodeficiency, immune thrombocytopenic purpura), Hepatitis, Anaphylaxis, Backache, Aseptic meningitis, Acute renal failure, Hypokalemic nephropathy, Pulmonary embolism, Transfusion related acute lung injury

NOTE: 冰箱冷藏，不可冷凍。

Contraindications: Isolated immunoglobulin A deficiency with antibodies to IgA; patients may react to immune globulins which contain immunoglobulin A

藥名相似:

外觀相似:

外觀描述: 50mL透明注射液

32.02 Serums

36026 ɔt be ruled out / Infant risk can

BERIGLOBIN P "貝靈" 克療丙注射劑

■▼Human normal immunoglobulin inj (IMIG)320mg/2mL syringe

Dosage: 2新北市衛生局提供 36026

ADULT
· Replacement therapy: SC, LD 0.2-0.5g/kg div. several days, MD 0.4-0.8g/kg/monthly div. weekly, max 0.1-0.15g/kg/day.
· Hepatitis A short- term prophylaxis(pre-exposure): IM, 0.17mL/kg. It can be given in combination with Hepatitis A vaccine.
· Hepatitis A prophylaxis(post-exposure): IM, 0.17mL/kg.

Pediatric
· Replacement therapy: Same as adult.
· Hepatitis A short- term prophylaxis(pre-exposure):Same as adult.
· Hepatitis A prophylaxis(post-exposure): Same as adult.
· 麻疹個案接觸者(疾管署)：一歲以下嬰幼兒及免疫低下者符合以下條件：
1.在衛生單位確認疫調接觸者名單內。
2.距離最後一次暴露小於或等於6天。
3.需經醫師評估。
一般嬰幼兒為0.25 ml/kg，免疫低下患者為 0.5 ml/kg。

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

COMMON
nausea, vomiting, joint pain, swelling, soreness, redness, induration, local heat, itching, bruising or rash, chills, fever, headache, generally feeling unwell moderate back pain, unconsciousness, dizziness, rash, whee zing.
SERIOUS
allergic reactions, anaphylactic shock.

NOTE: 冰箱冷藏，不可冷凍。

1.Do NOT use Beriglobin P:
· if patients are allergic (hypersensitive) to any of the components of the product.
· into a blood vessel.
· into a muscle if you suffer from a disorder of blood clotting.
2.Beriglobin P contains up to 110 mg sodium per dose (75 kg body weight) if the maxi mum daily dose is given (11.25 g = 70.3 ml). This should be taken into consideration if patients are on a controlled sodium diet.
3.If Beriglobin P* is accidentally administered into a blood vessel. Patients could develop a severe allergic reaction (anaphylactic shock). This reaction is seen as a fall in blood pressure and shortness of breath. Patients could also develop blood clots (thromboembolic events). Symptoms of these may include:
·severe chest pain or chest pressure (heart attack)
·weakness, paralysis or numbness on one side of the body, loss of vision in one or both eyes, speech difficulties (stroke)
·cough, chest pain, rapid breathing, rapid heart rate (pulmonary embolism)
·swelling, pain, redness of the leg (deep vein thrombosis)
4.接種IMIG注意事項(疾管署)：
·免疫低下患者最近三個星期內曾接受IVIG治療，且劑量≧100 mg/kg，可視同已具有免疫力，不需再施打IMIG。
·已接受IMIG者，應間隔6個月以上再接種活性減毒疫苗

。

·為病患接種IMIG後，請醫師於黃卡之空白欄位處載明IMIG及施打日期，以利後續活性疫苗接種時程之計算。

藥名相似:

外觀相似:

外觀描述: 2mL預充填注射針筒裝

32.02 Serums

37790 C / No report(毫

HEPATITIS B IMMUNE GLOBULIN (HUMAN), HYPERHEP B S/D B 型肝炎免疫人血球蛋白注射液

急用Hepatitis B immune Globulin (HBIG) 1100 IU/5mL vial

Dosage: 2急用藥 37790

Adult

· Prophylaxis against re-infection of a transplanted liver in HBsAg-positive patients: IM, 2000 IU monthly post transplantation

· Postexposure prophylaxis: IM, 0.06mL/kg, one dose within 24hrs after exposure & the second 1 month later

· Prophylaxis for sexual or intimate contacts of HBsAg-positive individuals: IM, 0.06mL/kg as a single dose, within 14 days of the last sexual or intimate exposure

Pediatric

· Neonates born to HBsAg-positive women: IM, 0.5mL within 12hrs after birth

· Children exposed to individuals with acute HBV infection (for unvaccinated infants< 12 months): IM, 0.5mL

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 0.5mL prefilled syringe(36005), 500IU/10mL Vial(37874, 急用藥-IV), 1100IU/5mL Vial(37790, 急用藥-IM), 健診(39316)

ADR:

COMMON
Erythema at injection site, injection site pain, nausea, vomiting, ecchymosis, mild leukopenia, mild AST/SGOT level raised, joint stiffness, myalgia, headache, mild serum creatinine raised, alkaline phosphatase raised, malaise

NOTE: 冰箱保存

· Avoid vaccines other than hepatitis B vaccine for 3 months after receiving HBIG.

藥名相似:

外觀相似:

外觀描述: 5mL透明注射液,『白』蓋透明玻璃小瓶

32.02 Serums

37812 /

CYTOTECT CP BIOTEST "百合" 施多特注射液

■急用Cytomegalovirus Immune globulin(CMV-IGIV) inj 50mL vial

Dosage: 2急用藥 37812

Adult

·

Pediatric

·

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P:

ADR:

NOTE: 冰箱避光

藥名相似:

外觀相似:

外觀描述: 50mL透明淡乳白色注射液,銀色鐵鋁瓶口,透明玻璃小瓶

32.02 Serums

37874 C / Infant risk can

HEPATECT CP INJECTION 立保 B 型肝炎抗體注射液

急用Hepatitis B immune Globulin (HBIG) 500IU/10mL vial

Dosage: 2急用藥 37874

Adult

· Prophylaxis against re-infection of a transplanted liver in HBsAg-positive patients: IV infusion, 10000 IU(200mL) during surgery in the anhepatic phase and 2000 IU(40mL) daily for 7 days after surgery.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 0.5mL prefilled syringe(36005), 500IU/10mL Vial(37874, 急用藥-IV), 1100IU/5mL Vial(37790, 急用藥-IM), 健診(39316)

ADR:

COMMON
erythema at injection site, injection site pain, nausea, vomiting, decreased white blood cell count(Mild), ecchymosis(Mild), alkaline phosphatase raised(Mild), AST/SGOT level raised(Mild), Joint stiffness(Mild), myalgia, headache, serum creatinine raised(Mild), malaise.
SERIOUS(仿單)
anaphylactic shock, acute renal failure, thromboembolic reactions such as myocardial infarction, stroke, pulmonary embolism and deep vein thrombosis.

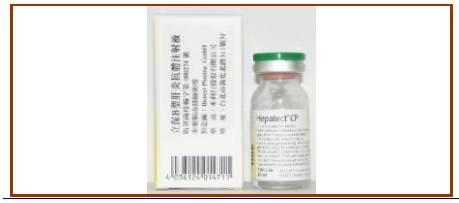
NOTE: 冰箱保存

· Infusion rate: Initial 0.1mL/kg/hr for 10mins, if well tolerated, it may gradually increased to Max. 1mL/kg/hr
· Maintain anti-HBs level at 100IU/L with monthly checks during subsequent long-term treatment (at least 6 months)
· Contraindications : Intolerance to homologous immunoglobulins; IgA deficiency
·50毫克/毫升人類蛋白質中至少96%是 IgG，其具有50國際單位/毫升B型肝炎病毒表面抗原(HBs)的抗體。
·溶液是透明、或稍微乳白及無色到淺黃。使用前，應以肉眼來檢查微粒子且為無色，當溶液產生混濁或沈澱時不可使用。

藥名相似:

外觀相似:

外觀描述: 10mL透明注射液,『綠』蓋透明玻璃小瓶



32.02 Serums

39316 **C /**

HEPATITIS B IMMUNE GLOBULIN (HUMAN), HYPERHEP B S/D B 型肝炎免疫人血球蛋白注射液

Hepatitis B Immune Globulin (HBIG) 0.5mL prefilled syringes(健診)

Dosage: 2衛福部提供 -疫苗 39316

Adult
·Postexposure prophylaxis: IM, 0.06 mL/kg, one dose within 24 hrs after exposure & the second 1 month later
·Prophylaxis for sexual or intimate contacts of HBsAg-positive individuals: IM, single dose with 0.06 mL/kg, within 14 days of the last sexual or intimate exposure

Pediatric
·Neonates born to HBsAg-positive women: IM, 0.5mL within 12 hrs after birth
·Children exposed to individuals with acute HBV infection (for unvaccinated infants< 12 months) : IM, 0.5mL

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 0.5mL (36005), 急用500IU/10mL(37874); 健診(39316)

ADR:

COMMON
erythema at injection site,pain at injection site,headache, myalgias, malaise,nausea, vomiting,joint stiffness,leukopenia (mild),elevated alkaline phosphatase, elevated AST (mild),elevated creatinine (mild),ecchymosis

NOTE: 冰箱冷藏，不可冷凍。

vaccinate with hepatitis B vaccine if exposed patient not previously vaccinated

藥名相似:

外觀相似:

外觀描述: 0.5mL透明注射液含藥注射器外包『紫』色針筒套 ，灰色蓋頭)

32.02 Serums

39333 **ɔt be ruled out / Infant risk can**

旅專(免費)HyperRAB* S/D Immune Globulin 狂犬病免疫球蛋白

旅專(免費)Rabies immune globulin 300IU/2mL vial

Dosage: 2衛福部提供 -疫苗 39333

Adult
·Rabies postexposure prophylaxis (previous unvaccinated against rabies): Local infiltration and IM, 20 IU/kg as a single dose at the same time as the first dose of rabies vaccine. It may be administered within 7 days after the first vaccine dose. If anatomically feasible, the full dose should be infiltrated around the wound(s), with the remainder given IM at a site distant from vaccine administration

Pediatric
The Advisory Committee on Immunization Practices (ACIP) and American Academy of Pediatrics (AAP) recommend that postexposure prophylaxis of rabies in children follow the same guidelines as those in adults

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 300IU/2mL Vial(39333, 免費)(39334, 自費)

ADR:

COMMON

Erythema, injection site pain, headache
SERIOUS
Anaphylaxis (rare)

NOTE: 冰箱冷藏，不可冷凍

·Never administer rabies vaccine and rabies immune globulin (RIG) in the same syringe or same anatomical site.
·RIG may inhibit the anamnestic response to the vaccine. RIG is unnecessary and should not administered to individuals who have been previously vaccinated.
·Immunization with live vaccines should not be given within 3 months after RIG administration.
·當依病人體重核算之毫升量不足浸潤傷口時，以生理鹽水將適當稀釋2 至3 倍。

藥名相似:

外觀相似:

外觀描述: 依屆時疾管局提供之廠牌

32.02 Serums

39334 **ɔt be ruled out / Infant risk can**

旅專(自費)HyperRAB* S/D Immune Globulin 300IU/2mL 狂犬病免疫球蛋白

旅專(自費)Rabies immune globulin 300IU/2mL vial

Dosage: 2衛福部提供-疫苗 39334

Adult
·Rabies postexposure prophylaxis (previous unvaccinated against rabies): Local infiltration and IM, 20 IU/kg as a single dose at the same time as the first dose of rabies vaccine. It may be administered within 7 days after the first vaccine dose. If anatomically feasible, the full dose should be infiltrated around the wound(s), with the remainder given IM at a site distant from vaccine administration

Pediatric
The Advisory Committee on Immunization Practices (ACIP) and American Academy of Pediatrics (AAP) recommend that postexposure prophylaxis of rabies in children follow the same guidelines as those in adults

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Inj: 300IU/2mL Vial(39333, 免費)(39334, 自費)

ADR:
COMMON
Erythema, injection site pain, headache
SERIOUS
Anaphylaxis (rare)

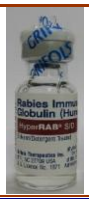
NOTE: 冰箱冷藏，不可冷凍

·Never administer rabies vaccine and rabies immune globulin (RIG) in the same syringe or same anatomical site.
·RIG may inhibit the anamnestic response to the vaccine. RIG is unnecessary and should not administered to individuals who have been previously vaccinated.
·Immunization with live vaccines should not be given within 3 months after RIG administration.
·當依病人體重核算之毫升量不足浸潤傷口時，以生理鹽水將適當稀釋2 至3 倍。

藥名相似:

外觀相似:

外觀描述: 依屆時疾管局提供之廠牌



32.06 Vaccines

28704 **C /**

RotaTeq (Rotavirus vaccine, live, oral, pentavalent) 輪達停口服活性五價輪狀病毒疫苗

Rotavirus oral Vaccine 2mL/Tu

Dosage: 1常備品 28704

Pediatric
· Prevention viral gastroenteritis due to rotaviruses: PO, 2mL at 6-12 weeks of age followed by 2 doses separated at 4-10 week intervals for a total of 3 doses. The third dose should not be given after 32 weeks of age. The ACIP recommends 2mL x 3 doses at 2, 4 and 6 mons

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P:

ADR:
COMMON
diarrhea, vomiting, irritability, otitis media, nasopharyngitis, and bronchospasm

NOTE: 冰箱冷藏，不可冷凍。

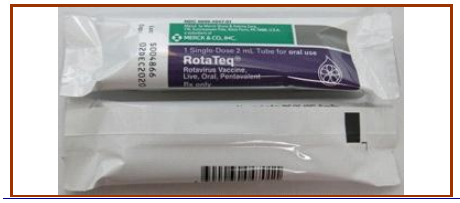
· 《Contraindications》History of intussusception; Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component [17]; hypersensitivity to any component of the vaccin; Severe Combined Immunodeficiency Disease (SCID)
;
· RotaTeq* is a live, oral pentavalent vaccine that contains 5 live reassortant rotaviruses. Each dose contains G1 reassortant 2.2*10(6) IU, P1 reassortant 2.3*10(6) IU, G2 reassortant 2.8*10(6) IU, G3 reassortant 2.2*10(6) IU, G4 reassortant 2*10(6) IU
· Oral poliovirus vaccination should be administered at least two weeks apart from

RotaTeq*
· May be administered with food and liquid, including breast milk
· Do not mix with any other vaccines or solutions
· If infant regurgitates, spits out or vomits during or after administration, it is not recommended to re-administer the dose; remaining recommended doses should be given at the appropriate intervals
· 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 不透明白色鋁袋包裝,有綠色和紫色區塊



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000825

32.06 Vaccines

28705 **C /**

Rotarix Oral Suspension 羅特律輪狀病毒疫苗口服懸液劑

Rotavirus oral susp vaccine 1.5mL in prefilled oral dosing syringe

Dosage: 1常備品 28705

NDA

Pediatric
· Prevention viral gastroenteritis due to rotaviruses: PO, 1.5mL x 2 doses; first dose may be given between 6-16 weeks of age with subsequent dose at least 4 weeks later; the course must be completed by the age of 24 weeks

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

Loss of appetite,Vomiting , Irritability, Cough , Fever

NOTE: 儲存2-8℃

· For oral use only; not for injection. It should be reconstituted with diluent before oral administration.
· Rotarix* is live attenuated human rotavirus, each dose contains RIX4414 strain 10(6) CCID50
· Taiwan ACIP recommends oral poliovirus vaccine should be administered two weeks apart from Rotarix*
· May be administered with food and liquid, including breast milk
· If infant spits out or regurgitates most of the vaccine dose, a single replacement dose may be given at the same vaccination visit
· 本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 透明澄清1.5mL口服懸液，盛裝於附有推桿活塞的口服給藥器

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000892

32.06 Vaccines

36051 **C / Infant risk is**

VAQTA* (HEPATITIS A VACCINE, INACTIVATED) "唯德" 不活化A型肝炎疫苗

(幼兒免費)Hepatitis A virus inj, inactivated 25U/0.5mL vial

Dosage: 2衛福部提供 -疫苗 36051

Adult
·Hepatitis A immunization: IM, 50U(1mL) x 1 dose; booster dose 6-18 months later

Pediatric
·Hepatitis A immunization (1-18yrs): IM, 25U(0.5mL) x 1 dose; booster dose 6-18 months later

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 25U/0.5mL Vaqta (36093自費)(36091免費);1440 Elisa Unit/1mL Havrix (36080自費)(36092免費)

ADR:

COMMON
anorexia, nausea, fatigue, malaise, fever, headache, injection site soreness
SERIOUS
anaphylaxis, anaphylactoid reaction (rare)

NOTE: 冰箱冷藏，不可冷凍。

1. Shake well before use.
2. Vaqta and Havrix can be administered interchangeably.

藥名相似:

外觀相似:

外觀描述: 0.5mL注射液,『紫』蓋,綠色瓶口,透明玻璃小瓶

32.06 Vaccines

36052 **C / Infant risk is**

AVAXIM* 80U Pediatric 巴斯德A型肝炎疫苗(兒童用)

Hepatitis A virus vaccine inj, inactivated 80U/0.5mL syringe

Dosage: 2衛福部提供 -疫苗 36052

Adult
·

Pediatric
·Hepatitis A immunization (1-18yrs): IM, 80U(0.5mL) x 1 dose; booster dose 6-36 months later

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 25U/0.5mL Vaqta (36093自費)(36091免費);1440 Elisa Unit/1mL Havrix (36080自費)(36092免費); 80U/0.5mL AVAXIM (36052免費)

ADR:

COMMON
anorexia, nausea, fatigue, malaise, fever, headache, injection site soreness
SERIOUS
anaphylaxis, anaphylactoid reaction (rare)

NOTE: 冰箱冷藏，不可冷凍。

·《仿單禁忌》：對活性成分、任何一種賦形劑、neomycin嚴重過敏(可能因製程使用而在劑量中有微量殘留)。先前接種此疫苗曾發生嚴重過敏。
·Shake well before use.
·Vaqta and Havrix can be administered interchangeably.

藥名相似:

外觀相似:

外觀描述: 每盒內含有預先充填於針筒內的0.5ml懸浮液

32.06 Vaccines

36054 **C / Infant risk is**

VAQTA (HEPATITIS A VACCINE, INACTIVATED) "唯德" 不活化A型肝炎疫苗

Hepatitis A virus, inactivated 50U/1mL vial

Dosage: 2衛福部提供 -疫苗 36054

Adult
·Hepatitis A immunization: IM, 50U(1mL) x 1 dose; booster dose 6-18 months later

Pediatric
·Hepatitis A immunization (1-18yrs): IM, 25U(0.5mL) x 1 dose; booster dose 6-18 months later

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Inj: 25U/0.5mL Vaqta (36093自費); 50U/1mL Vaqta (36054免費);1440 Elisa Unit/1mL Havrix (36080自費)(36092免費)

ADR:

NOTE: 冰箱冷藏，不可冷凍。

藥名相似:

外觀相似:

外觀描述: 1mL注射液，『橘』蓋，綠色瓶口，透明玻璃小瓶

32.06 Vaccines

36058 **C / Infant risk is**

TYPHIM VI 巴斯德傷寒疫苗

(旅專)Typhoid Vi Polysaccharide vaccine 0.5mL syringe

Dosage: 2衛福部提供 -疫苗 36058

Adult
· Typhoid fever; Prophylaxis: IM, 0.5 mL as a single dose; booster dose every 3 yr if re-exposure expected

Pediatric
· Typhoid fever; Prophylaxis: IM
≧2 yrs.
0.5 mL as a single dose; booster dose every 3 yrs. if re-exposure expected.
< 2 yrs.
Safety and effectiveness have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 0.5mL prefilled syringe (36058)

ADR:

NOTE: 冰箱冷藏

1.Each syringe contains: polysaccharides of Salmonella typhi (Ty2 strain) 25mcga)
2.Contraindications:hypersensitivity to vaccine components.

藥名相似:

外觀相似:

外觀描述: 0.5mL含藥透明溶液注射器,灰色蓋頭,透明推進器,白底黑字標籤

32.06 Vaccines

36069 **C / Unknown(有**

PNEUMOVAX 23 (PNEUMOCOCCAL VACCINE POLYVALENT) 紐蒙肺多價性肺炎鏈球菌疫苗

Pneumococcal vaccine polyvalent 0.5mL vial

Dosage: 1常備品 36069

Adult
· Streptococcus pneumoniae infection, immunization: IM or SC, 0.5 mL as single dose

Pediatric
· Streptococcus pneumoniae infection, immunization(>2 years): IM or SC, 0.5mL as single dose

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 0.5mL Syringe(7-valent): (36095)(37755, 捐贈); 0.5mL Vial(23-valent): 36069; 0.5mL Syringe(10-valent): (36059)(37740, 捐贈)

ADR:

COMMON
fever,injection site reaction
SERIOUS
anaphylaxis,fever,hemolytic anemia, thrombocytopenia

NOTE: 冰箱冷藏，不可冷凍。

1.Recommended for individuals 2 years of age and older at high-risk for serious pneumococcal disease
2.Penicillin prophylaxis against pneumococcal infection should not be discontinued after vaccination

藥名相似:

外觀相似:

外觀描述: 0.5mL透明注射液『紫』蓋透明玻璃小瓶，蓋上有FLIP及OFF字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000492

32.06 Vaccines

36072 **demonstrated / Infant risk is**

VARILRIX* 美瑞克

Varicella virus vaccine inj 1dose vial

Dosage: 1常備品 36072

Adult
· Chickenpox immunization: SC, 0.5 mL × 2 doses separated by 4-8 wks

Pediatric
· Chickenpox immunization: SC
12 mon-12 yrs: 0.5 mL × 1-2 dose separated by 4-6 wks at least.(VARILRIX* vaccine 美瑞克 仿單)
>13 yrs: same as adult.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 1 dose with 0.5 mL water for inj 自費(36072); 1 dose健診(39311)

ADR:

COMMON
fever, injection site reactions, rash
SERIOUS
anaphylaxis,ataxia, Bell's palsy, encephalitis, non-febrile seizures, transverse myelitis

NOTE: 冰箱冷藏，不可冷凍。

·Each dose contains : > 10(3.3) PFUs varicella virus (Oka strain)
·衛服部疾管署建議接種原則：(2017-05-15)
1.曾感染水痘或已接種2劑水痘疫苗者，無需再接種。
2.未曾感染水痘者：
(1)未滿13歲：未曾接種者，除公費提供第1劑外，自費接種第2劑；已接種1劑者，自費接種第2劑。
(2)滿13歲以上：未曾接種者，應接種 2 劑（自費）；已接種 1 劑者，自費接種第 2 劑。
(3)上述兩劑水痘疫苗接種應間隔至少28天。

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『粉紅』蓋透明玻璃小瓶，附0.5ml稀釋液透明玻璃安瓿裝

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000450

32.06 Vaccines

36073 **C / Unknown(有**

M-M-R II (MEASLES, MUMPS AND RUBELLA VIRUS VACCINE, LIVE) 麻疹、腮腺炎及德國麻疹三種混合疫苗注射劑

Measles, mumps and rubella vaccine (MMR) 1 dose vial

Dosage: 1常備品 36073

Adult
· Measles, mumps, rubella immunization: SC, 0.5 mL single dose

Pediatric
· Measles, mumps, rubella immunization: SC, 0.5 mL at 12 to 15 mon and then again at 4 to 6 yrs

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: MMR with 0.5 mL water for inj自費(36073);MMR健診(39307); Measles with 0.5mL water for inj 健診(39314)

ADR:

Injection site pain/erythema, rash, fever, cold symptoms, arthritis

NOTE: 冰箱冷藏 2-8°C，不可冷凍。

Each vial cotains: More Attenuated Enders' Strain (Measles), Jeryl Lynn Strain (Mumps), Wistar RA 27/3 Strain (Rubella)

藥名相似:

外觀相似:

外觀描述: 淡黃色乾粉、『藍』蓋透明玻璃小瓶，蓋上有FLIP及OFF字樣，附0.7ml稀釋液『深灰』蓋透明玻璃小瓶，蓋上有FLIP及OFF字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000364

32.06 Vaccines

36074 **C / Unknown(有**

ENGERIX -B 安在時 B 型肝炎疫苗

Hepatitis B vaccine inj 20mcg/1 mL/vial

Dosage: 1常備品 36074

ADULT
· Hepatitis B immunization: IM, 20 mcg (1 mL) x 3 doses at 0, 1, and 6 mon

Pediatric
· Hepatitis B immunization (0-19 yrs): IM, 10 mcg (0.5 mL) x 3 doses at 0, 1, and 6 mon

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 20 mcg/1mL vial 自費(36074), 20mcg/1ml健診(39317)

ADR:

COMMON
fatigue, malaise, weakness, fever, headache, injection site reaction, nausea, diarrhea
SERIOUS
anaphylaxis, pancytopenia

NOTE: 冰箱冷藏2-8℃，不可冷凍。

·《Contraindications》Severe allergic reaction after a previous dose of any hepatitis B-containing vaccine or to any vaccine component, including yeast；
·《仿單禁忌》：已知對此疫苗中任何成分過敏者；先前曾接踵Engerix-B後產生過敏病徵者。
HIV感染並未視為B型肝炎疫苗之禁忌症。
· Inject to the deltoid region in adults and to the anterolateral thigh in neonates and infants.
·The basic immunization schedule consists of 3 doses with the 2nd and 3rd doses at 1 and 6 mon after the first dose, respectively.
·When there is an immediate risk of infection, the immunization schedule consists of 4 doses with the 2nd, 3rd and 4th doses at 1, 2, and 12 mon after the first dose, respectively.

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液,"橙"蓋透明玻璃瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000301

32.06 Vaccines

36080 **C /**

HAVRIX 1440/720 JUNIOR 新赫寶克

Hepatitis A virus vaccine inactivated(HAV Antigen)1440 Elisa unit/1mL/pre-filled syringe

Dosage: 1常備品 36080

Adult
· Hepatitis A immunization: IM, 1440 Elisa Unit as a single dose

Pediatric
· Hepatitis A immunization (1-18 yrs): IM, 720 Elisa U x 1 dose and a booster dose (720 Elisa U) 6-12 mon later

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 740 Elisa Unit/0.5mL Havrix (36076自費)(36091免費);1440 Elisa Unit/1mL Havrix (36080自費)(36092免費)

ADR:

COMMON
anorexia, nausea, fatigue, malaise, fever, headache, injection site soreness
SERIOUS
anaphylaxis, anaphylactoid reaction

NOTE: 冰箱冷藏，不可冷凍。

1. The vial contains a sterile suspension. It should be shaken before use.
2. The basic immunization schedule consists of 2 doses: the first dose administered at an elected date and the second dose administered 6-12 mon after the first dose.

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液，預充填注射針筒

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000456

32.06 Vaccines

36093 **C / Infant risk is**

VAQTA (HEPATITIS A VACCINE, INACTIVATED) "唯德" 不活化 A 型肝炎疫苗

Hepatitis A virus vaccine, inactivated 25U/0.5mL vial

Dosage: 1常備品 36093

Adult
·Hepatitis A immunization: IM, 50U(1mL) x 1 dose; booster dose 6-18 months later

Pediatric
·Hepatitis A immunization (1-18yrs): IM, 25U(0.5mL) x 1 dose; booster dose 6-18 months later

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 25U/0.5mL Vaqta (36093自費)(36091免費);1440 Elisa Unit/1mL Havrix (36080自費)(36092免費)

ADR:

COMMON
anorexia, nausea, fatigue, malaise, fever, headache, injection site soreness
SERIOUS
anaphylaxis, anaphylactoid reaction (rare)

NOTE: 冰箱保存

·《仿單禁忌》：對本產品任何成分有過敏反應者；先前曾對A型肝炎疫苗或任一疫苗成份產生嚴重反應者。
·Shake well before use.
· Vaqta and Havrix can be administered interchangeably.

藥名相似:

外觀相似:

外觀描述: 0.5mL注射液,『紫』蓋,綠色瓶口,透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000501

32.06 Vaccines

36100 **B /**

GARDASIL [Quadrivalent Human Papillomavirus (Types 6,11,16,18) Recombinant Vaccine] 嘉喜[四價人類乳突病毒(第6,11,16,18型)基因重組疫苗]

Quadrivalent Human Papillomavirus (Type 6,11,16,18) Recombinant vaccine 0.5mL syringe

Dosage: 1常備品 36100

Adult (13-26 yrs)
· Prophylaxis of cervical adenocarcinoma in situ, cervical cancer, cervical intraepithelial neoplasia (grade 1,2,3), genital warts, vaginal intraepithelial neoplasia (grade 2,3), vulvar intraepithelial neoplasia (grade 2,3): IM, 0.5mL x 3 doses at 0, 2, and 6 months

Pediatric (≧ 9yrs)
Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: Cervarix* 0.5mL syringe(二價36105, 公費二價36121),Gardasil* 0.5mL Syringe(四價36100), Gardasil* 0.5mL Syringe(九價36101)

ADR:

COMMON
Injection site reactions(erythema, pain, pruritus, swelling), fever
SERIOUS
Appendicitis, gastroenteritis, pelvic inflammatory disease, asthma, bronchospasm

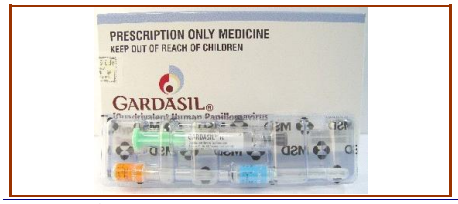
NOTE: 冰箱冷藏，不可冷凍。

·《Contraindications》Hypersensitivity, including severe allergic reactions to yeast or following previous administration of human papillomavirus recombinant quadrivalent vaccine；

藥名相似:

外觀相似:

外觀描述: 0.5mL含藥懸浮注射液注射器灰色頭塞，『淺綠』色推進器，另附一支1吋長之25號針及一支1吋長之23號針



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000827

32.06 Vaccines

36101 **B / Unsafe**

Gardasil 9 [Human Papillomavirus 9-valent Vaccine, Recombinant] 嘉喜 [九價人類乳突病毒(第6, 11, 16, 18, 31, 33, 45, 52, 58型)基因重組疫苗]

Human Papillomavirus 9-valent vaccine inj, Recombinant

Dosage: 1常備品 36101

Adult (Female 15-45 yrs)
· Prevention of disease caused by human papillomavirus (HPV): IM, 0.5 mL at 0, 2, and 6 mons

Pediatric (Female 9-14yrs)
· Prevention of disease caused by human papillomavirus (HPV): IM, 0.5 mL 3 doses at 0, 2, and 6 mons or 2 doses at 0 and 6-12 mons.
*If the second dose is less than 5 months from the first dose, the third dose should be applied at least 4 months after the second dose is applied.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: Cervarix* 0.5mL syringe(二價36105, 公費二價36121),Gardasil* 0.5mL Syringe(四價36100), Gardasil* 0.5mL Syringe(九價36101)

ADR:

COMMON
Erythema at injection site, injection site pain, swelling at injection site, headache
SERIOUS
Syncope

NOTE: 冰箱冷藏，不可冷凍。

· The vaccine should be administered as soon as possible after removal from refrigeration, but can be used if kept at temperatures between 8-25°C for no more than 72 hrs.
· 《Contraindications》Hypersensitivity reactions following a dose of human papillomavirus recombinant vaccine quadrivalent (Types 6, 11, 16, 18) or human papillomavirus 9-valent vaccine, recombinant；Severe allergic reactions to yeast。

藥名相似:

外觀相似:

外觀描述: 0.5mL含藥懸浮注射液注射器，紙盒裝一支『咖啡』色推進器，另附一支1吋長之25號針及一支1吋長之23號針

32.06 Vaccines

36104 **C / Unknown(有**

Adacel TM "巴斯德" 三合一補追疫苗

Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine(Tdap) 0.5mL vial

Dosage: 1常備品 36104

Adult
· Vaccination for diphtheria, pertussis and tetanus: IM, 0.5mL as a single dose, administed 5 years after last dose of DTP vaccine

Pediatric (≧4yrs)
· Vaccination for diphtheria, pertussis and tetanus: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: Adacel* 0.5mL Vial(36104), Boostrix* 0.5mL Vial(36111),

ADR:

COMMON
Injection site pain, injection site reaction, gastrointestinal symptom, fatigue, headache
SERIOUS
Anaphylaxis, seizure

NOTE: 冰箱冷藏，不可冷凍。

·《仿單禁忌》：已知對ADACEL*的任何成分有全身過敏反應者，或先前接踵本疫苗或接種含有本疫苗相同的一種或多種成分之某種疫苗後曾出現威脅生命反應者，禁止接踵ADACEL*。急性精神疾患(施打前一劑含有百日咳的疫苗後，若在7日內出現腦病變且無法將其歸咎於任何可辨識之病因，則任何含有百日咳支疫苗應禁止使用。)。

1.Each dose contains: Pertussis toxoid 2.5 mcg, filamentous haemagglutinin(FHA) 5 mcg, agglutinogens fimbriae 2+3(FIM) 5 mcg, pertactin 3 mcg, diphtheria toxoid 2 Lf, tetanus toxoid 5 Lf
2.Tdap contains lower amounts of diphtheria toxoid and some pertussis antigen than DTaP.
3.ACIP/AAP recommendation
(1)Adults who have or who anticipate having close contact with an infant younger than 12 mons of age (e.g., parents, childcare providers, health-care providers) should receive a single dose of Tdap. It should be administered at least 2 weeks prior to beginning close contact.
(2)Pregnancy
· Women of childbearing age be encouraged to receive a single dose of Tdap prior to pregnancy if they have not previously received or in the immediate postpartum period.
· When indicated during pregnancy, administration during the 2nd or 3rd trimester (and before 36 weeks of gestation) is preferred.
· Pregnancy is not generally considered a contraindication to Tdap, Td is preferred to Tdap when vaccination cannot be delayed during pregnancy.
4.The ACIP states that women, including those who are breastfeeding, should receive Tdap during the immediate postpartum period if they have not previously received

藥名相似:

外觀相似:

外觀描述: 0.5mL透明注射液『橘』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000840

32.06 Vaccines

36105 **UK / Unknown(有**

Cervarix TM Human Papillomavirus vaccine Type 16 and 18 (Recombinant, AS04 adjuvanted) 保蓓TM人類乳突病毒第16/18型疫苗

Human Papillomavirus vaccine Type16,18 (Recombinant, ASO4 adjuvanted) vaccine 0.5mL syringe

Dosage: 1常備品 36105

Adult (≦25 yrs)
· Prevention of cervical cancer , cervical intraepithelial neoplasia(CIN) (grade 1,2,3), adenocarcinoma in situ of cervix(AIN), ans vulvar epithelium neoplasm/vaginal epithelial neoplasm(VIN/VaIN)(grade 1) caused by human papillomavirus (HPV) type16 and 18: IM, 0.5mL × 3 doses at 0, 1, and 6 months

Pediatric
· Prevention of cervical cancer , cervical intraepithelial neoplasia(CIN) (grade 1,2,3), adenocarcinoma in situ of cervix(AIN), ans vulvar epithelium neoplasm/vaginal epithelial neoplasm(VIN/VaIN)(grade 1) caused by human papillomavirus (HPV) type16 and 18:
9-14 yrs: IM, 0.5mL × 2 doses at 0 and 5-13 months, or × 3 doses at 0, 1, and 6 months
≧15yrs: IM, 0.5mL × 3 doses at 0, 1, and 6 months

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: Cervarix* 0.5mL syringe(二價36105, 公費二價36121),Gardasil* 0.5mL Syringe(四價36100), Gardasil* 0.5mL Syringe(九價36101)

ADR:

COMMON
·Dermatologic: Erythema at injection site (48.4%), Injection site pain (91.9%), Swelling at injection site (44.3%)
·Gastrointestinal: Gastrointestinal symptom (27.9%)
·Musculoskeletal: Arthralgia (20.7%), Myalgia (48.8%)
·Neurologic: Headache (53.4%)
·Other: Fatigue (54.6%)
SERIOUS
·Cardiovascular: Syncope
·Dermatologic: Erythema multiforme
·Immunologic: Hypersensitivity reaction
·Other: Angioedema

NOTE: 冰箱冷藏，不可冷凍。

·《仿單禁忌》：Cervarix不可用於已知對此疫苗之任何成分過敏者。
· If flexibility in the vaccination schedule is necessary, the second dose can be administered between 1-2.5 mons after the first dose

藥名相似:

外觀相似:

外觀描述: 0.5mL含藥懸浮注射液注射器，另附一支23號針

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000856

32.06 Vaccines

36110 **C / Caution**

PREVENAR 13* 0.5mL syringe 沛兒肺炎鏈球菌十三價結合型疫苗

Pneumococcal 13-valent conjugate vaccine 0.5mL syringe

Dosage: 1常備品 36110

·Pneumococcal infectious disease, prophylaxis
≧50 yrs: IM, one single dose.

·Pneumococcal infectious disease, prophylaxis (primary series):
2-6 mon: IM, 0.5 mL x 4 doses at 2, 4, and 6 mon of age and booster at 12-15 mon of age; first dose may be given as 6 wks of age
·Pneumococcal infectious disease, prophylaxis (previously unvaccinated):
7-11 mon: IM, 0.5 mL x 3 doses; give 2 doses at least 4 wks apart, third dose after one-year birthday, separated from the second dose by at least 2 mon
12-23 mon: IM, 0.5 mL x 2 doses given at least 2 mon apart
24 mon-17 yrs (healthy children): IM, one single dose
24-71 mon with underlying medical conditions: IM, 0.5 mL x 2 doses given at least 2 mon apar.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 0.5mL Vial(23-valent): 36069; 0.5mL Syringe(10-valent): (36059); 0.5mL Syringe(13-valent):(36110)(37738, 免費疫苗)

ADR:

COMMON
Red color, swelling or tenderness at injection site, decrease in appetite, decreased sleep, hypersomnia, irritability
SERIOUS
Gastroenteritis, seizure, bronchiolitis, pneumonia

NOTE: 冰箱冷藏，不可冷凍。

·《Contraindications》Severe allergic reactions (eg, anaphylaxis), to any component of the vaccine or diphtheria toxoid；
·Prevenar 13* is indicated for active immunization for the prevention of invasive Streptococcal pneumoniae disease caused by serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F.
·Children who have received pneumococcal 7-valent vaccine may complete immunisation by switching to Prevenar 13 at any point in the schedule.
·The minimum interval to vaccination with 23-valent pneumococcal polysaccharide vaccine after the last dose of PCV (7-valent or 13-valent) is 8 wks.
·疫苗中的肺炎鏈球菌的莢膜多醣體均與白喉CRM197蛋白質載體接合，吸附於磷酸鋁上。每0.5 mL 含有32 μg 白喉CRM197 蛋白質載體與0.125 mg 的鋁。
·已接種此疫苗兩個月至五歲之嬰兒或幼童，可在12-23個月時合併接種此疫苗與結合型破傷風流行性腦脊髓膜炎多醣體子型A、C、W和Y疫苗。
·已接種此疫苗50歲(含)以上之成人，可合併接種季節性四價去活化流行性感冒疫苗。

藥名相似:

外觀相似:

外觀描述: 0.5mL含藥懸浮注射液注射器，『白』色推進器，附1支針頭

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000906

32.06 Vaccines

36112 **UK /**

boostrixTM polio 補施追安痺威疫苗

(小兒免費健診)Tetanus toxoid, diphtheria toxoid, acellular pertussis and inactivated poliomyelitis vaccine(減量四合一)Tdap-IPV 0.5mL vial

Dosage: 2衛福部提供-疫苗 36112

Adult
· Vaccination for diphtheria, tetanus, pertussis and poliomyelitis: IM, 0.5mL as a single dose

Pediatric (≧4yrs)
· Vaccination for diphtheria, tetanus, pertussis and poliomyelitis: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

NOTE: 冰箱冷藏，不可冷凍。

1.Each dose contains: Pertussis toxoid 2.5 mcg, Filamentous haemagglutinin(FHA) 5 mcg, Fimbriae types 2+3 5 mcg, pertactin 3 mcg, diphtheria toxoid ≧2 IU(2Lf), tetanus toxoid ≧20 IU(5 Lf), inactivated poliomyelitis virus type 1 40 D, inactivated poliomyelitis virus type 2 8D, inactivated poliomyelitis virus type 3 32D
2.It is not intended for primary immunization.

藥名相似:

外觀相似:

外觀描述: 每盒內含有預先充填於針筒內之白色懸浮液

32.06 Vaccines

36113 C /

(健診)ENGERIX*-B 10 mcg/0.5mL 安在時B型肝炎疫苗

(小兒免費健診)Hepatitis B vaccine 10mcg/0.5 mL vial

Dosage: 2衛福部提供-疫苗 36113

ADULT
·政府免費提供使用於幼兒常規接種

Pediatric
·Hepatitis B immunization (0-19 yrs): IM, 10mcg/0.5mL × 3 doses at 0, 1, and 6 mon (依衛福部疾管署106年1月13日疾管防字第1060200020號函辦理)

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 20 mcg/1mL vial 自費(36074), 10mcg/ 0.5ml健診(36113), 20mcg/1ml健診(39317)

ADR:

COMMON
fatigue, malaise, weakness, fever, headache injection site reaction, nausea, diarrhea
SERIOUS
anaphylaxis, pancytopenia (rare)

NOTE: 冰箱冷藏，不可冷凍。

1. Inject to the deltoid region in adults and to the anterolateral thigh in neonates and infants.
2. The basic immunization schedule consists of 3 doses with the 2nd and 3rd doses at 1 and 6 mon after the first dose, respectively.
3. When there is an immediate risk of infection, the immunization schedule consists of 4 doses with the 2nd, 3rd and 4th doses at 1, 2, and 12 mon after the first dose, respectively.

藥名相似:

外觀相似:

外觀描述: 0.5mL注射液，『藍』蓋'灰色頭塞，『透明』玻璃瓶

32.06 Vaccines

36117 C / Caution

ZOSTAVAX [zoster virus vaccine live (Oka/Merck), MSD] 伏帶疹 活性帶狀皰疹疫苗

Zoster virus inj vaccine live(Oka/Merck) 0.65mL syringe

Dosage: 1常備品 36117

Adult
· Herpes zoster; Prophylaxis(≧50y~79y): sc, one syringe dose.

Pediatric
· Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj:0.65mL syringe(36117)

ADR:

COMMON
Erythema at injection site, Induration at injection site, Injection site pain, Injection site pruritus, Injection site reaction, Rash, varicella-like, Swelling at injection site, Abdominal pain, Constipation, Diarrhea, Loss of appetite, Nausea, Vomiting, Lymphadenopathy, Arthralgia, Myalgia, Stiff neck, Headache ,Otitis, Feeling nervous, Irritability Respiratory: Cough, Respiratory tract infection, Fatigue, Fever.
SERIOUS
Congestive heart failure, Erythema multiforme, Henoch-Sch?nlein purpura, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Thrombocytopenic purpura, Anaphylaxis, Herpes zoster ophthalmicus, Polymyalgia rheumatica , Aseptic meningitis, Cerebrovascular accident, Encephalitis, Febrile seizure (less than 0.1%), Guillain-Barr? syndrome, Ischemic stroke, Seizure, Non-febrile, Pulmonary edema

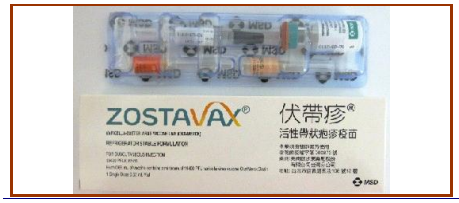
NOTE: 冰箱冷藏，不可冷凍。

1. Antibody-containing products; blood or plasma transfusions or immune globulin administration within previous 11 months (specific interval depends on product).
2.Concomitant use of ZOSTAVAX* and pneumococcal polyvalent vaccine (PNEUMOVAX* 23) should not be given concurrently.
3.The use of varicella-zoster virus vaccine (ZOSTAVAX*) are contraindicated during pregnancy and pregnancy should be avoided for 3 months following vaccination.

藥名相似:

外觀相似:

外觀描述: 白色凍晶乾粉、『深橘色』蓋透明玻璃小瓶，附0.75mL稀釋液『深灰』針筒裝



32.06 Vaccines

36119 **ɔt be ruled out / Infant risk can**

Imojev 巴斯德細胞型日本腦炎活性減毒疫苗

自費Japanese Encephalitis vaccine inj pow in vial

Dosage: 1常備品 36119

Adult
·Japanese encephalitis virus, immunization: SC, 0.5mL as a single dose; there is no need for a booster dose for at least 5 years after the first vaccination

Pediatric (≧ 9 mons~ < 18 yrs)
·Japanese encephalitis virus, immunization: SC, 0.5 mL/dose; a booster dose can be given after 12~24months of the first vaccination

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 1mL Vial(39309 健診)(39326, 旅遊門診); 0.5mL(39346, 健診)(36119, 自費)(37730, 捐贈專案)

ADR:

COMMON
chills, fever, malaise, dizziness, headache, injection site reaction, tenderness, redness, swelling, myalgia, nausea, vomiting, abdominal pain, rash
SERIOUS
angioedema of the extremities or face, encephalitis, encephalopathy, seizures, and peripheral neuropathy, respiratory distress (rare)

NOTE: 冰箱冷藏，不可冷凍

·《仿單禁忌》：
對疫苗之任何成分曾有嚴重過敏反應，或之前接種本疫苗或接種與本疫苗含有相同成分或組成的疫苗後曾出現嚴重過敏反應者或有嚴重過敏病史者。
先天或後天免疫缺損而致細胞性免疫不全者，包括接受免疫抑制治療（例如化學治療、14天或以上的高劑量全身性皮質類固醇）。
感染人類免疫缺陷病毒（Human Immunodeficiency Virus-HIV）的病人，不論其已出現症狀，或未出現症狀但有免疫功能缺損之證據者。
·SC administration only.

藥名相似:

外觀相似:

外觀描述: 凍晶疫苗:『黃』蓋透明玻璃小瓶；稀釋液:『白』蓋透明玻璃小瓶，附注射器及2支針頭)

32.06 Vaccines

36120 **C / No report(毫**

NIMENRIX* A, C, W-135 and Y conjugate vaccine 0.5mL vial 4價流行性腦脊髓膜炎結合型疫苗（MCV4）

Meningococcal polysaccharide vaccine (Groups A / C / Y and W-135) 0.5mL vial

Dosage: 2衛福部提供 36120
-疫苗

·Meningococcal infectious disease immunization: IM, 0.5mL as a single dose; revaccination every 5 years later may be indicated for individuals at high-risk for infection.(official recommendations)

≧12 months
·Meningococcal infectious disease immunization: same as adult.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 0.5mL vial(with diluent)(39322, Sanofi Pasteur)(36120, Pfizer)

ADR:

VERY COMMON
Fever, swelling, pain and redness, at injection site, fatigue
COMMON
Injection site haematoma
UNCOMMON
Malaise, injection site reaction(including induration, pruritus, warmth, anaesthesia)
RARE
Extensive limb swelling at the injection site, frequently associated with erythema, sometimes involving the adjacent joint or swelling of the entire injected limb

NOTE: 冰箱冷藏2-8°C，不可冷凍。

·Each dose(0.5mL) contains 5mcg of polysaccharide for Neisseria meningitidis serogroups A, C, W-135 and Y.
·Protective antibody levels may be achieved 7-10 days after vaccination

藥名相似:

外觀相似:

外觀描述: 凍晶粉末，『褐』色蓋玻璃小瓶，附稀釋液 預填式注射器裝

32.06 Vaccines

36121 **UK / Unknown(有**

Cervarix TM Human Papillomavirus vaccine Type 16 and 18 (Recombinant, AS04 adjuvanted) 保蓓TM人類乳突病毒第16/18型疫苗

(公費)Human Papillomavirus vaccine Type16,18 (Recombinant, ASO4 adjuvanted) vaccine 0.5mL syringe

Dosage: 2衛福部提供-疫苗 36121

Adult (≦25 yrs)
· Prevention of cervical cancer , cervical intraepithelial neoplasia(CIN) (grade 1,2,3), adenocarcinoma in situ of cervix(AIN), ans vulvar epithelium neoplasm/vaginal epithelial neoplasm(VIN/VaIN)(grade 1) caused by human papillomavirus (HPV) type16 and 18: IM, 0.5mL × 3 doses at 0, 1, and 6 months

Pediatric
· Prevention of cervical cancer , cervical intraepithelial neoplasia(CIN) (grade 1,2,3), adenocarcinoma in situ of cervix(AIN), ans vulvar epithelium neoplasm/vaginal epithelial neoplasm(VIN/VaIN)(grade 1) caused by human papillomavirus (HPV) type16 and 18:
9-14 yrs: IM, 0.5mL × 2 doses at 0 and 5-13 months, or × 3 doses at 0, 1, and 6 months
≧15yrs: IM, 0.5mL × 3 doses at 0, 1, and 6 months

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: Cervarix* 0.5mL syringe(二價36105, 公費二價36121),Gardasil* 0.5mL Syringe(四價36100), Gardasil* 0.5mL Syringe(九價36101)

ADR:

COMMON
·Dermatologic: Erythema at injection site (48.4%), Injection site pain (91.9%), Swelling at injection site (44.3%)
·Gastrointestinal: Gastrointestinal symptom (27.9%)
·Musculoskeletal: Arthralgia (20.7%), Myalgia (48.8%)
·Neurologic: Headache (53.4%)
·Other: Fatigue (54.6%)
SERIOUS
·Cardiovascular: Syncope
·Dermatologic: Erythema multiforme
·Immunologic: Hypersensitivity reaction
·Other: Angioedema

NOTE: 冰箱冷藏，不可冷凍。

·《仿單禁忌》：Cervarix不可用於已知對此疫苗之任何成分過敏者。
· If flexibility in the vaccination schedule is necessary, the second dose can be administered between 1-2.5 mons after the first dose
· 處方規定
1.衛生局提供之臺北市公費人類乳突病毒疫苗（HPV疫苗）特約醫療院所免費HPV疫苗。
2.接種對象需攜帶「接種通知單」、「接種紀錄卡」及「接種同意書及評估單」，並由家長陪同至本市HPV疫苗合約醫療院所接種HPV疫苗，雙方皆需於接種同意書及評估單勾選同意且簽名，再進行評估與接種服務。
3. 新增服務對象為具我國國籍，本市91年9月1日至93年9月1日出生之低收入戶及中低收入戶之青少女，本局擬於109年4月20日寄發接種通知單及關懷包，預計109年12月31日前完成接種。
4.限婦產科及兒科醫師完成國健署「HPV疫苗接種教育課程」訓練，有符合接種資格之醫師開立處方。

藥名相似:

外觀相似:

外觀描述: 0.5mL含藥懸浮注射液注射器，另附一支23號針

32.06 Vaccines

37721 **C / Unknown(有**

PNEUMOVAX* 23 (PNEUMOCOCCAL VACCINE POLYVALENT) 紐蒙肺多價性肺炎鏈球菌疫苗

(衛生局65-74歲)免費Pneumococcal vaccine polyvalent 0.5mL vial

Dosage: 2台北市衛生局提供 37721

Adult
· Streptococcus pneumoniae infection, immunization: IM or SC, 0.5 mL as single dose

Pediatric
· Streptococcus pneumoniae infection, immunization(>2 years): IM or SC, 0.5mL as single dose

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 0.5mL Vial(23-valent;36069自費,37764免費75歲以上,37721免費台北市65-74歲);0.5mL syring (7-valent;36095)

ADR:

COMMON
fever,injection site reaction
SERIOUS
anaphylaxis,fever,hemolytic anemia, thrombocytopenia

NOTE: 冰箱冷藏，不可冷凍。

1.Recommended for individuals 2 years of age and older at high-risk for serious pneumococcal disease
2.Penicillin prophylaxis against pneumococcal infection should not be discontinued after vaccination
3.提供台北院區需設籍台北市；淡水院區需設籍新北市，且當年度為65-74歲長者

藥名相似:

外觀相似:

外觀描述: 0.5mL透明注射液『紫』蓋透明玻璃小瓶

32.06 Vaccines

37738 **C / Caution**

PREVENAR 13* 0.5mL syringe 沛兒肺炎鏈球菌十三價結合型疫苗

免費Pneumococcal 13-Valent Conjugate vaccine 0.5mL syringe

Dosage: 2衛福部提供-疫苗 37738

Pediatric
· Pneumococcal infectious disease, prophylaxis (primary series):
2-6 mon: IM, 0.5 mL x 4 doses at 2, 4, and 6 mon of age and booster at 12-15 mon of age; first dose may be given as 6 wks of age
· Pneumococcal infectious disease, prophylaxis (previously unvaccinated):
7-11 mon: IM, 0.5 mL x 3 doses; give 2 doses at least 4 wks apart, third dose after one-year birthday, separated from the second dose by at least 2 mon
12-23 mon: IM, 0.5 mL x 2 doses given at least 2 mon apart
24 mon-17 yrs (healthy children): IM, one single dose
24-71 mon with underlying medical conditions: IM, 0.5 mL x 2 doses given at least 2 mon apar

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 0.5mL Vial(23-valent): 36069; 0.5mL Syringe(10-valent): (36059); 0.5mL Syringe(13-valent):(36110)(37738, 免費疫苗)

ADR:

COMMON
Red color, swelling or tenderness at injection site, decrease in appetite, decreased sleep, hypersomnia, irritability
SERIOUS
Gastroenteritis, seizure, bronchiolitis, pneumonia

NOTE: 冰箱冷藏，不可冷凍

· Prevenar 13* is indicated for active immunization for the prevention of invasive Streptococcal pneumoniae disease caused by serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F.
· Children who have received pneumococcal 7-valent vaccine may complete immunisation by switching to Prevenar 13 at any point in the schedule.
· The minimum interval to vaccination with 23-valent pneumococcal polysaccharide vaccine after the last dose of PCV (7-valent or 13-valent) is 8 wks.

藥名相似:

外觀相似:

外觀描述: 0.5mL含藥懸浮注射液注射器，『白』色推進器，附1支針頭

32.06 Vaccines

37764 **C / Unknown(有**

PNEUMOVAX 23 (PNEUMOCOCCAL VACCINE POLYVALENT) 紐蒙肺多價性肺炎鏈球菌疫苗

(75歲以上)免費Pneumococcal vaccine polyvalent 0.5mL vial

Dosage: 2衛福部提供-疫苗 37764

Adult
· Streptococcus pneumoniae infection, immunization: IM or SC, 0.5 mL as single dose

Pediatric
· Streptococcus pneumoniae infection, immunization(>2 years): IM or SC, 0.5mL as single dose

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 0.5mL Vial(23-valent;36069自費,37764免費75歲以上,37721免費台北市65-74歲);0.5mL syring (7-valent;36095)

ADR:

COMMON
fever,injection site reaction
SERIOUS
anaphylaxis,fever,hemolytic anemia, thrombocytopenia

NOTE: 冰箱儲存

1.Recommended for individuals 2 years of age and older at high-risk for serious pneumococcal disease
2.Penicillin prophylaxis against pneumococcal infection should not be discontinued after vaccination

藥名相似:

外觀相似:

外觀描述: 0.5mL透明注射液『紫』蓋透明玻璃小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000492

32.06 Vaccines

37789 ɔt be ruled out / Infant risk can

VERORAB powder and solvent for suspension for injection "巴斯德"狂犬病疫苗

急用Rabies Virus Vaccine

Dosage: 2急用藥 37789

因應國際貨源嚴重短缺，疾管署修訂國內人用狂犬病疫苗適用對象、區域及接種劑次，請見『◇NOTE：』內容

·Rabies immunization(pre-exposure treatment): IM, 0.5mL each on days 0, 7, 21 (or 28)

·Rabies immunization(post-e0.51mL each on days 0, 3, 7, 14, 28 (5-dose schedule); alternative schedule is 2 doses on day 0 (0.5 mL given into the right and 0.5 mL into the left deltoid muscle), and 0.5 mL each on days 7 and 21

Previously vaccinated: IM, 0.5 mL each on days 0 and 3

Pediatric

·Rabies immunization(pre-exposure treatment): Same as adult

·Rabies immunization(post-exposure treatment): Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 1 dose with 0.5mL solvent in syringe (37789)

ADR:

COMMON

Injection site reaction, Rash, Abdominal pain, Nausea, Localized enlarged lymph nodes, Arthralgia, Myalgia, Dizziness, Headache, Influenza-like symptoms, Malaise.

SERIOUS

Anaphylaxis, Encephalitis, Guillain-Barre syndrome, Transfusion reaction due to serum protein reaction.

NOTE: 冰箱冷藏2-8℃，不可冷凍。

·包裝內含預填式針筒裝稀釋液，僅供與藥品凍晶混和配置使用，勿用於病人給藥；施行肌肉注射時，需另使用新的注射針筒與針頭，針頭長度應選擇適合病人年齡、體重。

1.Each dose contains inactivated rabies virus (strain Flury LEP) not less than 2.5 IU.

2.Rabipur* Vaccine is a purified chick embryo cell culture (PCEC) rabies vaccine.

3.國內人用狂犬病疫苗供貨趨穩，疾管署調整疫苗接種適用對象(2019/5/14)：

一、暴露後預防接種：

(一)健保給付適用對象調整為遭「鼬獾、白鼻心、蝙蝠及台東市錢鼠等野生哺乳類動物」抓咬傷；流浪犬貓抓咬傷者仍暫不提供給付(詳如附表)。

(二)民眾遭其他野生動物或流浪犬貓抓咬傷，如要求接種，可提供自費接種。

二、暴露前預防接種：開放前往狂犬病高風險國家民眾可自費接種。

藥名相似:

外觀相似:

外觀描述: 一盒一支裝，每盒內變更為白色凍晶乾粉、『藍』蓋透明玻璃小瓶，附0.5mL稀釋液針筒裝)

32.06 Vaccines

39311 demonstrated / Infant risk is

VARIVAX -VARICELLA VIRUS VACCINE 伏痘敏 活性水痘疫苗

Varicella virus vaccine (with 0.5 mL water for inj) 1 dose vial(健診)

Dosage: 2衛福部提供-疫苗 39311

疾管署提供兒童常規疫苗

(疾管署建議)

·12個月至12歲兒童：出生滿12個月接種第1劑公費疫苗，可於滿4到6歲自費接種第2劑。

·13歲(含)以上自費接種：未曾接種疫苗且未得過水痘者，應接種兩劑，兩劑間隔四至八週。

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Inj: 1 dose自費(36072); 1 dose健診(39311), 1 dose健診(39312)

ADR:

COMMON

Injection site reaction, varicella-like rash, fever

SERIOUS

Stevens-Johnson syndrome, toxic epidermal necrolysis, thrombocytopenic purpura, anaphylaxis, herpes zoster ophthalmicus, encephalitis, febrile seizure

NOTE: 冰箱冷藏,不可冷凍

1. 接種前24小時內曾接受特定抗病毒藥物者（如：acyclovir、famciclovir或valacyclovir），於接種後間隔14天以後再重新開始服用這些藥物。

2. 18歲以下兒童接種水痘疫苗後6週內宜避免使用水楊酸類藥品(salicylates)。

3. 與其他活性減毒疫苗(例如MMR、活性減毒日本腦炎疫苗)如未同時接種，應間隔至少28天以上。

4. 接種免疫球蛋白、輸血後之接種間隔：

·接受一般肌肉注射免疫球蛋白治療或B型肝炎免疫球蛋白（HBIG）者，宜間隔3個月後再接種。

·輸過血或接受靜脈注射血液製品者，宜間隔6個月後再接種。小於1歲之麻疹個案接觸者，如已施打肌肉注射免疫球蛋白(IMIG)，應間隔6個月以上再接種MMR或水痘疫苗。

·曾靜脈注射高劑量（≥1g/kg）免疫球蛋白治療時，宜間隔11個月後再接種。

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『粉紅』蓋透明玻璃小瓶；附有0.5mL稀釋液，『灰』蓋透明玻璃小瓶裝

32.06 Vaccines

39315 **ɔt be ruled out / Infant risk can**

FREEZE-DRIED BCG VACCINE 凍結乾燥卡介苗

(健診)Bacillis Calmette-Guerin vaccine (BCG) 1.5mg pow in amp

Dosage: 2衛福部提供-疫苗 39315

Adult
·Tuberculosis; prophylaxis: Percutaneous, 0.1mL

Pediatric
·Tuberculosis; prophylaxis: Percutaneous, 0.1mL

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 1.5mg with 3mL N.S.(39315), 0.5mg with 1mL diluent (39340)

ADR:

COMMON
Percutaneous injection site reaction, nausea, lymphadenopathy, axillary or cervical, induration [percutaneous], cystitis, dysuria, hematuria, increased frequency of urination, urgent desire to urinate, influenza-like illness, malaise, shivering
SERIOUS
Caseous lesion, percutaneous puncture site, hepatitis, serum blood urea nitrogen raised, anaphylaxis, intravesical and percutaneous infection due to Mycobacterium bovis, suppurative lymphadenopathy, with draining sinuses, percutaneous, osteomyelitis, nephritis, pyelonephritis, renal abscess, renal failure, epididymitis, granulomatous prostatitis, orchitis, interstitial lung disease, pneumonia, disseminated mycobacteriosis, sepsis

NOTE: 冰箱冷藏，不可冷凍

·《仿單禁忌》：
1.結核菌素測驗陽性者。可疑之結核病患者物直接接種卡介苗，應先做結核菌素測驗，另服用抗結核病藥物患者不適合注射卡介苗。
2.早產兒或體重2500克以下之新生兒。
3.患急性熱病、水痘感染與麻疹及其復原期者，全身性皮膚炎患者須暫緩接踵。
4.有免疫機能不全或有其他家族史及其他經醫師診斷為不適於預防接種者。
5.曾注射本品有過敏反應者。
6.服用類固醇或受免疫抑制治療者(幅射治療者)；罹患淋巴瘤、白血病、帕金氏症或其他網狀內皮系統癌或具有免疫缺陷患者(如愛滋病，包含愛滋帶原母親所生嬰兒)。

抽3毫升(mL)稀釋液(NS)，先注入一半於卡介苗安瓿內，搖勻後再注入另一半。不論年齡給藥劑量均為 0.1mL (0.05mg)。

藥名相似:

外觀相似:

外觀描述: 依屆時衛生所提供之廠牌

32.06 Vaccines

39321 **C / Infant risk can**

Stamaril* vaccine 1dose vial 黃熱病疫苗

Yellow fever virus vaccine 1dose vial

Dosage: 2衛福部提供-疫苗 39321

Adult
·Yellow fever immunization: IM, SC, 1 dose ≥10days before travel with booster doses at 10-year intervals

Pediatric(≥9 mons)
·Yellow fever immunization: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj:10 dose (39329); 1 dose with 0.5mL diluent syringe(39321)

ADR:

COMMON
Myalgia, headache, fever
SERIOUS
Anaphylaxis, post smallpox vaccination encephalitis, multiple organ failure, yellow fever vaccine-associated viscerotropic disease

NOTE: 冰箱保存

·Each dose contains attenuated yellow fever virus 17D strain ≥1000U
·Cholera vaccines should not be given together with yellow fever vaccine or in the preceding 3 weeks

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『紫』蓋透明玻璃小瓶，附一支預先充填好0.5mL賦形劑溶液的針筒，推進器與針筒合一

32.06 Vaccines

39325 C /

旅專IMOVAX* Polio vaccine 小兒麻痺注射疫苗

旅專Poliomyelitis vaccine Inactivated 0.5mL

Dosage: 2衛福部提供-疫苗 39325

Adult

· Poliomyelitis immunization: IM or SC, 0.5mL x 3 doses given at 0, 1-2 mons and 6-12 mons. If sufficient time is not available to follow the above schedule, the following alternatives are recommended: 1) if only 2-3 mons are available, 0.5mL x 3 doses given at least 1 month apart; 2) if only 1-2 mons are available, 0.5mL x 2 doses given at least 1 month apart; or 3) if < 1 mon, 0.5mL as a single dose

Pediatric

·Poliomyelitis immunization: IM or SC, 0.5mL x 4 doses at 2, 4, and 6-18 mons of age and booster at 4-6 yrs of age

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 0.5mL Vial(39325, 旅遊門診); Soln: 10 dose (39305, 健診)

ADR:

COMMON

Swelling, injection site pain, loss of appetite, vomiting, fatigue, irritability, fever

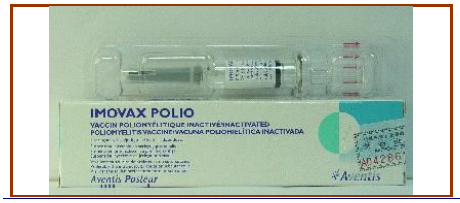
NOTE: 冰箱冷藏，不可冷凍。

· Each 0.5mL contains type 1,2,3 inactivated poliomyelitis vaccine

藥名相似:

外觀相似:

外觀描述: 0.5mL含藥透明溶液注射器 ，灰色蓋頭



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000440

32.06 Vaccines

39331 C /

PENTAXIM* inj vaccine 白喉破傷風非細胞性百日咳、不活化小兒麻痺及b型嗜血桿菌疫苗

(小兒免費健診)五合一 DTaP-IPV+Hib inj vaccine

Dosage: 2衛福部提供-疫苗 39331

Adult

Pediatric

· DTaP, IPV and Hib immunization: IM, 0.5 mL x 4 doses at 2, 4, 6 and 18 months of age. Where more rapid protection is preffered, the first three doses may be administered at intervals of four weeks.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: (小兒免費健診)Pediacel*Vaccine(五合一)DTaP-IPV+Hib(39331);DTaP-IPV-Hib vaccine 0.5 Ml vial (36098)

ADR:

NOTE:

·《仿單禁忌》：allergic to one of the vaccine's components, to any manufacturer process residues(glutaraldehyde, neomycin, streptomycin and polymyxin B) that may be present as traces, or a pertussis vaccine(acellular or whole cells), or experienced an allergic reaction after injection of a vaccine containing the same substances; suffer from evolving encephalopathy(cerebral lesions); suffered from encephalopathy(cerebral lesions) within 7 days of a previous dose of a pertussis vaccine(acellular or whole cdells pertussis); has a fever or an acute disease(the vaccination must postponed)；
The vial contains : Diphtheria toxoid 15Lf, Tetanus toxoid 5Lf, Pertussis toxoid (PT) 20μg, Filamentous haemagglutinin (FHA) 20μg, Pertactin 3μg, Fimbrial agglutinogens 2+3 (FIM) 5μg, Inactivated polio virus type I 40DU, Inactivated polio virus type II 8DU, Inactivated polio virus type III 32DU, purified polyribose ribitol phosphate capsular polysaccharide(PRP) 10μg of Haemophilus influenzae type b covalently bound to 20μg of tetanus protein.

藥名相似:

外觀相似:

外觀描述: 每盒內含有預先充填於針筒內之DTaP-IPV懸浮液，及另一凍晶乾燥之Hib粉末

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=10000440

32.06 Vaccines

39343 C /

Tetraxim suspension for injection 巴斯德四合一疫苗

(健診) 四合一 Vaccine (DTaP-IPV)

Dosage: 2衛福部提供-疫苗 39343

--

Pediatric

· DTaP and IPV immunization: IM, 0.5 mL x 4 doses at 2, 4, 6 and 18 months of age. Where more rapid protection is preffered, the first three doses may be administered at intervals of four weeks.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: (小兒免費健診)Pediacel*Vaccine(五合一)DTaP-IPV+Hib(39331);DTaP-IPV-Hib vaccine 0.5 Ml vial (36098)

ADR:

COMMON
Injection site reaction, Loss of appetite, Somnolence, Irritability, Fever.
SERIOUS
Anaphylaxis, Afebrile seizure, 40℃(104 °F) or higher rectal temperature of Fever.

NOTE: 冰箱冷藏，不可冷凍。

·《Contraindications》encephalopathy (eg, coma, decreased level of consciousness, prolonged seizure) not attributable to another identifiable cause within 7 days of previous pertussis-containing vaccine; hypersensitivity or serious allergic reaction (eg, anaphylaxis) to any vaccine component; progressive neurologic disorder (eg, infantile spasm, uncontrolled epilepsy, progressive encephalopathy); defer vaccination until neurologic status is clarified and stabilized；
·《仿單禁忌》：已知對巴斯德四合一疫苗中的任何成分過敏、對製程中任何建測不到的微量殘留成分(戊二醛、neomycin、streptomycin及polymyxin B)過敏，或對百日咳疫苗(非細胞性或全細胞性)過敏，或先前接種本疫苗或接種與本疫苗含有相同成分的疫苗曾出現危及生命反應者。漸進性腦病變者。先前接踵任何含有百日咳抗原(權細胞性或非細胞性百日咳疫苗)的疫苗後，7天內出現沒有可辨識原因所造成的腦病變者。
·The vial contains : Diphtheria toxoid 15Lf, Tetanus toxoid 5Lf, Pertussis toxoid (PT) 20μg, Filamentous haemagglutinin (FHA) 20μg, Pertactin 3μg, Fimbrial agglutinogens 2+3 (FIM) 5μg, Inactivated polio virus type I 40DU, Inactivated polio virus type II 8DU, Inactivated polio virus type III 32DU, purified polyribose ribitol phosphate capsular polysaccharide(PRP) 10μg of Haemophilus influenzae type b covalently bound to 20μg of tetanus protein.

藥名相似:

外觀相似:

外觀描述: 每盒內含有預先充填於針筒內之DTaP-IPV懸浮液

32.06 Vaccines

39346 **ɔt be ruled out / Infant risk can**

Imojev 巴斯德細胞型日本腦炎活性減毒疫苗

(健診)Japanese Encephalitis vaccine inj pow in vial

Dosage: 2衛福部提供-疫苗 39346

Adult
·Japanese encephalitis virus, immunization: SC, 0.5mL as a single dose; there is no need for a booster dose for at least 5 years after the first vaccination

Pediatric (≧9 mons~ < 18 yrs)
·Japanese encephalitis virus, immunization: SC, 0.5 mL/dose; a booster dose can be given after 12~24months of the first vaccination

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 1mL Vial(39309 健診)(39326, 旅遊門診); 0.5mL(39346, 健診)(36119, 自費)(37730, 捐贈專案)

ADR:

COMMON
chills, fever, malaise, dizziness, headache, injection site reaction, tenderness, redness, swelling, myalgia, nausea, vomiting, abdominal pain, rash
SERIOUS
angioedema of the extremities or face, encephalitis, encephalopathy, seizures, and peripheral neuropathy, respiratory distress (rare)

NOTE: 冰箱冷藏，不可冷凍

·《Contraindications》Severe allergic reaction (eg, anaphylaxis) to a previous dose of the vaccine, any other Japanese encephalitis virus vaccine, or any component of the product, including protamine sulfate；
·SC administration only.

藥名相似:

外觀相似:

外觀描述: 凍晶疫苗:『黃』蓋透明玻璃小瓶；稀釋液:『白』蓋透明玻璃小瓶，附注射器及2支針頭)

32.06 Vaccines

39348 **C /**

PRIORIX* 派立克

Measles, mumps and rubella vaccine (MMR)(with 0.5 mL water for inj)1 dose vial(健診)

Dosage: 2衛福部提供-疫苗 39348

Adult
· Measles, mumps, rubella immunization: SC, 0.5 mL single dose

Pediatric
· Measles, mumps, rubella immunization: SC, 0.5 mL at 12 to 15 mon and then again at 4 to 6 yrs

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: MMR with 0.5 mL water for inj自費(36073);MMR健診(39307); Measles with 0.5mL water for inj 健診(39314); Rubella免費, 育齡(39319)

ADR:

Injection site pain/erythema, rash, fever, cold symptoms, arthritis

NOTE: 冰箱冷藏 2-8°C，不可冷凍。

·《Contraindications》Hypersensitivity to any component of the vaccine, including gelatin; Currently pregnant or pregnancy for 3 months following vaccinatiom; Anaphylactic or anaphylactoid reactions to neomycin; Active febrile infection or febrile respiratory illness; in cases of moderate or severe acute illness with or without fever, defer vaccination unless the benefit of protection outweighs the risk of adverse reaction However, the Advisory Committee on Immunization Practices (ACIP) recommends that all vaccines can be administered to persons with minor illnesses such as diarrhea, mild upper respiratory infection with or without low-grade fever, or other low-grade febrile illness.
; Patients receiving immunosuppressive therapy, except for those receiving corticosteroids as replacement therapy; Blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems; Primary and acquired immunodeficiency states, including patients immunosuppressed in association with AIDS or other clinical manifestations of infection with HIV, cellular immune deficiencies, and hypogammaglobulinemic and dysgammaglobulinemic states; Severe immunodeficiency (eg, from hematologic and solid tumors, congenital immunodeficiency, long-term immunosuppressive therapy); HIV with severe immunocompromise (age-specific CD4+ T-lymphocyte less than 15%); Family history of congenital or hereditary immunodeficiency, until immunocompetence of potential vaccine recipient is demonstrated ;
·Each vial cotains: More Attenuated Enders' Strain (Measles), Jeryl Lynn Strain (Mumps), Wistar RA 27/3 Strain (Rubella)

藥名相似:

外觀相似:

外觀描述: 『白』色凍晶乾粉、『淺綠』蓋透明玻璃小瓶，附0.5mL稀釋液『 透明』玻璃安瓿)

34.02 Gastrointestinal Smooth Muscle Relaxants

22044 UK / Caution

Catilon Tablets 40mg 腸必寧錠 40 毫克

Otilonium bromide 40mg tab

Dosage: 1常備品 22044

Adult
· Irritable bowel syndrome: PO, 40mg bid-tid

Pediatric(<18yrs)
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Tab: 40mg(22044)

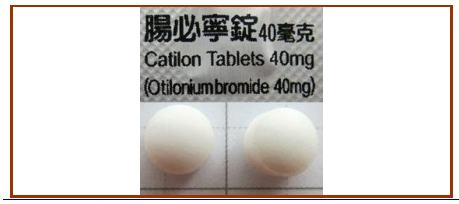
ADR:

NOTE: 室溫儲存25℃以下

藥名相似:

外觀相似: Mopride* 5mg Tab (22043)

外觀描述: 白色圓錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049193

34.02 Gastrointestinal Smooth Muscle Relaxants

26405 UK /

COSPANON CAPSULES 可使保朗膠囊

Flopropione 40mg cap

Dosage: 1常備品 26405

Adult
· Relief of spasmodic symptoms associated with hepatobiliary/pancreatic disorders: PO, 40-80mg tid
· Relief of spasmodic symptoms associated with urinary calculi: PO, 80mg tid

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Cap: 40mg(26405)

ADR:
Nausea, vomiting, heartburn, epigastric fullness, skin rash

NOTE: 室溫儲存

藥名相似:

外觀相似: Methycobal* 500 mcg Cap(25205),

外觀描述: 濁紫紅色/淡黃色膠囊，有CS 40字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1005954

34.02 Gastrointestinal Smooth Muscle Relaxants

26415 /

DOBECON SUGAR COATED TABLETS 100MG "YUNG SHIN" 肚比康糖衣錠１００毫克

Mebeverine HCl 100 mg tab

Dosage: 1常備品 26415

Adult
· Irritable bowel syndrome: PO, ac, 100mg tid - qid

Pediatric
>10 yrs: same as adult

Dosing adjustments in hepatic impairment:
Use with caution

Dosing adjustments in renal impairment:
Use with caution

P: Tab: 100mg(26415)

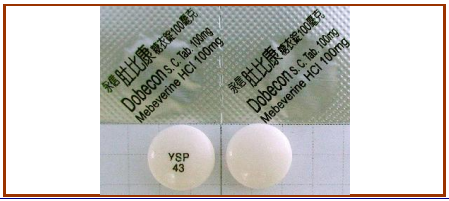
ADR:
Dizziness, headache, nausea, skin reaction

NOTE: 室溫儲存
It should be avoided in patients with paralytic ileus or porphyria

藥名相似:

外觀相似: Defense* 300mg Tab (25003)

外觀描述: 白色圓扁錠，有YSP及43字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045247

34.02 Gastrointestinal Smooth Muscle Relaxants

26416 UK / Unsafe

DICETEL 50MG FILM COATED TABLETS 得舒特膜衣錠50毫克

Pinaverium bromide 50mg FC tab

Dosage: 1常備品 26416

Adult
· Functional intestinal disturbance, biliary disorders: PO, 50-100mg tid with meal; Max. 300mg/day

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Tab: 50mg(26416)

ADR:

Abdominal pain, diarrhea, nausea, vomiting, dysphagia, rash, pruritus, urticaria, erythema, hypersensitivity reaction

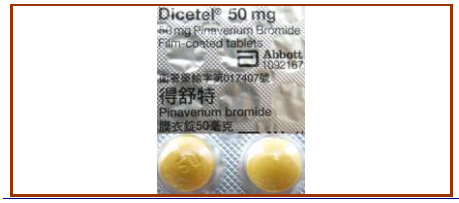
NOTE: 室溫儲存

MICROMEDEX 2.0
藥品仿單

藥名相似:

外觀相似:

外觀描述: 淡橘色圓形錠，一面有"50"字樣



34.04 Genitourinary Smooth Muscle Relaxants

26406 B /

FOXATE F.C. TABLETS 200MG 伏順膜衣錠２００毫克

Flavoxate HCl 200mg tab

Dosage: 1常備品 26406

Adult
· Urologic disorders: PO, 100-200mg tid-qid

Pediatric
· Urologic disorders(>12 yrs): same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 200mg(26406)

ADR:

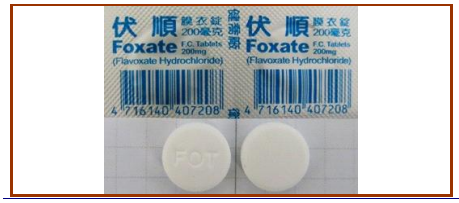
COMMON
Nausea, vomiting, xerostomia, headache, somnolence, blurred vision, feeling nervous, pharyngeal dryness
SERIOUS
Leukopenia, confusion, raised intraocular pressure

NOTE: 室溫儲存

藥名相似: Tab: 200mg(26406)

外觀相似: Seroquel* 100mg Tab (22946)

外觀描述: 白色圓扁錠，一面有FOT字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044572

34.04 Genitourinary Smooth Muscle Relaxants

26421 ɔt be ruled out / Infant risk can

Betmiga Prolonged-release Tablets 25mg 貝坦利持續性藥效錠25毫克

Mirabegron 25mg PR tab

Dosage: 1常備品 26421

Adult
· Overactive bladder, monotherapy or in combination with solifenacin, with symptoms of urge urinary incontinence, urgency, and urinary frequency: PO, monotherapy: initial, 25mg QD with or without food, may increase to 50mg QD based on efficacy and tolerability; combination therapy: initial, mirabegron 25mg QD with solifenacin succinate 5mg QD; after 4 to 8 wks may increase mirabegron to 50mg QD based on efficacy and tolerability

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

·Mild (Child-Pugh A): No dosage adjustment needed
·Moderate (Child-Pugh B): Do not exceed 25mg/day
·Severe (Child-Pugh C): Not recommended

Dosing adjustments in renal impairment:

·Clcr 30 to 89 mL/min: No dosage adjustment needed
·Clcr 15 to 29 mL/min: Do not exceed 25mg/day
·ESRD (Clcr < 15 mL/min): Not recommended

P: Tab: 25mg(26421)

ADR:

COMMON
Hypertension, tachycardia, constipation, xerostomia, headache, urinary tract infectious disease, nasopharyngitis
SERIOUS
Cerebrovascular accident, urinary retention, cancer
POSTMARKETING REPORTS
Nausea, diarrhea, dizziness, angioedema (angioedema of the face, lips, throat, tongue with or without respiratory symptoms)

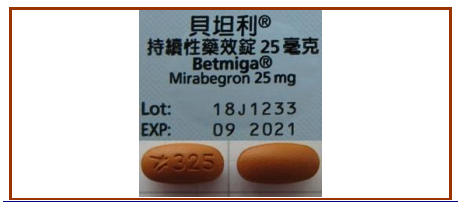
NOTE: 室溫儲存

·Swallow whole; do not crush or chew
·不良反應上市後經驗：加註有病人使用本藥產生混亂、幻覺、失眠及焦慮的現象。大多數病人在使用本藥前已有此症狀或是併用可能造成上述現象的藥物。本藥與這些症狀的關連性尚未確立。
·有報告指出曾發生臉、嘴唇、舌頭及/或喉頭的血管性水腫。案例發生於第一次劑量給藥後的數小時後或重覆劑量後。若發生於舌頭、下咽部或喉頭，應即刻停止治療，並開始適當治療及/或處置以確保呼吸道暢通。
·於開始併用 digoxin 的病人，起初應使用最低劑量。應監測 digoxin 血清濃度，並以漸進式調整劑量，以得到想要的臨床效果。

藥名相似:

外觀相似:

外觀描述: 褐色橢圓形膜衣錠，印有325及商標



34.06 Respiratory Smooth Muscle Relaxants

26404 C / Infant risk is

NOSMA SUSTAINED-RELEASE MICROSPHERES CAPSULES 125MG "WECAM" "惠勝" 漠喘緩釋微粒膠囊１２５毫克

Theophylline 125mg SRMC (sustained release microsphere capsule)

Dosage: 1常備品 26404

Adult
·Bronchospasm: PO, initial 300 mg/day div q12h, if toleranted, increase to Max 400-600 mg/day

Pediatric
·Bronchospasm:
6-15yrs (<45kg): PO, initial 12-14 mg/kg/day div q8-12h, if toleranted, increase to 16-20 mg/kg/day (Max 300-400 mg/day)
>16yrs or 6-15yrs (>45kg): PO, initial 300 mg/day div q8-12h, if toleranted, increase to Max 400-600 mg/day

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: 125mg SRMC(26404), 250mg SRMC(26403)

ADR:

COMMON
nausea, vomiting, headache, insomnia, tremor, irritability, restlessness
SERIOUS
atrial fibrillation, tachyarrhythmia, Stevens-Johnson syndrome, intracranial hemorrhage, seizure

NOTE: 室溫儲存

·《Contraindications》hypersensitivity to theophylline, or to any product component；
·Capsule can be opened and the contents sprinkled on soft food. Do not chew beads
·Dosage should be calculated on the basis of lean body weight, then adjust based on serum concentrations, clinical response and tolerance of the patient

藥名相似: Cap: 125mg SRMC(26404), 250mg SRMC(264

外觀相似: 22876 Topamax* 25mg Topiramate

外觀描述: 白色/透明膠囊,有Nosma125及Wecam字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045539

34.06 Respiratory Smooth Muscle Relaxants

26413 C / Infant risk is

TABELLAE AMINOPHYLLINAE 100MG "Y.Y."(鋁箔/膠箔)"應元"氨基非林錠

Aminophylline tab 100mg

Dosage: 1常備品 26413

Adult
·Bronchospasm: (Dosage expressed as anhydrous theophylline)
PO, initial 300 mg/day div q6-8h, if toleranted, increase to Max 400-600 mg/day

Pediatric
·Bronchospasm: (Dosage expressed as anhydrous theophylline)
Premature < 24 days: PO, 1 mg/kg q12h
Premature≧24 days: PO, 1.5 mg/kg q12h
Infant<26 wks: [(0.2 x age in wks)+ 5]xBW(kg)=mg/day div q8h
Infant 26-52wks:[(0.2 x age in wks)+ 5]xBW (kg)=mg/day div q6h
1-15yrs (<45kg): PO, initial 12-14 mg/kg/day div q4-6h, if toleranted, increase to 16-20 mg/kg/day (Max 300-400 mg/day)
>16yrs or 1-15yrs (>45kg): PO, initial 300 mg/day div q6-8h, if toleranted, increase to Max 400-600 mg/day

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 100mg(26413), Inj: 250mg/10mL(33260)

ADR:

COMMON
nausea, vomiting, headache, insomnia, tremor, irritability, restlessness
SERIOUS
atrial fibrillation, tachyarrhythmia, Stevens-Johnson syndrome, intracranial hemorrhage, seizure

NOTE: 室溫儲存

1. Approximate aminophylline dosage = theophylline dosage/0.8
2. Dosage should be calculated on the basis of lean body weight, then adjust based on serum concentrations, clinical response and tolerance of the patient
3. IV aminophylline is preferred over other routes of administration for the treatment of acute bronchospasm.

藥名相似: Tab: 100mg(26413), Inj: 250mg/10mL(33260)

外觀相似:

外觀描述: 白色圓扁錠，一面中間有一刻痕，有YP及109字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12003633

34.06 Respiratory Smooth Muscle Relaxants

28682 C / Infant risk is

CENTERTHEO* LIQUID 5.34MG/ML "CENTER" "晟德"適優喘液5.34毫克/毫升

Theophylline liq 5.34mg/mL, 60mL/B

Dosage: 1常備品 28682

Adult
·Bronchospasm: PO, Initial 300mg/day div. q6-8h, if

tolerated, increase to Max. 400-600 mg/day

Pediatric
·Bronchospasm: PO,
Premature neonates <24 days: 1mg/kg q12h
Premature neonates ≧24 days: 1.5mg/kg q12h
Full-term infants <26 wks:[(0.2 x age in wks) + 5] x BW(kg) = daily dose(mg) div. q8h
Infants 26-52 wks:[(0.2 x age in wks) + 5] x BW(kg) = daily dose(mg) div. q6h
1-15 yrs (<45kg): Initial 12-14mg/kg/day (Max. 300mg) div. q4-6h; if tolerated, increase to 16-20mg/kg/day (Max. 400-600mg)
1-15 yrs (>45kg) or >16yrs: Same as adult

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Cap: 125mg SRMC(26404); Liq: 5.34mg/mL, 60mL/B(28682)

ADR:

COMMON
Nausea, vomiting, headache, insomnia, tremor, irritability, restlessness
SERIOUS
Atrial fibrillation, tachyarrhythmia, Stevens-Johnson syndrome, intracranial hemorrhage, seizure

NOTE: 室溫儲存

Dosage should be calculated on the basis of lean body weight, then adjust based on serum concentrations, clinical response and tolerance of the patient.
含阿斯巴甜，苯酮尿症者不宜使用。

藥名相似:

外觀相似:

外觀描述: 60mL 淡茶色溶液,半透明塑膠瓶

34.06 Respiratory Smooth Muscle Relaxants

33260 **C / Infant risk is**

ASIPHYLLINE INJECTION 心安寧注射液 2 5 0 公絲

■Aminophylline inj 250mg/10mL amp

Dosage: 1常備品 33260

Adult (Dosage expressed as anhydrous theophylline)
·Acute bronchospasm: IV infusion, LD 4.6mg/kg over 30 min; MD as follows:
<60 yrs (nonsmoking): 0.4 mg/kg/h (Max 900 mg/day)
>60 yrs: 0.3 mg/kg/h up to 17 mg/h (Max 400 mg/day)
Cardiac decompensation, cor pulmonale, hepatic dysfunction, sepsis with multi-organ failure, shock: 0.2 mg/kg/h up to 17 mg/h (Max 400 mg/day)

Pediatric (Dosage expressed as anhydrous theophylline)
·Acute bronchospasm: IV infusion, LD 4.6mg/kg over 30 min; MD as follows:
Neonates ≦24 days: 1 mg/kg q12h
Neonates >24 days: 1.5 mg/kg q12h
Infants 6 wks-1yr: 0.008 x (age in weeks) + 0.21 mg/kg/h
1-9yrs: 0.8 mg/kg/h
9-12yrs: 0.7 mg/kg/h
12-16yrs (smoking): 0.7 mg/kg/h
12-16ys (nonsmoking): 0.5 mg/kg/h (Max 900 mg/day)
>16yrs (nonsmoking): 0.4 mg/kg/h (Max 900 mg/day)

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 250mg/10mL amp (33260), Tab: 100mg(26413)

ADR:

NOTE: 室溫儲存

1. Each amp contains 250mg hydrous aminophylline equivalent to 197.5mg of anhydrous theophylline (Approximate aminophylline dosage = theophylline dosage/0.8)
2. Dosage should be calculated on the basis of lean body weight, then adjust based on serum concentrations, clinical response and tolerance of the patient

藥名相似:

外觀相似:

外觀描述: 10mL透明液體，褐色塑膠包裝，瓶身印有條碼

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12009994

36.02 Vitamin B Complex

26807 risk is minimal / Infant risk is

PYRIDOXINE HCL* TABLETS 50MG "JOHNSON" "強生" 鹽酸口比多辛錠 5 0 毫克

Pyridoxine HCl (vitamin B6) 50mg tab

Dosage: 1常備品 26807

Adult

· Recommended Dietary Allowance (RDA): PO, men and women, to 50 yr of age, 1.3 mg/day; men over 50 yr, 1.7 mg/day; women over 50, 1.5 mg/day; pregnancy 1.9 mg/day; lactation 2 mg/day.

· Peripheral neuropathy, drug-induced (prophylaxis): PO, 25-50 mg/day

· Peripheral neuropathy, drug-induced (treatment): PO, 50-300 mg/day

· Pyridoxine deficiency, dietary or drug-induced: PO, 5-25 mg/day for 3 wk; then 1.5-5 mg/day in a multivitamin preparation

Pediatric

· Recommended Dietary Allowance (RDA): PO, (0-6 mons) 0.1 mg/day; (7-12 mons) 0.3 mg/day; (1-3 yr) 0.5 mg/day; (4-8 yr) 0.6 mg/day; (9-13 yr) 1 mg/day; (males 14-18 yr) 1.3 mg/day; (females 14-18 yr) 1.2 mg/day

· Peripheral neuropathy, drug-induced (treatment): PO, 50-200 mg/day

· Pyridoxine deficiency: PO, 5-25 mg/day for 3 wk; then 1.5-5 mg/day in a multivitamin preparation

Dosing adjustments in hepatic impairment:

Recommended doses for deficiency are 5-25 mg/day for 3 wks, MD,1.5-2.5 mg/day in a multivitamin preparation (AMA, 1990).

Dosing adjustments in renal impairment:

Dosage adjustment required

P: Tab: 50mg(26807)

ADR:

COMMON
Decreased folic acid, paresthesia, somnolence

NOTE: 室溫儲存

·《Contraindications》hypersensitivity to pyridoxine products ;
·高劑量Pyridoxine可能發生周邊神經病變(感覺 刺痛、灼熱或麻木)[Pyridoxine (vitamin B6)成分藥品安全資訊風險溝通表。(109.06.16)]：通常與高劑量使用或長期使用含vitamin B6產品有關，與正常飲食中攝入的vitamin B6無關。若病人出現周邊神經病變症狀，需回顧其vitamin B6攝取來源，例如：維生素B群、複方維生素及/或含鎂製劑產品，特別是合併使用多種製劑。Vitamin B6可能會以其化學名稱列於標示上，包括pyridoxine hydrochloride、pyridoxal 5-phosphate或pyridoxal 5-phosphate monohydrate。

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有JCP字樣，另一面有011字樣。

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12001821

36.02 Vitamin B Complex

26810 risk is minimal / Infant risk is

AELOCON* S.C. TABLETS "EVEREST" "永勝"愛樂康糖衣錠

Thiamine disulfide 50mg, Riboflavin 5mg tab

Dosage: 1常備品 26810

Adult

·Neuritis, Thiamine deficiency, Neuralgia: PO,1-3 tab/day qd or div. Into 3 doses.

Pediatric

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 55mg(26810)

ADR:

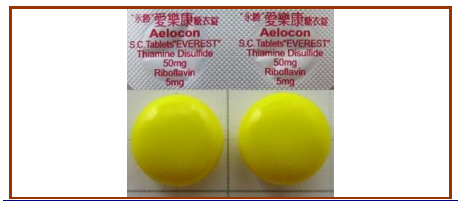
NOTE: 室溫儲存

1.RIBOFLAVIN imparts a yellow-orange color to urine.
2.The RDA of thiamine in pregnancy is 1.4 mg/day. The RDA of thiamine for lactating women is 1.5 mg/day.

藥名相似:

外觀相似:

外觀描述: 黃色圓形糖衣錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1037689

36.02 Vitamin B Complex

36819 risk is minimal / Infant risk is

Vitamin B1 Injection 50mg/ml "T.F." 維生素乙 1 注射液 50毫克/毫升

Thiamine inj 100mg/2mL amp

Dosage: 1常備品 36819

Adult

· Recommended Dietary Allowance (RDA): men, 1.2 mg/day; women, 1.1 mg/day; pregnancy and lactation, 1.4 mg/day

· Wernicke's encephalopathy: IV,IM, 100 mg/day for 3 days; up to 1000 mg may be necessary in the first 12 hr; then IM 50-100 mg/day.

· Neuritis of prenancy with severe vomiting:IM, 5-10 mg/day

· Beriberi: IM, 10-20 mg or slow IV infusion 3 times/day for up to 2 wk; then PO,MD.5-10 mg/day for 1 month

Pediatric
· Beriberi: IM / IV 10-25 mg for 2 wk; thenPO, 5-10 mg/day for 1 month.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj:100mg/2mL Amp(36819)

ADR:

COMMON
IV injection site reaction
SERIOUS
hypersensitivity/anaphylaxis (parenteral administration (rare)

NOTE: 室溫儲存

[C] if used in doses above the RDA (1.5mg)

藥名相似:

外觀相似:

外觀描述: 2mL透明注射液,透明安瓿,白底粉紅字標籤,頸部有藍灰點

36.02 Vitamin B Complex

36824 **risk is minimal / Infant risk can**

VITAMIN B COMPLEX* INJECTION "ASTAR" "安星" 複合維他命 B 注射液

Thiamine 100mg [A,C], Riboflavin 5mg [A,C], Pyridoxine(B6) 5mg [A,C], Nicotinamide 50mg [A,C], Cal. Pantothenate 5mg [A,C]/1mL, 2mL/amp

Dosage: 1常備品 36824

·Vitamin B complex deficiency: IM,IV,1-2ml qd-bid

.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 2mL amp(36824)

ADR:

NOTE: 室溫儲存15-30℃

·Only for IM , If IV adminitration, it should be diluted with D5W or NS and IV slowly.
·Protect from light

藥名相似:

外觀相似:

外觀描述: 2mL注射液，『棕』色安瓿頸部有『藍』點

36.04 Vitamin C

36802 **ɔt be ruled out / Infant risk can**

VITACICOL INJECTION 美達康針

Ascorbic acid 100mg/2mL amp

Dosage: 1常備品 36802

Adult
· Recommended Dietary Allowance (RDA): males, 90 mg/day; females, 75 mg/day; pregnancy, 85 mg/day; lactation, 120 mg/day; smoker, add an additional 35 mg daily
· Vitamin C deficiency: IM,IV,SC, 70-150 mg/day, doses 3 to 5 times the RDA may be adequate for conditions with increased requirements.
· Burns, severe: IM,IV,SC, 1-2 g/day
· Parenteral nutrition, maintenance requirement: IV, 200 mg/day
· Scurvy: IM,IV,SC, 300~1000 mg/day, doses up to 6 g/day have been administered
· Wound healing: IM,IV,SC, 300-500 mg/day for 7-10 days pre- and post-operatively; larger doses have also been used

Pediatric
· Recommended Dietary Allowance (RDA): 0-6 months, 40 mg/day; 7-12 months, 50 mg/day; 1-3 yr, 15 mg/day; 4-8 yr, 25 mg/day; 9-13 yr, 45 mg/day; males 14-18 yr, 75 mg/day; females 14-18 yr, 65 mg/day
· Parenteral nutrition additive, maintenance requirement: Infants, IV, 15-25 mg/kg/day, Max 80 mg/day; Children and Adolescents, IV, 80 mg/day
· Scurvy: IM,IV, 100-300 mg/day in divided doses for 1 week followed by 100 mg/day until normalization of tissue saturation

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj:100mg/2ml Amp(36802)

ADR:

COMMON
Injection site pain, swelling at injection site
SERIOUS
Hemolysis, oxalate nephropathy

NOTE: 室溫儲存

1. Therapeutic doses of injectable ascorbic acid were rated FDA Pregnancy Category C. However, nutritional supplement doses of vitamins and minerals are generally considered safe during pregnancy. Dietary vitamin C requirements are generally increased during pregnancy.
2. Avoid rapid IV injection; may cause temporary faintness or dizziness.

藥名相似:

外觀相似:

外觀描述: 2mL透明注射液，透明安瓿頸部有藍點

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12003074

36.06 Vitamin D

26815 C / Unknown(有

U-Ca soft capsule 0.25mcg (CALCITRIOL) "SINPHAR" 活維D軟膠囊0．25微克（活性維生素D3）

Calcitriol (1α-25-Dihydroxy-Vitamin D3) 0.25mcg soft cap

Dosage: 1常備品 26815

Adult

· Hyperparathyroidism in renal disease: (predialysis patients) PO, initial, 0.25 mcg/ day; may be increased to 0.5 mcg/day

· Hypocalcemia in renal disease: (dialysis patients) PO,initial, 0.25 mcg qd or every other day(may require 0.5-1 mcg/day); increases of 0.25 mcg/day may be made at 4-8 wk intervals

· Hypoparathyroidism, Pseudohypoparathyroidism:PO, initial, 0.25 mcg/day in morning; dose may be increased at 2-4-wk intervals; common effective MD. 0.5-2 mcg/day

· Vitamin D-dependent rickets:PO, 1 mcg/day

· Vitamin D-resistant rickets (familial hypophosphatemia):PO, initial, 0.015-0.02 mcg/kg/day;MD, 0.03-0.06 mcg/kg/day ;Max. 2 mcg/day

Pediatric

· Hyperparathyroidism in renal disease: predialysis patients)<3 yr : PO, 0.01-0.015mcg/kg/day; >3 yr : initial, 0.25 mcg/day ; may be increased to 0.5 mcg/day

· Hypocalcemia in premature infants: PO, 1 mcg /day for 5 day

· Hypocalcemia in renal disease: (dialysis patients) PO, 0.25-2 mcg/day

· Hypoparathyroidism, seudohypoparathyroidism: < 1 yr : PO, 0.04-0.08 mcg/kg /day(evaluate dosage at 2-4 wk intervals);1-5 yr : 0.25-0.75 mcg /day (evaluate dosage at 2-4 wk intervals); >6 yr :0.5-2 mcg /day

· Vitamin D-dependent rickets: PO, 1 mcg /day

· Vitamin D-resistant rickets (familial hypophosphatemia): PO, initial, 0.015-0.02 mcg/kg /day;MD. 0.03-0.06 mcg/kg /day; Max. 2mcg /day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Dosage adjustment required

P: Cap: 0.25mcg(26815); Oint: 30g/tube(29407); Inj: 1mcg/1mL Amp(36801)

ADR:

Vitamin D toxicity (hypercalcemia syndrome), nausea, vomiting, dry mouth, constipation, polyuria, polydipsia, nocturia, and deterioration of renal function.

NOTE: 室溫避光

(1) Magnesium-containing preparations (e.g., antacids) and calcitriol should not be used concomitantly in patients on chronic renal dialysis because such use may lead to the development of hypermagnesemia.

(2) 1 mcg of colecalciferol or ergocalciferol is equivalent to 40 units of vitamin D.

藥名相似:

外觀相似:

外觀描述: 紅/白色卵圓形軟膠囊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1040864

36.06 Vitamin D

36801 C / Infant risk can

CALTSUE INJECTION 1 μg/mL 鈣注益 注射液1微公克/毫升

Calcitriol inj 1mcg/1mL amp

Dosage: 1常備品 36801

Adult

·Hypocalcemia (renal dialysis): IV, initial 1.0mcg (0.02mcg/kg) to 2.0mcg three times weekly (every other day); may be increased by 0.5-1mcg at 2-4 week intervals if needed. Max. 8mcg three times weekly.

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Dosage adjustment required

P: Cap: 0.25mcg(26815);Oint: 30g/tube(29407); Inj: 1mcg/1mL Amp(36801), 2mcg/1mL Amp(36809)

ADR:

vitamin D intoxication, hypercalcemia syndrome

NOTE: 室溫儲存

(1) IV may be administered undiluted as bolus through catheter at end of hemodialysis

(2) For efficacy, dietary calcium must be adequate (minimum of 800 mg daily)

(3) If the serum calcium times phosphate (Ca x P) product exceed 70, calcitriol should be discontinued.

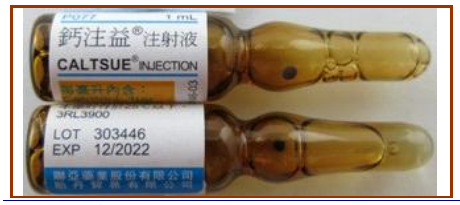
(4) 1 mcg of colecalciferol or ergocalciferol is equivalent to 40 units of vitamin D.

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液『棕』色安瓿，藍白底黑字標

籤，頸部有藍點



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049154

36.10 Multivitamin

36812 ɔt be ruled out / Infant risk is

LYO-POVIGENT* inj 4mL amp 利保維源注射劑

Multivitamin inj (MVI) 4mL amp

Dosage: 1常備品 36812

Adult

·Multivitamin deficiency: IV infusion, 2-5mL/24hr

小兒PN總量小於1L者，添加0.5mL；大於1L者，添加2mL，添加頻次為QW1,3,5，若遇假日則順延一日。

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: Strovitan*(26806); Inj: Lyo-Povigent* 5mL Amp(36812)

ADR:

· Vitamin B1 may cause hypersensitivity.

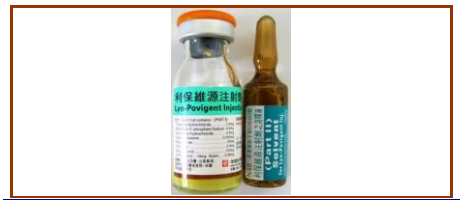
NOTE: 冰箱冷藏，不可冷凍

1. Each vial contains : (Part I)
Vit B1 3.9 mg [A, C], Vit B2 4.6mg [A, C], Vit B6 4.9mg [A, C], Cyanocobalamin 0.005mg, Niacinamide 40mg [A, C], Folic acid 0.4mg [A/C], Vit C 100mg [A, C], D-Panthenol 14mg [C] & Biotin 0.06mg
2.Each amp contains : (Part II)
Vit A 3300 IU [A, C], Cholecalciferol 0.005mg (200 IU) [A, D], dL-α-Tocopheryl acetate 10mg [A, C] & Phytonadione 2mg.
3. [C, D] if used in dose above the RDA
4. MVI should be diluted and don't IV push directly, otherwise It may cause vertigo.

藥名相似:

外觀相似:

外觀描述: 黃色乾粉『橘』蓋透明玻璃小瓶及一棕色稀釋液安瓿



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1039392

38.00 Local Anesthetics

29104 B / Infant risk is

Lidocaine Solution 4% "Yihhaw" "鎰浩" 利多卡因液 4%

Lidocaine soln 4% 30mL bot

Dosage: 1常備品 29104

Adult
· Before bronchoscopy, bronchography, laryngoscopy, oesophagoscopy, endotracheal intubation, and biopsy in the mouth and throat: 40-300mg(1-7.5mL)
·Surface anaesthesia of mucous membranes of the mouth, throat, and upper gastrointestinal tract: Max.200mg(5mL).Spray, 200-400mg(5-10mL)

Pediatric
<12 years: Max.3mg/kg

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P: Surfance anesthesia- Soln: 4% 30mL/bot(29104)；Spray: 10% 500dose/bot(29109)；Jelly: 2% 30g(29101)；TTS: 5% patch(29133)；Cream: EMLA*(29103), 兒癌EMLA*(29902)

ADR:

COMMON
confusion, dizziness, drowsiness, headache
constipation, nausea, vomiting, hypotension
local irritation (topical products; ie, erythema, edema), paresthesias, tremors
SERIOUS
arrhythmias, cardiac arrest, methemoglobinemia, seizures

NOTE: 室溫儲存

藥庫發固定數code: 37208, 37202, 37209, 29101, 38816

藥名相似:

外觀相似:

外觀描述: 褐色玻璃瓶，30mL藥液

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049979

38.00 Local Anesthetics

29109 B /

QUICAINE* Spray 10% 益麻噴霧劑 10%

Lidocaine spray 10% 10mg/dose, 50mL/bot, 500 doses/bot

Dosage: 1常備品 29109

Adult
·Otorhinolaryngology: Topical, 3 metered doses
·Paracentesisa: Topical, 3 metered doses
·During delivery: Topical, up to 20 metered doses
·Introduction of instruments, tubes and catheters into the respiratory and digestive tract: Topical, up to 20 metered doses for procedures in pharynx, larynx and trachea. During prolonged procedures or combined with other lidocaine products, total dose should not exceed 400mg. With applications mainly to the larynx, trachea and bronchi, dose should not exceed 20 metered doses
·Dental practice: Topical, 1-5 metered doses

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Surfance anesthesia- Spray: 10% 500dose/bot(29109)；Soln: 4% 30mL/bot(29104)；Jelly: 2% 30g(29101)；TTS: 5% patch(29133)；Cream: EMLA*(29103), 兒癌EMLA*(29902)

ADR:

Local irritation (ie, erythema, edema)

NOTE: 室溫保存25℃以下

·The nozzle must not be shortened, otherwise the spray function will be destroyed.
·If cleaning of the nozzle is desired, the entire nozzle can be submersed in boiling water for 5 mins.

藥名相似:

外觀相似:

外觀描述: 50mL白色噴霧瓶，裝貼藍紅相間標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1055411

40.02A Ear Preparations

29085 C / Unknown(有

EARFLO* OTIC SOLUTION 耳復欣點耳液

Ofloxacin Otic soln 0.3% 5mL/bot

Dosage: 1常備品 29085

Adult
·Otitis: Otic, 6-10 drops bid, the eardrop should be allowed to maintain in the ear for 10 minutes.

Pediatric
·Otitis(1-12 yrs): Otic, 5 drops bid, the eardrop should be allowed to maintain in the ear for 10 minutes.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Otic soln: 0.3% 5mL/Bot(29085)

ADR:

NOTE: 室溫儲存

The patient should lie with the affected ear upward and the solution instilled into the ear canal; this position should be maintained for 5 minutes to facilitate penetration of the drops into the ear.This procedure should be repeated if necessary for the opposite ear.

藥名相似:

外觀相似:

外觀描述: 白色外包裝紙盒, 印有黑色"耳復欣點耳液"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1047116

40.02A Ear Preparations

29096 / Unknown(有

OTOZAMBON EAR DROPS 耳多贊邦點耳液劑

Polymyxin B Sulfate 80,000IU[B], Neomycin Sulfate 40mg[D], Lidocaine HCl 320mg[B] Otic soln 8mL/bot

Dosage: 1常備品 29096

Adult
·Acute and chronic otitis externa: Otic, 4-5 drops bid-qid

Pediatric
·Acute and chronic otitis externa: Otic, 2-3 drops tid-qid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: 250mg(20862), Oint: 30g(29309), Otic soln: 8mL/Bot(29096)

ADR:

NOTE: 室溫儲存

禁忌：鼓膜有穿孔之場合對所含成份有過敏性之患者

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023964

40.02A Ear Preparations

29112 /

MYCOMB OTIC DROPS "SINPHAR" 美康耳用滴劑

Triamcinolone acetonide 1mg/mL[C], Neomycin 2.5mg/mL[D], Gramicidin 0.25mg/mL, Nystatin100,000units/mL[C], Chloroxylenol 3mg/mL, 5mL/bot

Dosage: 1常備品 29112

Adult
·Antibacterial and antifungal: Otic, 2-3 drops tid-qid

Pediatric
·Antibacterial and antifungal: Otic, 2-3 drops tid-qid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Otic soln: 5mL/Bot(29112); Inj: 40mg/ml (35210); Cream: 6gm/tube (29412); Nasal spray: 120puff/B (29090)

ADR:

NOTE: 室溫保存

藥名相似:

外觀相似:

外觀描述: 5mL耳滴藥水，白色圓蓋，白色圓形滴耳瓶，白底紅字標簽

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1022867

40.02B Nose Preparations

29090 C / Unsafe

TRISONIN* AQUEOUS NASAL SPRAY 55 MCG/DOSE 特索寧水性鼻用噴液劑55微公克/劑量

Triamcinolone acetonide nasal spray 55mcg/PF 120PF/bot

Dosage: 1常備品 29090

Adult & child≥12yrs
·Rhinitis: initial, 220mcg/day as 2 sprays in each nostril qd; MD, 110 mcg/day as 1 sprays in each

nostril qd.

Pediatric (6-11yrs)
·Rhinitis: 110mcg/day as 1 sprays in each nostril qd

Dosing adjustments in hepatic impairment:

Dosage adjustments may be necessary in patients with liver failure.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Nasal spray: Nasacort 120 puffs/B(29090); Inj: 40mg/1ml(35210);Cream: 6gm(29412); Mycomb* otic drops(29112)

ADR:

COMMON
Cushing's syndrome, euphoria/depression, GI distress, growth depression, hypertension, impaired skin healing, increased risk of infection, osteoporosis, skin atrophy
SERIOUS
adrenocortical insufficiency, cataracts, glaucoma, hyperglycemia, tuberculosis reactivation

NOTE: 儲存25℃以下

藥名相似:

外觀相似:

外觀描述: 鼻噴劑懸浮液,白色噴鼻塑膠瓶 ,紙盒與瓶身白底綠/黑色字標籤,有『綠』色區塊圖形

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1057919

40.02B Nose Preparations

29124 **C / Caution**

BUTARO NASAL SPRAY 10MG/ML "LOTUS" "美時" 全妥噴鼻液10毫克/毫升

Butorphanol tartrate nasal spray 10mg/mL, 2.5mL/bot 鼻用

Dosage: 1常備品 29124

Adult
· Pain relief: Initial 1mg (1 spray in 1 nostril), followed by 2nd dose in 60-90 min, if necessary, repeat every 3-4 hr as needed. However, if pain is severe, a 2mg (1 spray in each nostril) dose may be given, but should not be repeated until 3-4 hrs later

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Initial dose should be limited to 1mg followed by second dose in 90-120 min as needed, subsequent doses if required should be given at intervals of not less than 6 hours

Dosing adjustments in renal impairment:

Initial dose should be limited to 1mg followed by second dose in 90-120 min as needed, subsequent doses if required should be given at intervals of not less than 6 hours

P: Nasal spray: 10mg/mL, 2.5mL/Bot(29124)

ADR:

COMMON
Nausea, vomiting, asthenia, dizziness, insomnia, sedated, somnolence, nasal congestion
SERIOUS
Blood pressure alteration, palpitations, tinnitus, respiratory depression, upper respiratory infection

NOTE: 室溫保存

· It must be fully primed prior to initial use; reprime the pump sprayer if not used for 48 hours or longer
· After priming each metered spray delivers an average of 1mg of butorphanol tartrate
· A bottle will deliver an average of 14-15 doses or 8-10 doses with intermittent use
· Aim pump sprayer away from people and animals when priming

藥名相似:

外觀相似:

外觀描述:

40.02B Nose Preparations

29126 **C / Unsafe**

NASONEX AQUEOUS NASAL SPRAY 內舒拿水溶性鼻用噴液劑

Mometasone furoate 50mcg/puff 140puffs/bot

Dosage: 1常備品 29126

Adult
·Seasonal/perennial allergic rhinitis: initial 2 sprays/nostril qd; if symptoms are controlled, dose may be decreased to 1 spray/nostril qd; if symptoms are inadequately controlled, dose may be increased to Max. 4 sprays/nostril qd
·Nasal polyp: 2 sprays/nostril qd-bid

Pediatric (3-11 yrs)
·Seasonal/perennial allergic rhinitis: 1 spray/nostril qd

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Nasal spray: 50mcg/puff, 140puffs/B(29126); Cream: 0.1%, 5g/tube(29427)

ADR:

COMMON
Headache, epistaxis, pharyngitis, nasal burning, nasal irritation, nasal ulceration, sneezing
SERIOUS
Hypersensitivity reactions (e.g. bronchospasm, dyspnea), anaphylaxis, angioedema

NOTE: 室溫保存

·If the spray pump has not been used for 14 days or longer, it should be reprimed before next use

藥名相似: Nasal spray: 50mcg/puff, 140puffs/B(29126);

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022924

40.02B Nose Preparations

29127 C /

Azetin Nasal Spray 140mcg/dose 噴立停 鼻用噴液劑140微公克/劑量

Azelastine nasal spray 0.14mg/puff, 120puffs/bot

Dosage: 1常備品 29127

Adult
·Allergic rhinitis: 1 spray/nostril bid

Pediatric (≥6 yrs)
·Allergic rhinitis: 1 spray/nostril bid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Nasal spray: 0.14mg/puff, 100puffs/B(29108)

ADR:

COMMON
Bitter taste, headache, somnolence, fatigue, epistaxis, sneezing, nasal stinging/burning

NOTE: 室溫保存

·Each mL contains 1mg of azelastine HCl (0.1%)

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048635

40.02B Nose Preparations

29134 C /

Avamys Nasal Spray 艾敏釋鼻用噴液懸浮劑

Fluticasone furoate 27.5mcg/puff, 120puffs/bot

Dosage: 1常備品 29134

Adult
·Rhinitis: initial 2 sprays/nostril qd (110mcg/day) ; MD, 1 sprays/nostril qd(55mcg/day)

Pediatric
·Rhinitis(child 2-11yrs): initial 1 spray/nostril qd (55mcg/day); Max. 2 sprays/nostril qd(110mcg/day).

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Inhalation Aerosol: Seretide 250 Evohaler 120puff/B(29091); Seretide 125 Evohaler 120puff/B(29097); Seretide 50 Evohaler 120puff/B(29113); Flixotide Evohaler: 120puff/B(29111); Nasal spray: Flixonase 120puffs/set(29059); Cream: Cutivate 0.05% 5g(29428)

ADR:

COMMON
Epistaxis, oropharyngeal candidiasis, pharyngitis
SERIOUS
Adrenal suppression, anaphylaxis, glaucoma, hypersensitivity reactions

NOTE: 室溫保存

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024877

40.02C Mouth Preparations

29087 / Unsafe

DEXA ORABASE 0.1% (DEXAMEHASONE) "SINPHAR" 得舒口內膏 0．1％（迪皮脂醇）〝杏輝〞

Dexamethasone 0.1%[C] 5g /tube

Dosage: 1常備品 29087

Adult
· Stomatitis or glossitis: Local, apply several times daily

Pediatric
Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Tab: 0.5mg(25605), Oralbase: 5g(29087), Cream: color 5g(29580), Oph soln: tobradex 5mL/Bot(29191), Inj: 5mg/1mL(35201)

ADR:

Mild euphoria/depression, GI distress, Cushing's syndrome, impaired skin healing, muscle weakness

NOTE: 室溫儲存

Each g contains : Dexamethasone 1.0mg
賦形劑: Sod. Polyacrylate 、Colloidal silicon dioxide 、Liquid petrolatum、Lanolin、White petrolatum.

藥名相似:

外觀相似:

外觀描述: 5公克口內膏，白色鋁管，『黑』色上蓋，有"綠"色區塊及線條

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1042271

40.02C Mouth Preparations

29088 **demonstrated / Unsafe**

MUNDISAL GEL 蒙得莎凝膠

Choline Salicylate 8.7%[C] gel 10g/tube

Dosage: 1常備品 29088

Adult
·Stomatitis: Local, apply 1cm q3-4h as needed

Pediatric(4 month-2yr)
·Stomatitis: Local, apply 0.5cm q3-4h.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Oral gel: 10g(29088)

ADR:

仿單：若發生請立即停用並就醫診治，嚴重水楊酸鹽中毒症狀：嗜睡、過度換氣、代謝性酸中毒、低血糖、發燒、震顫、行為異常、意識混亂、產生幻覺、昏迷、抽搐。

NOTE: 儲存於25℃以下，必要時可於冰箱冷藏。

Each g contains : Choline salicylate 87mg
·儲存於25℃以下，必要時可於冰箱冷藏。
·孕婦自懷孕滿六個月到生產前，請勿使用本藥。
·兒童與青少年因病毒感染而發燒時，須經由醫師處方才能使用作為第二線治療藥物，以降低發生雷氏症侯群的風險。
·本藥可能會加強其他局部塗抹物質的吸收。
·每日最大用量250mg choline salicylate，最高使用頻率每天不超過8~10次。

藥名相似:

外觀相似:

外觀描述: 10克凝膠，白色瓶蓋，白色鋁軟管，白底黑字印刷有藍色商標及紫色區塊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021417

40.02C Mouth Preparations

29159 **UK / Unknown(有**

Comfflam* forte anti-inflammatory throat spray 3mg/ml 康護寧加強消炎噴液劑3毫克/毫升

Benzydamine HCl throat spray 3mg/mL 30mL/bot

Dosage: 1常備品 29159

Adult
·Relief of painful and inflammatory conditions of the mouth and throat: Local, 2-4 times sprays directly onto the sore/inflamed area and swallow gently. Repeat q1.5-3h as necessary.

Pediatric(6-12yr)
·Relief of painful and inflammatory conditions of the mouth and throat: Local, 2 times sprays directly onto the sore/inflamed area and swallow gently. Repeat q1.5-3h as necessary.

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P: Oral spray: 30mL/B(29110), 15mL/B(29160)

ADR:

Numbness or stinging sensations of the oral mucosa, hypersensitivity reactions

NOTE: 室溫儲存

·《仿單禁忌》：對benzydamine或其他所列成分過敏者。
·Comfflam spray should generally be used undiluted, but if stinging occurs it may be diluted with water.
·Comfflam is a NSAID.

藥名相似: Oral spray: 30mL/B(29110), 15mL/B(29160)

外觀相似:

外觀描述: 30mL透明溶液，白色定量噴液唧筒，綠色瓶蓋

40.02C Mouth Preparations

29160 **b2 / Unknown(有**

DIFFLAM FORTE ANTI-INFLAMMATORY THROAT SPRAY 3.0MG/ML 得伏寧加強消炎噴液劑3.0毫克/毫升

Benzydamine HCl 3mg/mL 15mL/bot

Dosage: 1常備品 29160

Adult
·Relief of painful and inflammatory conditions of the mouth and throat: Local, 2-4 sprays directly into the sore/inflamed area and swallow gently. Repeat q1.5-3h as necessary.

Pediatric
·Relief of painful and inflammatory conditions of the mouth and throat: Local, spray directly into the sore/inflamed area and swallow gently. Repeat q1.5-3h as necessary.
> 12yrs: 2-4 sprays.
6-12yrs: 2 sprays.

Dosing adjustments in hepatic impairment:

Use with caution

Dosing adjustments in renal impairment:

Use with caution

P: Oral spray: 30mL/B(29110), 15mL/B(29160)

ADR:

Numbness or stinging sensations of the oral mucosa, hypersensitivity reactions

NOTE: 室溫儲存

·《仿單禁忌》：對benzydamine或其他所列成分過敏者。

藥名相似:

外觀相似:

外觀描述: 15mL透明溶液，白色定量噴液唧筒，綠色瓶蓋

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025194

40.04 Local Anesthetics

29101 **B / Infant risk is**

XYLOCAINE JELLY 2% 苦息樂卡因凝膠

Lidocaine HCl 2% 30g/tube Jelly

Dosage: 1常備品 29101

Adult

·Surface anesthesia: topical, use as needed

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Surface anesthesia- Jelly: 2% 30g(29101)；Soln: 4% 30mL/bot(29104)；Spray: 10% 500dose/bot(29109)；TTS: 5% patch(29133)；Cream: EMLA*(29103), 兒癌EMLA*(29902)

ADR:

local irritation (ie, erythema, edema)

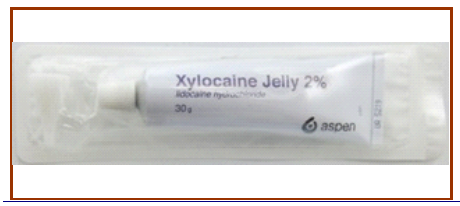
NOTE: 室溫儲存

1.applying a topical product to larger areas or for longer than recommended times may increase the risk of adverse effects
2.preparations containing preservatives should not be used for spinal or epidural anesthesia
3.藥庫發固定數code: 37208, 37202, 37209, 29101, 38816

藥名相似:

外觀相似:

外觀描述: 30克外用凝膠，白蓋軟管，白底紫色字印刷，有商標與紫色區塊



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021286

40.06 Mouthwashes and Gargles

29121 **C /**

PARMASON GARGLE SOLUTION 寶馬生漱口水

Chlorhexidine Gluconate Gargle 200mL/bot

Dosage: 1常備品 29121

Adult

·Gingivitis: 10-20mL bid-tid, oral rinsing for 20-30 sec.

Pediatric

·Gingivitis: 10-20mL bid-tid, oral rinsing for 20-30 sec.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed.

Dosing adjustments in renal impairment:

No dosage adjustment needed.

P: Soln: 0.2%(29121)

ADR:

COMMON
altered taste, skin irritation, tooth staining
SERIOUS
anaphylaxis, corneal injury - associated with chlorhexidine disinfectant solution eye contact

NOTE: 室溫儲存

·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1031170

42.02A Sympathomimetics

29273 B /

BRIMONIDINE TARTRATE* OPHTHALMIC SOLUTION 0.2% 愛爾康衛目明點眼液0.2%

Brimonidine tartrate oph soln 0.2%, 5mL/bot

Dosage: 1常備品 29273

Adult
·Open-angle glaucoma, ocular hypertension: Ophthalmic, 1 drop bid-tid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph soln: 0.2% 5mL/bot(29273), Combigan* 5mL/B(29299); Gel: 0.3% 30g (29616)

ADR:

COMMON
Xerostomia, foreign body sensation, headache, somnolence, blurred vision, burning sensation in eye, conjunctival discoloration, itching of eye, lid retraction, burning sensation, fatigue
SERIOUS
Cardiac dysrhythmia, hypertension, palpitations, syncope, bulbar conjunctival follicles, conjunctival hemorrhage, ocular immune hypersensitivity reaction, ocular hyperemia

NOTE: 室溫儲存25℃以下

藥名相似:

外觀相似:

外觀描述: 5mL塑膠眼藥滴瓶，外包裝標籤有紫色及黃色線條

42.02B Beta-blockers

29270 B / Unknown(有

Mikelan LA Ophthalmic Solution 2% 大塚美特朗持續性點眼液 2%

Carteolol HCl 2% oph soln 2.5mL/bot

Dosage: 1常備品 29270

Adut
· Open-angle glaucoma, ocular hypertension: Ophthalmic, 1 drop qd in affected eye(s)

Pediatric
safety and effectiveness is not established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph soln: 2% 2.5mL/bot (29270)

ADR:

COMMON
Angina, asthenia (7% .), dizziness (4% to 15% .), headache (4% to 17% .), insomnia (2% to 12%.), blurred vision, burning sensation in eye (25%), conjunctival edema (25%), conjunctival hyperemia (25%), epiphora (25%), eye irritation (25%)
SERIOUS
Cardiac dysrhythmia, heart failure, bronchospasm

NOTE: 室溫避光

1.ocular administration can result in some systemic absorption, the precautionary statements regarding oral and ocular administration are the same.
2.interference with glaucoma testing.
3.ophthalmic use in patients with narrow-angle or angle-closure glaucoma (only in combination with a miotic)
4.ophthalmic use may produce additive systemic effects in patients receiving an oral beta-blocker.

藥名相似:

外觀相似:

外觀描述: 黃色上蓋， 2.5mL透明澄清點眼液

42.02B Beta-blockers

29283 ɔt be ruled out / Infant risk can

TIMOPTOL OPHTHALMIC SOLUTION 0.5% 青眼露滅菌眼藥水 0 · 5 %

Timolol maleate oph soln 0.5%, 5mL/bot

Dosage: 1常備品 29283

ADULT
· Glaucoma: Ophthalmic, 1 drop qd-bid

≧ 2ys
· Open-angle glaucoma: Ophthalmic, 1 drop qd-bid.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph Soln: 0.25% 5mL/bot (29282), 0.5% 5mL/bot (29283), Cosopt* 5mL/bot(29298)

ADR:

COMMON
Dizziness, Headache, Blurred vision, Burning sensation in eye, Conjunctivitis, Discharge from eye, Foreign body sensation, Itching of eye, Pain in eye, Watery eye, Depression, Upper respiratory infection.
SERIOUS
Bradyarrhythmia, Cardiac dysrhythmia, Heart block, Heart failure, Myocardial infarction, Syncope, Hyperthyroidism, Hypoglycemia, Anaphylaxis, Hypersensitivity reaction, Systemic lupus

erythematosus, Choroidal detachment,
Bronchospasm, Pulmonary edema, Angioedema.

NOTE: 室溫儲存30℃以下

藥名相似:

外觀相似:

外觀描述: 白蓋眼藥水瓶，內含5mL眼藥水

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2019259

42.02B Beta-blockers

29291 C /

BETOPTIC S STERILE OPHTHALMIC SUSPENSION 〝愛爾康〞貝特舒眼用懸浮液

Betaxolol HCl oph susp 0.25%, 5mL/bot

Dosage: 1常備品 29291

Adult
·chronic open angle glaucoma :Ophthalmic, 1-2 drops bid

Pediatric
.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 20mg(22108); Oph susp: 0.25% 5mL/bot(29291)

ADR:

Burning sensation in eye

NOTE: 室溫儲存25°C以下

藥名相似:

外觀相似:

外觀描述: 5mL眼藥水,淺藍色蓋,半透明圓形眼藥瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2018776

42.02C Direct-acting Chloinergic Miotics

29232 C / Infant risk can

ISOPTO CARPINE 2% "愛爾康比利時廠"愛舒特開明眼藥水 2 %

Pilocarpine HCl oph soln 2%, 15mL/bot

Dosage: 1常備品 29232

Adult
·Glaucoma: Ophthalmic, 1 drops up to 4 times per day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 5mg (22005); Oph soln: 2% 15mL/B (29232), 4% 5mL/B (29228)

ADR:

COMMON
blurred vision, burning or itching of eyes, difficulty in night vision
SERIOUS
retinal detachment

NOTE: 室溫儲存8-30℃

藥名相似:

外觀相似:

外觀描述: 15mL眼藥水,綠色蓋眼藥瓶，白底黑字標籤有綠色及淺綠色條紋

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2016483

42.02D Carbonic Anhydrase Inhibitors

29236 C / Infant risk can

AZARGA* EYE DROPS, SUSPENSION 複方愛舒壓懸浮液

複方Brinzolamide 1% & Timolol 0.5%, 5mL/bot

Dosage: 1常備品 29236

Adult
·Glaucoma: Ophthalmic, 1 drop bid

NDA

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

Clcr<30ml/min: use not recommended

P: Oph soln: Timolol 0.5% 5mL/bot (29297), Cosopt* 5mL/bot(29298), Azarga* 5mL/bot(29236)

ADR:

COMMON
blurred vision, bitter taste, headache, burning sensation in eye, cataract, conjunctival hyperemia, corneal anesthesia, dry eyes, reduced visual acuity.
SERIOUS
allergic reactions, chest pain (rare).

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 5mL眼藥水,白色蓋,白色圓形眼藥瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025115

42.02D Carbonic Anhydrase Inhibitors

29295 C /

AZOPT* 1% STERILE OPHTHALMIC SUSPENSION 愛爾康比利時廠愛舒壓點眼懸液劑

Brinzolamide oph susp 1%, 5mL/bot

Dosage: 1常備品 29295

Adult
·Open-angle glaucoma, ocular hypertension: Ophthalmic, 1 drop bid-tid

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Oph susp: 1% 5mL/bot (29295)

ADR:

COMMON
blurred vision, bitter taste, headache
SERIOUS
allergic reactions, chest pain (rare)

NOTE: 室溫儲存 4-30°C

1.Shake well before use, administer at least 5 min apart from other ocular agents
2.Remove contact lenses before administration, may reinsert lenses 15 min after instillation

藥名相似:

外觀相似:

外觀描述: 白色紙盒綠色斜線條紋

42.02E Prostaglandin Analogue

29249 C / Infant risk can

DUOTRAV eye drops, solution 複方舒壓坦點眼液

Travoprost 0.004% & Timolol 0.5% 2.5mL/bot

Dosage: 1常備品 29249

Adult
·Glaucoma: Ophthalmic, 1 drop once daily in the morning or evening

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Oph soln: Travoprost 0.004% 2.5mL/bot(29294);Timolol GFS 0.5% 5mL/bot(29297); Cosopt* Oph soln 5 mL/bot(29298); Combigan* oph soln 5mL/bot(29299); Duotrav* Eye Drops 2.5mL/bot(29249)

ADR:

COMMON
Blepharitis, blurred vision, burning sensation in eye, cataract, conjunctival hyperemia, corneal anesthesia, dry eyes foreign, body sensation, itching of eye, ocular hyperemia, pain in eye, reduced visual acuity
SERIOUS
Angina, bradyarrhythmia, bronchospasm, chest pain, cataract, hypertension, hypotension, iris color change, myocardial infarction

NOTE: 室溫儲存

1.Store at 2-25°C. Discard 4 weeks after first opening.
2.Avoid abrupt withdrawal; increased risk of myocardial infarction or exacerbation of angina; gradual dose reduction recommended; monitoring recommended.
3.Contraindications:
·Travoprost: specific contraindications have not been determined.
·Timolol Maleate: atrioventricular block(second- and third-degree), bronchial asthma(active or history of; deaths due to bronchospasm have been reported with systemic or ophthalmic use, COPD(severe), cardiogenic shock, hypersensitivity to timolol or any component of the product, cardiac failure(overt), sinus bradycardia.

藥名相似:

外觀相似:

外觀描述: 2.5mL透明無色至淡黃色眼藥水,白色蓋,白色眼藥瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024766

42.02E Prostaglandin Analogue

29254 C / Infant risk can

TAFLOTAN* OPHTHALMIC SOLUTION 泰福羅坦眼藥水

Tafluprost opht soln 0.0015% 2.5mL bot

Dosage: 1常備品 29254

·Open-angle glaucoma, Ocular hypertension: ophthamic, 1 drop once daily in the evening

·safety and efficacy not established

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:

NDA

P: Oph soln: 0.0015% 2.5mL/bot(29254)

ADR:

COMMON
Headache, Conjunctival hyperemia, Eye irritation, Itching of eye, Blurred vision, Pain in eye.
SERIOUS
Application site pigmentation changes, Eyelashes, Eyelash formation, Hyperpigmentation of eyelid, Cataract, Deformity of eyelid, Dry eye syndrome, Iris color change, Iritis, Macular retinal edema, Uveitis.

NOTE: 室溫儲存30℃以下

·intraocular inflammation, active, may be exacerbated.
· macular edema, including cystoid macular edema, has been reported with prostaglandin F2-alpha analogs; caution advised in aphakic patients, pseudophakic patients with a torn posterior lens capsule, or patients with known risk factors for macular edema.
·pigmentation of the iris, permanent, has been reported; monitoring recommended.

藥名相似:

外觀相似:

外觀描述: 2.5mL眼藥水,『綠』色蓋,半透明點眼瓶,塑膠收縮膜標籤,有綠色/粉紅色條文

42.02E Prostaglandin Analogue

29255 C / Caution

LUMIGAN* PF Eye Drops "愛力根"露明目單支裝眼用液劑 0.03% (愛爾蘭廠)

Bimatoprost oph soln 0.03%, 0.4mL/amp, 30amp/box

Dosage: 1常備品 29255

Adult
· Ocular hypertension: Ophthalmic, 1 drop once daily in the evening
· Open-angle glaucoma: Ophthalmic, 1 drop once daily in the evening

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph soln: 0.01% 3mL/bot(29250), 0.03% 0.4mL/amp(29255)

ADR:

COMMON
Conjunctival hyperemia, Dry eye, Eye irritation, Iris color change, Itching of eye, Abnormal hair growth, Application site pigmentation changes, Eyelid/eyelash/periocular skin, Eyelid erythema, Common cold, Upper respiratory infection
SERIOUS
Macular retinal edema

NOTE: 室溫儲存

· 《Contraindications》Hypersensitivity to bimatoprost or any component of the product ; Active or suspected ocular or periocular infections (intracameral implant) ; Corneal endothelial cell dystrophy (intracameral implant) ; Prior corneal transplantation or endothelial cell transplants (intracameral implant) ; Posterior lens capsule absent or ruptured (intracameral implant) 。

藥名相似:

外觀相似:

外觀描述: 0.4mL眼藥水 · 單支塑膠安瓿 · 30支白色塑膠盒裝

42.02E Prostaglandin Analogue

29256 C /

IZBA* 30 ug/ml Eye Drops, Solution 愛爾康易舒壓點眼液 0.003%

Travoprost oph soln 0.003%, 2.5mL/bot

Dosage: 1常備品 29256

Adult
·Open-angle glaucoma, ocular hypertension: Ophthalmic, 1 drop once daily in the evening

·Safety and effectiveness have not been established in pediatric patients.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph soln: 0.004% 2.5mL/bot(29294), 0.003% 2.5mL/bot(29256)

ADR:

COMMON
Foreign body sensation,Blepharitis, Blurred vision, Itching of eye , Ocular hyperemia , Pain in eye, Reduced visual acuity

SERIOUS
Angina, Bradyarrhythmia, Chest pain, Hypertension, Hypotension, Cataract , Iris color change

NOTE: 室溫儲存30°C以下

藥名相似:

外觀相似:

外觀描述: 2.5mL眼藥水,白色蓋,半透明眼藥瓶,外有錫箔袋包裝

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022540

42.02E Prostaglandin Analogue

29284 C / Caution

XALATAN 50UG/ML (0.005%) 舒而坦眼藥水

Latanoprost oph soln 0.005% 2.5mL bot

Dosage: 1常備品 29284

Adult
·Open-angle glaucoma: Ophthamic, 1 drop once daily in the evening

Pediatric
·Open-angle glaucoma: Ophthamic, ≧6 yrs: 1 drop once daily in the evening

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph soln: 0.005% 2.5mL/bot(29284), Xalacom* 2.5mL/B(29247)

ADR:

COMMON
·Ophthalmic: Blurred vision (8%), Burning sensation in eye (7% to 9%), Conjunctival hyperemia (8%), Foreign body sensation (13%), Iris color change (7%), Itching of eye (8%), Punctate keratitis (10%)
·Respiratory: Influenza, Nasopharyngitis, Upper respiratory infection
SERIOUS
Ophthalmic: Bacterial keratitis, Reactivation, Cystoid macular edema, Herpes simplex keratitis, Reactivation, Iridocyclitis, Macular retinal edema
仿單刊載上市後其他不良反應
·神經系統：眩暈、頭痛。
·心臟障礙：心絞痛、心悸、不穩定型心絞痛。
·呼吸道、胸腔：氣喘、呼吸困難、氣喘惡化、急性氣喘發作。
·皮膚：皮疹、搔癢症。
·肌肉骨骼：肌痛、關節痛。
·全身疾病與投藥部位：胸痛。

NOTE: 冰箱冷藏，不可冷凍。

·仿單上市後監視期不良反應加註「某些有角膜明顯受損的患者，曾報導在使用含磷眼藥水發生角膜鈣化，但非常罕見」。(版本CDS 20130807-1)
·仿單內容更新加註(A)接受單眼治療的患者會有發生異色性虹膜的潛在可能。(B)隱形眼鏡可能會吸收本產品所含之benzalkonium chloride。(版本CDS 20160112-3)

藥名相似:

外觀相似:

外觀描述: 2.5cc眼藥水,白色蓋,半透明眼藥瓶

42.02F Combinations

29237 C / Infant risk can

SIMBRINZA* 10mg/ml + 2mg/ml eye drops, suspension 勝克壓10毫克/2毫克複方點眼液

Brinzolamide 1% & Brimonidine tartrate 0.2%, 5mL/bot

Dosage: 1常備品 29237

· Ocular hypertension: ophthalmic, 1 drop bid
· Open-angle glaucoma: ophthalmic, 1 drop bid

Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

COMMON
Taste sense altered, Xerostomia, Blurred vision, Eye irritation, Hypersensitivity reaction, Ocular.

NOTE: 室溫儲存25℃以下

·《Contraindications》hypersensitivity to any component of the product; neonates and infants younger than 2 years；

藥名相似:

外觀相似:

外觀描述: 5mL眼藥水,白色蓋,白色圓形眼藥瓶．白底黑字標籤有紫色與綠色線條

42.02F Combinations

29298 C /

COSOPT OPHTHALMIC SOLUTION 康舒目點眼液劑

Dorzolamide 2 % & Timolol 0.5% oph soln 5mL/bot

Dosage: 1常備品 29298

Adult
·Glaucoma: Ophthalmic, 1 drop bid

PEDIATRIC
·NDA

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr<30ml/min: use not recommended

P: Oph soln: Timolol 0.25% 5mL/bot (29282), Timolol

0.5% 5mL/bot (29283), Cosopt* 5mL/bot(29298)

ADR:

COMMON
Blepharitis, Blurred vision, Burning sensation in eye , Conjunctival hyperemia , Excessive tear production , Itching of eye , Light intolerance, Pain in eye

SERIOUS
Heart block, Myocardial infarction (rare),bronchospasm (rare)

NOTE: 室溫儲存

藥名相似: Oph soln: Timolol 0.25% 5mL/bot (29282), Ti

外觀相似:

外觀描述: 5mL眼藥水,白色蓋,半透明方形眼藥瓶

42.02F Combinations

29299 **C / Unknown(有**

COMBIGAN EYE DROPS 康甙庚眼用液劑

複方Brimonidine 0.2% &Timolol 0.5% oph soln 5mL

Dosage: 1常備品 29299

Adults
Glaucoma: Ophthalmic, 1 drop bid

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Oph soln: Brimonidine* 0.2% 5mL/B (29273), Timolol 0.25% 5mL/B (29282), Timolol 0.5% 5mL/B (29283), Timolol GFS 0.5% 5mL/B (29297), Xalacom* 2.5mL/B (29247), Cosopt* 5mL/B (29298), Combigan* 5mL/B (29299)

ADR:

COMMON
Xerostomia, asthenia, headache, somnolence, allergic conjunctivitis, conjunctival hyperemia, acute follicular conjunctivitis, itching of eye, pain in eye, depression
SERIOUS
Bradyarrhythmia, heart failure, corneal erosion, vitreous detachment, bronchospasm, respiratory failure

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 5mL眼藥水,白色蓋,白色圓形眼藥瓶,標籤有藍色及桃紅色字樣及圖紋

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024294

42.04A Antibacterials

29187 **C / Unsafe**

CHLORAMPHENICOL OPHTHALMIC SOLUTION 0.25% "SYNMOSA" "健喬" 氯絲菌素眼藥水0．25%

Chloramphenicol (C.M.) oph soln 0.25%, 10mL/bot

Dosage: 1常備品 29187

Adult
·Ocular infective conditions: Ophthalmic, 1 drops q1-4h

Pediatric
.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Cap: 250mg(20930); Oint: 1% 5g(29300); Oph soln: 0.25% 10mL(29187); Inj: 1g Vial (30930)

ADR:

Burning sensation in eye

NOTE: 冰箱冷藏．不可冷凍。

藥名相似: Cap: 250mg(20930); Oint: 1% 5g(29300); Oph

外觀相似:

外觀描述: 10mL眼藥水,白色蓋,白色圓形眼藥瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1032282

42.04A Antibacterials

29188 **D / Caution**

GENDERMIN OPHTHALMIC OINTMENT 3MG/GM (GENTAMICIN SULFATE) 漸得明眼藥膏 3 毫克/公克(硫酸紫菌素)

Gentamicin sulphate oph oint 0.3%, 5g/tube

Dosage: 1常備品 29188

ADULT
· Ocular infective conditions: Ophthalmic, bid-tid

Pediatric
.

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Oph oint: 0.3% 5g(29188); Oph soln: 0.3% 5mL(29189), Cream: 0.1%

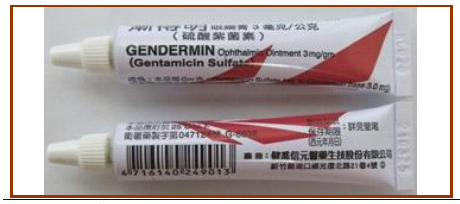
ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 5克眼藥膏，白蓋鋁管，白底黑字印刷，有暗紅色區塊及藍色商標



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1047124

42.04A Antibacterials

29189 C /

GENTAMICIN EYE DROPS "SINPHAR" 見大黴素點眼液

Gentamicin oph soln 0.3% 5mL bot

Dosage: 1常備品 29189

Adult

· Superficial infections: Ophthalmic, 1-2 drops q4h, in severe infections, up to 2 drops every hour may be used

Pediatric

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph oint:0.3% 5g(29188); Oph soln:0.3% 5ml(29189); Cream:0.1% 15g(29302); Inj:80mg/2ml(30866)

ADR:

NOTE: 儲存25℃以下

藥名相似:

外觀相似:

外觀描述: 5mL眼藥水，白色眼藥瓶，有紫色圖樣及紫色蓋

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1022198

42.04A Antibacterials

29190 D / Infant risk can

TOBREX EYE OINTMENT "愛爾康"點必效眼藥膏

Tobramycin Oph oint 0.3%, 3.5g/tube

Dosage: 1常備品 29190

Adult

·Mild to moderate disease: Ophthalmic, bid-tid

·Severe infection: Ophthalmic, apply q3-4h

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Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph oint: 3.5g(29190); Oph susp: Tobradex* 5mL(29191); Inhalation ampule: 300mg/5mL(專案用藥, 29807); Inj: 80mg/2mL Vial(30870)

ADR:

Conjunctival Erythema, Lid Itching and swelling

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 3.5克眼藥膏,白色軟管,有藍色花紋

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2016851

42.04A Antibacterials

29193 C / Unsafe

SINOMIN OPHTHALMIC SOLUTION 止膿敏點眼液

Sulfamethoxazole(Sulfisomezole) oph soln 4% 15mL/bot

Dosage: 1常備品 29193

Adult

·Ocular infective conditions: Ophthalmic, 1 drop tid-qid

Pediatric

.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph soln: 15mL/bot(29193)

ADR:

Itching of eye ,eyelid red and swollen,conjunctival hyperemia

NOTE: 室溫儲存

藥名相似: Oph soln: 15mL/bot(29193)

外觀相似:

外觀描述: 15mL眼藥水,白色蓋,白色圓形眼藥瓶，白底深藍色字標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045960

42.04A Antibacterials

29200 D / Infant risk is

TETRACYCLINE HCL OPHTHALMIC OINTMENT 1% "SYNMOSA" "健喬"鹽酸四環素眼藥膏 1 %

Tetracycline HCl oph oint 1%, 5g/tube

Dosage: 1常備品 29200

Adult
·Ocular infective conditions: Ophthalmic, tid-qid

PEDIATRIC
·

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Cap:250mg(21032); VT:150mg(29029); Oph oint:1% 5g(29200)

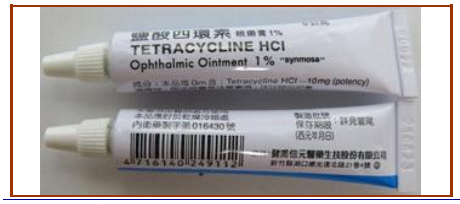
ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色上蓋，5克眼藥膏



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12016430

42.04A Antibacterials

29205 C / Unsafe

Cravit ophthalmic solution 可樂必妥眼藥水

Levofloxacin oph soln 0.5%, 5mL/bot

Dosage: 1常備品 29205

Adult
·Ocular infective conditions: Ophthalmic, 1 drop tid. Dose may be adjusted according to the symptoms

PEDIATRIC

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Tab: 500mg(21270); Oph soln: 0.5% 5mL/bot(29205); Inj: 250mg/50mL Vial(31184)

ADR:

transient decreased vision, foreign body sensation, transient ocular burning, ocular pain, and photophobia,lid edema, ocular dryneaa, and ocular itching,Instillation site irritation/discomfort, ocular infection, chemosis, corneal erosion, corneal ulcer , diplopia,floaters,hyperemia and lid erythema

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 5mL眼藥水,粉紫色蓋,半透明淺藍色圓形眼藥瓶,白底藍字標籤,有黃色及粉紫色區塊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024398

42.04B Antivirals

29194 B / Infant risk is

Devirus Ophthalmic Ointment 力克眼用軟膏

Acyclovir oph oint 3%, 4.5g/tube

Dosage: 1常備品 29194

Adult
·Herpes simplex keratitis: Ophthalmic, 5 times/day; should continue for at least 3 days after healing

--

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Tab: 200mg(27226); Oph Oint: 3% 4.5g(29194); Inj: 250mg vial(37605)

ADR:

conjunctivitis,blepharitis

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 4.5克眼藥膏,白色軟管,藥名為灰色字

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049558

42.06 Anti-inflammatory Agents

29180 / Unknown(有

EYE BETASON-N OINTMENT "WINSTON" "溫士頓" 眼用比達爽軟膏

Betamethasone disodium phosphate 0.2% [C], Fradiomycin sulfate 0.35% [D] Oph oint, 3g/tube

Dosage: 1常備品 29180

Adult
·Ocular inflammatory/infective conditions: Ophthalmic, one to several times/day

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:

NDA

P: Oph oint: BETASON-N* eye oint 0.2% 3g/tube (29180); Oph soln: Rinderon*-A 0.1% 5mL/B (29182); Cream: Rinderon*-VA 0.06% 5g/tube (29411); Inj: 4mg/amp(35205), 1mL/amp(35203)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 3克眼藥膏,白色塑膠管,印有黃色條紋及藥名

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1010478

42.06 Anti-inflammatory Agents

29182 / Unsafe

EYE RINDERON-A SOLUTION 眼科用臨得隆複合液

Betamethasone disodium phosphate 0.1% [C], Fradiomycin sulfate 0.35% [D] Oph soln, 5mL/bot

Dosage: 1常備品 29182

Adult
·Ocular inflammatory/infective conditions: Ophthalmic, 1-2 drops tid-qid

Pediatric

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph oint: Rinderon*-A 0.1% 3g/tube (29180); Oph soln: Rinderon*-A 0.1% 5mL/B (29182); Cream: Rinderon*-VA 0.06% 5g/tube (29411); Inj: 4mg/amp(35205), 1mL/amp(35203)

ADR:

Serious:Cataract, Glaucoma

NOTE: 冰箱冷藏，不可冷凍。

藥名相似:

外觀相似:

外觀描述: 5cc眼藥水,白色蓋,白色圓形眼藥瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1004975

42.06 Anti-inflammatory Agents

29185 UK / Unknown(有

VISCONE EYE DROPS 0.1% "SINPHAR" 如視點眼液 0．1％〝杏輝〞

Fluorometholone oph soln 0.1%, 5mL/bot

Dosage: 1常備品 29185

Adult
·Ocular inflammatory conditions: Ophthalmic, 1 drop bid-qid

PEDIATRIC
.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph susp: 0.1% 5mL/bot (29185)

ADR:

NOTE: 室溫保存

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043184

42.06 Anti-inflammatory Agents

29191 a / Unknown(有

TOBRADEX OPHTHALMIC SUSPENSION 點必舒眼用懸浮液

Dexamethasone 0.1% [a], Tobramycin 0.3% [D], 5mL/bot

Dosage: 1常備品 29191

Adult
·Ocular inflammatory/infective conditions: Ophthalmic, initial 1-2 drops q2h; MD 1-2 drops q4-6h

--

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph oint: 3.5g(29190); Oph susp: Tobradex* 5mL(29191); Inhalation ampule: 300mg/5mL(專案用藥, 29807); Inj: 80mg/2mL Vial(30870)

ADR:

Common:
Lid itching and swelling, conjunctival erythema
Serious:
Glaucoma, Raised intraocular pressure
Other: Secondary infection

NOTE: 室溫儲存30℃以下

藥名相似:

外觀相似:

外觀描述: 5mL眼藥水,白色蓋,白色圓形眼藥瓶,包裝有藍色與褐色條紋

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2018617

42.06 Anti-inflammatory Agents

29195 C / Infant risk is

1% PRED FORTE OPHTHALMIC SUSPENSION 倍力特眼用懸浮液 1 %

Prednisolone acetate oph susp 1%, 5mL/bot

Dosage: 1常備品 29195

Adult
·Ocular inflammatory conditions: Ophthalmic, 1-2 drops bid-qid

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 5mg (25602); Oph susp: 1% 5mL/bot (29195); Oral Soln: 60mg/60mL/B (28703)

ADR:

COMMON
Raised intraocular pressure

SERIOUS
Optic nerve and pathway injury,Secondary infection

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 5mL眼藥水，白色蓋，白色圓形眼藥瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2018654

42.06 Anti-inflammatory Agents

29197 C / Unknown(有

ACULAR OPHTHALMIC SOLUTION 0.5% W/V 愛克樂眼藥水 0 . 5 % W / V

Ketorolac tromethamine 0.5%, 5mL/bot

Dosage: 1常備品 29197

Adult
·Extraction of cataract: Ophthalmic, 1 drop qid starting 24 hrs post-op, continue for 2 weeks
·Seasonal allergic conjunctivitis: 1 drop qid

Pediatric

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph soln: 0.5% 5mL/B(29197); Inj: 30mg/1mL Amp(32438)

ADR:

Common
Burning sensation in eye, Corneal edema, Eye irritation, Iritis , Keratitis
Serious
Corneal epithelial degeneration, Corneal erosion, Corneal thinning, Perforation of cornea

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 5cc眼藥水,白色蓋,白色圓形眼藥瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022653

42.06 Anti-inflammatory Agents

36852 C / Unknown(有

Ozurdex (dexamethasone intravitreal implant) 0.7mg 傲迪適眼後段植入劑

Dexamethasone 0.7mg intravitreal implant

Dosage: 1常備品 36852

Adult
· Macular retinal edema: 1 implant (0.7 mg) via INTRAVITREAL injection into eye; may repeat in contralateral eye
· Posterior uveitis, Noninfectious: 1 implant (0.7 mg) via INTRAVITREAL injection into eye; may repeat in contralateral eye.

Pediatric
safety and effectiveness of the intravitreal implant is not established in pediatric patients

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 0.5mg(25605); 急用Tab: 4mg(25607); Cream: Color* 5g(29580);Oral paste: 0.1% 5g(29087); Oph susp: Tobradex* 5mL(29191); inj: 5mg/1mL(35201) ; Intravitreal implant: 0.7mg(36852)

ADR:

COMMON
Hypertension (Diabetic macular edema, 13%), atrophic condition of skin, finding of skin healing, Impaired, cushing's syndrome, decreased body growth, at risk for infection, abnormal vision (9%),

cataract (Diabetic macular edema, 68%; retinal vein occlusion and uveitis, 5%), conjunctival edema (5%), conjunctivitis (6%), dry eye (5%), raised intraocular pressure (Diabetic macular edema, 35%; retinal vein occlusion and uveitis, 25%), vitreous floaters (5%), depression, euphoria, pulmonary tuberculosis.
SERIOUS
Cardiomyopathy, hyperglycemia, primary adrenocortical insufficiency, pancreatitis, osteoporosis, conjunctival hemorrhage (Diabetic macular edema, 23%; retinal vein occlusion and uveitis, 22%), glaucoma (Diabetic macular edema, 1.2%), keratitis (2%), retinal tear (2%), retinal vascular disorder (3%), uveitis (2%)

NOTE: 室溫儲存

Ophthalmic:
1.Endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachment have occurred with intravitreal injections; monitoring recommended.
2.Glaucoma, posterior subcapsular cataract formation, or increased secondary ocular infections may occur.
3.Active ocular herpes simplex; corticosteroids should not be used [2][19][18]
4.History of ocular herpes simplex; caution advised.
5.Absent or torn posterior capsule; increased risk of implant migration.
6.Intraocular pressure elevations have been associated with corticosteroid therapy; monitoring recommended during long-term use.
7.Use not recommended in patients with optic neuritis due to increased risk of new episodes.

藥名相似: dextromethorphan

外觀相似:

外觀描述: 一整盒包裝內有膠膜包護紙盒包裝

42.10 Miotics

29221 C / Unsafe

NEOSTIGMINE METHYLSULFATE OPHTHALMIC SOLUTION (O.N.S.D.) 0.01% 硫酸甲酯新斯狄明點眼液 0．0 1 %

Neostigmine methylsulfate (ONSD) oph soln 0.01%, 10mL/bot

Dosage: 1常備品 29221

Adult
·Ophthalmic, 2 drops tid

Pediatric
·

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Oph slon: 0.01% 10mL/bot (29221); Inj: 0.5mg/mL Amp (31601)

ADR:

Miosis,Visual disturbance

NOTE: 儲存於30℃以下

藥名相似: Oph slon: 0.01% 10mL/bot (29221); Inj: 0.5m

外觀相似:

外觀描述: 10mL 眼藥水，淡藍色上蓋，白色圓形PE眼藥瓶，淺綠色標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1029343

42.12A Cycloplegics/Mydriatics

29235 C /

"AIM"ATROPINE* Eye Drops 0.01% "麥迪森"亞妥明眼藥水0.01%

Atropine sulfate oph soln 0.01%, 0.5mL/amp, 30amp/box

Dosage: 1常備品 29235

Adult
·Mydriasis/cycloplegia: Ophthalmic, 1-2 drop tid
·Refraction examination: Ophthalmic, 1-2 drop bid, 1-3 days prior to examination

Pediatric
·Mydriasis/cycloplegia: Ophthalmic, 1 drop tid

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Oph soln: 0.5% 10mL (29242), 1% 10mL (29252), 0.125% 10mL (29810, 急用藥),0.125% 5mL (29238), 0.25% 10mL (29809, 急用藥); Inj: 1mg/1mL(31630)

ADR:

COMMON
Blurred vision, light intolerance
SERIOUS
Raised intraocular pressure

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to any component of the product; Pediatric patients with prior severe systemic reaction to atropine; Primary glaucoma or predisposition to narrow anterior chamber angle glaucoma；

藥名相似:

外觀相似:

外觀描述: 0.5mL眼藥水,每支塑膠安瓿,紅底白字標籤,每盒30支

42.12A Cycloplegics/Mydriatics

29238 C /

TROPINE* EYE DROPS 0.125% "MEDICINE" (ATROPINE SULFATE) "麥迪森" 雅托平眼藥水 0.125%

Atropine sulfate oph soln 0.125%, 5mL/bot

Dosage: 1常備品 29238

Adult
·Mydriasis/cycloplegia: Ophthalmic, 1-2 drop tid
·Refraction examination: Ophthalmic, 1-2 drop bid, 1-3 days prior to examination

Pediatric
·Mydriasis/cycloplegia: Ophthalmic, 1 drop tid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph soln: 1% 10mL (29252), 0.125% 10mL (29810, 急用藥),0.125% 5mL (29238), 0.01%, 0.5mL/amp, 30amp/box (29235); Inj: 1mg/1mL(31630)

ADR:

COMMON
Blurred vision, light intolerance
SERIOUS
Raised intraocular pressure

NOTE: 室溫儲存

·《Contraindications》Hypersensitivity to any component of the product; Pediatric patients with prior severe systemic reaction to atropine; Primary glaucoma or predisposition to narrow anterior chamber angle glaucoma ;

藥名相似:

外觀相似:

外觀描述: 5mL眼藥水,『粉紅』色蓋,圓形眼藥瓶,『粉紅』色標籤有膚色黃色區塊

42.12A Cycloplegics/Mydriatics

29246 C / Unknown(有

MYDRIACYL 1% 愛爾康比利時廠麻睫散瞳點眼劑 1 %

Tropicamide oph soln 1%, 5mL/bot

Dosage: 1常備品 29246

Adult
·Refraction examination: Ophthalmic, 1 drop, repeat in 5 mins
·Funduscopic examination: Ophthalmic, 1 drop, 15-20 min before examination

NDA

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph soln: 1% 5mL/bot(29246)

ADR:

COMMON
blurred vision, ocular irritation, headache
SERIOUS
Light intolerance (rare), Raised intraocular pressure

NOTE: 室溫儲存8-30°C

1.Since elderly patients are more prone to increased intraocular pressure, caution is advised in these patients when using mydriatics and cycloplegics.
2.Infants and children, may cause central nervous system disturbances

藥名相似:

外觀相似:

外觀描述: 5mL眼藥水,紅色蓋,半透明圓形眼藥瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2016711

42.12A Cycloplegics/Mydriatics

29252 C /

ATROPINE SULPHATE OPHTHALMIC SOLUTION 1% "WU FU" 硫酸阿托品點眼液 1 %

Atropine sulfate oph soln 1%, 10mL/bot

Dosage: 1常備品 29252

Adult
·Mydriasis/cycloplegia: Ophthalmic, 1-2 drop tid
·Refraction examination: Ophthalmic, 1-2 drop bid, 1-3 days prior to examination

PEDIATRIC
·Amblyopia: Ophthalmic, 1 drop qd

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph soln: 0.5% 10mL (29242), 1% 10mL (29252); Inj: 1mg/1mL(31630)

ADR:

Common
Blurred vision, light intolerance
Serious
raised intraocular pressure

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 10mL眼藥水,紅色蓋,白色圓形眼藥瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1032050

42.14 Antiallergic Agents

29261 C / Unknown(有

Curzolan Eye Drops 可舒炎眼藥水

Antazoline HCl 0.5mg/mL [C], tetrahydrozoline HCl 0.4mg/mL [C] oph soln, 10mL/bot

Dosage: 1常備品 29261

Adult
·Allergic conjunctivitis: Ophthalmic, 1 drop q3h during the acute phase; MD 1 drop bid-tid

Pediatric
·

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph soln: 10mL/bot, each mL contains: antazoline HCl 0.5mg, tetrahydrozoline HCl 0.4mg, methylhydroxypropylcellulose , benzalkonium chloride 0.05mg (29261)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 10mL白色瓶蓋眼用瓶，黃底/白/橘套色塑膠包膜，黑色字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049334

42.14 Antiallergic Agents

29262 B / Infant risk can

EMADINE STERILE OPHTHALMIC SOLUTION 愛敏定眼眼液

Emedastine Oph soln 0.05%, 5mL/bot

Dosage: 1常備品 29262

Adult
·Allergic conjunctivitis: Ophthalmic, 1 drop bid-qid

Pediatric
·<3y safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph soln: 0.05% 5mL/bot (29262)

ADR:

blurred vision, burning or stinging,cornel infilates, cornel staining, keratitis, dry eyes, ocular discomfort, and foreign body sensation

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 5mL眼藥水,白色蓋,白色圓形眼藥瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022856

42.14 Antiallergic Agents

29263 C / No report(毫

ZADITEN 0.25MG/ML EYE DROPS 立敏停點眼液 0.25 毫克/毫升

Ketotifen oph soln 0.25mg/mL, 5mL/bot

Dosage: 1常備品 29263

Adult
·Prophylaxis of eye itching due to allergic conjunctivitis: Ophthalmic, 1 drop in affected eyes twice daily

Pediatric (≧3 yrs)
·Prophylaxis of eye itching due to allergic conjunctivitis: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 1mg(27220); Oph soln: 0.025% 5mL/bot(29263)

ADR:

COMMON
Headache, dry eyes, eye irritation, conjunctival pain in eye, pharyngitis, rhinitis, influenza

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 5mL眼藥水,白色蓋,白色圓形眼藥瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023793

42.16 Miscellaneous

29274 /

TEARS NATURALER FREE EYE DROPS "愛爾康法國廠"淚然人工淚液點眼液

Hydroxypropyl methylcellulose 3mg/mL(2%), Dextran 70 1mg/mL Eye Drops 0.8mL/amp 32amp/box

Dosage: 1常備品 29274

Adult

·Relief symptoms of dry eyes: Ophthalmic, 1-2 drops as needed

PEDIATRIC

.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph soln: Systane*(29276), Tears Naturale*(29281), Tears Nature* Free Lubricant(29274), Blink*(173001), GenTeal*(172801); Oph oint: Duraters*(29288)

ADR:

NOTE: 儲存25℃以下

Preservative-free formulation, singe-dose containers, discard 12hrs after opening

藥名相似:

外觀相似:

外觀描述: 0.8mL眼藥水,半透明單支裝,每盒32支

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024167

42.16 Miscellaneous

29275 C / Unsafe

RESTASIS OPHTHALMIC EMULSION 0.05% "愛力根"麗眼達眼用乳劑0.05%

Cyclosporine Oph Emulsion 0.05% 0.4mL/amp 30amp/box

Dosage: 1常備品 29275

Adult

· Ocular inflammation associated keratoconjunctivitis sicca: Ophthalmic, 1 drop twice daily in each eye approximately 12 hrs apart

Pediatric

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph emulsion: 0.05% 0.4mL/amp 30amp/box(29275); Soft cap: 25mg(27214), 100mg(27234); Inj: 50mg/1mL Amp(37602); Soln: 50mL/B (28701, 急用藥)

ADR:

Burning sensation in eye, conjunctival hyperemia, discharge from eye, excessive tear production, pain in eye, visual disturbance

NOTE: 室溫儲存

1.Invert the single-use amp several times to obtain a uniform emulsion before using. Discard amp immediately after use

2.Wait 15 mins after administration to insert contact lenses or use artificial tears

藥名相似:

外觀相似:

外觀描述: 0.4mL眼用乳劑,半透明單支裝,每盒30支)

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2024206

42.16 Miscellaneous

29279 / Unsafe

Ginpol Gel 睛瑩眼用凝膠

Carbomer 940 oph gel 0.2%, 10g/tube

Dosage: 1常備品 29279

ADULT

· Relief of dry eye: Ophthalmic, 1 drop 3-5 times daily as needed

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph gel: 0.2% 10g/tube (29279)

ADR:

Transient blurring in vision

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述:

42.16 Miscellaneous

29281 UK / Unsafe

TEARS NATURALE 淚然點眼液 "愛爾康比利時廠"

Hydroxypropylmethylcellulose, Dextran 70, Borax, NaCl, KCl Oph soln 15mL/bot

Dosage: 1常備品 29281

Adult
·Relief of dry eyes: Ophthalmic, 1-2 drops if necessary

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Oph soln: 15mL/B(29281), Systane*(29276), Tears Nature* Free Lubricant(29274), Blink*(173001), GenTeal*(172801); Oph oint: Duraters*(29288)

ADR:

NOTE: 儲存30℃以下

·Soft contac lenses must be taken out before applying eye drops and not replaced for at least 15 minutes.
·Each mL contains Hydroxypropylmethylcellulose 3mg, Dextran 70 1mg, Borax 3.5mg, NaCl 6mg, KCl 1.2mg and preservative Polyquaternium-1 0.011mg.
·開瓶後28天，請丟棄，勿繼續使用(仿單版次 06-2017)。

藥名相似:

外觀相似:

外觀描述: 15mL眼藥水,白色蓋,半透明圓形眼藥瓶,標籤有藍色及綠色線條)

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2017091

42.16 Miscellaneous

29288 risk is minimal / Infant risk is

DURATEARS STERILE OPH OINT 淚膜眼藥膏〝愛爾康比利時廠〞

White petrolatum, Anhydrous liquid lanolin, Mineral oil oph oint, 3.5g/tube

Dosage: 1常備品 29288

Adult
·Relief of dry eyes: Ophthalmic, apply a small amount (about 1cm) in the eyes as needed

Pediatric
·NDA

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Oph soln: Systane*(29276), Tears Naturale*(29281), Tears Nature* Free Lubricant(29274), Blink*(173001), GenTeal*(172801); Oph oint: Duraters*(29288)

ADR:

NOTE: 室溫儲存

1.開瓶 28 天(四週)後請勿繼續使用。
2.使用眼藥膏時可能有視線模糊之現象產生，故建議在睡前使用較適宜。

藥名相似:

外觀相似:

外觀描述: 3.5克淡黃.透明.均質眼藥膏,白色軟管,有淺藍色及淺綠色條紋

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2017121

42.16 Miscellaneous

29812 UK / Caution

KARY UNI OPHTHALMIC SUSPENSION 柯寧優尼點眼懸液

Pirenoxine 0.005% oph susp 5mL bot

Dosage: 1常備品 29812

Adult
·Cataract: Ophthalmic, 1-2 drops 3-5 times daily

Pediatirc
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Oph Susup: 0.05% 5mL/bot (29812)

ADR:

Blepharitis, contact dermatitis, superficial keratitis, conjunctival hyperemia, irritation, pruritis

NOTE: 儲存30℃以下

藥名相似:

外觀相似:

外觀描述: 5mL眼藥水,白蓋,半透明淺橘色圓形眼藥瓶,白底藍字標籤,有綠色及粉藍色區塊)

42.16 Miscellaneous

36851 C / Unknown(有

VISUDYNE POWDER FOR SOLUTION FOR INFUSION 15MG/VIAL 維視達凍晶注射劑 1 5 毫克

Verteporfin 15mg vial

Dosage: 1常備品 36851

Adult
·Classic or occult subfoveal choroidal neovascularization :
1.First step :
IV infusion over 10 min, 6mg/m(2) diluted in 30 ml infusion solution ,followed by photoactivation

2.Second step: the light activation of Verteporfin 15 minutes after the start of the infusion. For this, a diode generating non-thermal red light (wavelength 689nm) is delivered via a slit lamp mounted fibre optic device and a suitable contact lens.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 15mg vial (36851)

ADR:

COMMON
headache, injection site reactions, temporary photosensitivity, visual disturbances
SERIOUS
anemia, atrial fibrillation, hypertension, peripheral vascular disorder, cataracts, eye hemorrhage, severe vision decrease, elevated liver function tests, gastrointestinal cancers

NOTE: 室溫儲存

Following injection, avoid exposure of skin or eyes to direct sunlight or bright indoor light for 5 days

藥名相似:

外觀相似:

外觀描述: 墨綠色乾粉,『綠』蓋透明玻璃小瓶,蓋上有FLIP及OFF字樣 ,附有一個維視達輸注管組

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023479

42.16 Miscellaneous

37787 **C / Unsafe**

Lucentis solution for injection 10mg/mL in pre-filled syringe 樂舒睛注射劑 10毫克/毫升 (預充填注射針筒)

Ranibizumab inj 1.65mg/0.165mL in pre-filled syringe

Dosage: 1常備品 37787

Adult
· Neovascular (wet) age-related macular degeneration: Intravitreal, 0.5mg (0.05mL) inject into the affected eye once a month for 3 mons; with ranibizumab being given if the patient had a loss of greater than 5 letters in visual acuity; the interval between consecutive doses should be at least 1 mon

Pediatric
·Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 1.65mg/1.65mL syringe(37787)

ADR:

COMMON
Headache, blepharitis, cataract , conjunctival hemorrhage, dry eye, foreign body sensation in the eyes, inflammatory disorder of the eye, lacrimation and lacrimal drainage, pain in eye, raised intraocular pressure, vitreous floaters, nasopharyngitis, upper respiratory infection
SERIOUS
Arterial thromboembolism, atrial fibrillation, cerebrovascular accident, atrophic iris, central retinal vein occlusion, endophthalmitis, glaucoma, iridocyclitis, retinal detachment, retinal hemorrhage, retinal tear, thrombosis of retinal artery

NOTE: 冰箱冷藏，不可冷凍。

· Adequate anesthesia and a broad-spectrum microbicide should be given prior to injection
· Intraocular pressure increase has been observed within 60 minutes of injection; Therefore, intraocular pressure should be monitored

藥名相似:

外觀相似:

外觀描述: 0.165毫升預充填注射針筒裝

42.16 Miscellaneous

37795 **C / Unsafe**

Eylea aflibercept (rch) 40 mg/mL solution for intravitreal injection vial 采視明瓶裝注射液

Aflibercept inj 2mg/0.05mL vial

Dosage: 1常備品 37795

Adult
· Neovascular (wet) age-related macular degeneration: Intravitreal, 2 mg (0.05 mL) inject into the affected eye once a month for 3 mons; then once every 8 weeks; adequate anesthesia and a topical broad-spectrum microbicide should be given prior to the injection
· Central retinal vein occlusion with macular edema: Intravitreal, 2 mg (0.05 mL) inject into the affected eye once a month ; adequate anesthesia and a topical broad-spectrum microbicide should be given prior to the injection

PEDIATRIC
· Safety and effectiveness have not been established in pediatric patients

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 2mg/0.05mL vial (37795-玻璃體內注射), 100mg/4mL/vial (37995-靜脈輸注,捐贈)(31275-靜脈輸注, 急用)

ADR:

COMMON
Cataract, conjunctival hemorrhage, conjunctival hyperemia, corneal erosion, pain in eye, raised intraocular pressure, vitreous detachment, vitreous floaters
SERIOUS
Arterial thrombosis, hypersensitivity reaction, endophthalmitis, retinal detachment, retinal tear

NOTE: 冰箱冷藏，不可冷凍。

· For ophthalmic intravitreal injection only.
· Each vial contains 0.278mL (40 mg/mL), designed to deliver 0.05 mL (2 mg) for single-use.
· Attach the filter needle to the syringe; withdraw all of the vial contents. Eliminate bubbles and excess drug to obtain the line that marks 0.05 mL on the syringe.

藥名相似:

外觀相似:

外觀描述: 注射液,玻璃小瓶裝

44.02 Antihemorrhoid Preparations

29550 / Unknown(有

ALCOS-ANAL OINTMENT 益痔康軟膏

Sodium oleate 100mg/g 20g/tu

Dosage: 1常備品 29550

Adult
· Hemorrhoids: qd-bid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Supp: (29551); Oint: 20 g/Tube, (29550)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 20G軟管,紙盒,有綠色及白色區塊,黑色字體

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1042844

44.02 Antihemorrhoid Preparations

29551 / Unknown(有

ALCOS-ANAL SUPPOSITORIES 益痔康栓劑

Sodium oleate 200mg

Dosage: 1常備品 29551

Adult
· Hemorrhoids: qd-bid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Supp: (29551); Oint: 20 g/Tube, (29550)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 子彈型白色臘質栓劑,白色塑膠膜,白底綠字印刷,有"alcos-anal"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043161

44.02 Antihemorrhoid Preparations

29552 C / Infant risk can

HIGH-XYLMOL* OINTMENT "SINPHAR" "杏輝"樂癒痔軟膏

Phenylephrine HCL 0.1%, Betamethasone valerate 0.05% & Lidocaine HCL 2.5%, 10g/tube

Dosage: 1常備品 29552

Adult
· Hemorrhoids: bid-tid

Pediatric
·Safety and efficacy have not been established in patients less than 2 years old.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Soln:4% 30mL(29104); Cream: EMLA (29448) ; Cream: Rinderon*-VA 0.06% 5g/Tube(29411); Oint:HIGH-XYLMOL* oint. 10g/tube (29552)

ADR:

NOTE: 25℃以下

藥名相似:

外觀相似:

外觀描述: 10克軟膏,白/綠色鋁管

44.02 Antihemorrhoid Preparations

29553 UK /

POSULINE* SUPPOSITORIES "P.L." "培力" 宜痔平栓劑

Policresulen 100mg & Cinchocaine HCl 2.5mg supp

Dosage: 1常備品 29553

Adult
· Hemorrhoids: Rectally, 1 supp bid-tid. May reduce to 1 supp daily.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Supp: POSULINE*(29553); Oint: Proctosedyl* Oint (29554)

ADR:

Burning, itching, erythema, papules, pruritus.

NOTE: 室溫儲存25℃以下

The occasional discomfort (e.g. burning or itching) is caused by the active ingredient and in most cases disappears after a short time.

藥名相似:

外觀相似:

外觀描述: 黃色子彈型蠟質栓劑，白色塑膠膜，白底綠字印刷

44.02 Antihemorrhoid Preparations

29554 / Unknown(有

PROCTOSEDYL OINTMENT 保痔寧軟膏

Cinchocaine HCl 5mg/g [a], Hydrocortisone 5mg/g [D], 15g/tube

Dosage: 1常備品 29554

Adult

· Hemorrhoids: qd-bid

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj:100mg (35202); Cream: 1% 10g/Tube (29423); Enema: 60mL/B (29422); Oint: 50g/BX (29495), Proctosedyl Oint (29554); Proctosedyl Supp (29555)

ADR:

Contact dermatitis

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 15克軟膏,白色蓋鋁軟管,白底印刷有藍色"Proctosedyl"字樣,有橘色/藍色區塊.

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022386

44.04A Antibiotics

29017 B /

FREE GEL 7.5MG/GM (METRONIDAZOLE) "SWISS" 膚麗凝膠（咪唑尼達）

Metronidazole Topical gel 0.75% 15g/tube

Dosage: 1常備品 29017

Adult

·Rosacea: Topical, applied as a thin film twice daily (morning and evening) to affected areas

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 250mg(20834); Dental Gel: 25%, 0.3g/Tube(29162); Vaginal Gel: 0.75%, 25g/Tube(29019); Topical Gel: 0.75%, 15g/Tube(29017); Inj: 500mg/100mL(30831)

ADR:

Tearing of the eyes, transient redness, mild dryness, burning, skin irritation

NOTE: 室溫儲存

·Cosmetics may be used after application of metronidazole topical ge

藥名相似:

外觀相似:

外觀描述: 白色上蓋軟管

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1035696

44.04A Antibiotics

29302 D / Caution

GENTAMYCIN* CREAM 1MG/GM "SINPHAR" "杏輝"紫菌素乳膏 1 毫克 / 公克

Gentamicin sulfate cream 0.1% 15g/tube

Dosage: 1常備品 29302

Adult

· Skin infections: topical, tid-qid

Pediatric

·Same as adult.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph oint: 0.3% 5g(29188); Oph Soln: 0.3% 5mL(29189); Cream: 0.1% 15g(29302); Inj: 80mg/2mL Vial(30866)

ADR:

NOTE: 儲存25℃以下

Garamycin cream is not for ophthalmic use.

藥名相似:

外觀相似:

外觀描述: 15公克藥膏，『黑』色上蓋，金屬軟管，白底『橘』色字商品名，『紫紅』色字及線條

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1034124

44.04A Antibiotics

29304 C / Unknown(有

Fusidic Acid Cream 20mg/gm "Sinphar" "杏輝" 褐黴素乳膏 20 毫克/公克

Fusidic acid cream 100mg/5g tube

Dosage: 1常備品 29304

Adult
· Skin infections: topical, bid-tid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 250mg(21061); Cream: 2% 5g/Tube(29304); Oph Soln: 1% 5mL/Bot(29296)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 5g鋁軟管,黑色上蓋,白底"紫"色字,有紫色條紋

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049339

44.04A Antibiotics

29306 B / Unsafe

B.&N. Bactermin Ointment "西德有機"利膚癒康軟膏

Mupirocin 2% oint, 15g/tube

Dosage: 1常備品 29306

Adult
·Skin infections: topical, tid

Pediatric
·Skin infections: >2months, topical, tid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oint: 2% 15g/Tube (29306)

ADR:

Stinging, burning, pruritus

NOTE: 室溫儲存

1. The ointment is not suitable for ophthalmic or intra-nasal use.
2. Mupirocin is active against S. aureus, including MRSA, other staphylococci and streptococci. It is also active against G(-) pathogens, such as E. coli and H. influenzae.

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049744

44.04A Antibiotics

29307 D / Caution

Spersin Ointment 使皮新軟膏

Neomycin sulfate 5mg/g [D], Bacitracin 400U/g [C], Polymyxin B sulphate 5000U/g [B] oint, 10g/tube

Dosage: 1常備品 29307

ADULT
· Skin infections: topical, 1-3 times daily

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oint: 10 g/tube (29307), Biomycin Oint: 40 g/tube (29317) , POLA* gauze dressing 1% 10cm*10cm/SH (29314) , Neomycin sulfate 250mg cap (20862)

ADR:

COMMON
Contact dermatitis.
SERIOUS
Ototoxicity, Nephrotoxicity.

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 10克軟膏，白色上蓋軟管，白/黃色紙盒中有黑色區塊

44.04A Antibiotics

29317 UK / Unknown(有

BIOMYCIN OINTMENT "CBC" 〝生化〞欣黴素藥膏

Neomycin sulfate 5.0mg/g [D], Tyrothricin 0.5mg/g , 40g/tube

Dosage: 1常備品 29317

ADULT
· Antiseptic: topical, apply directly to affected area as needed

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oint: 40g/Tube(29317)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 40克外用藥膏，白/藍色鋁管

44.04A Antibiotics

29331 **C / Infant risk can**

CHLORAMPHENICOL* OINTMENT "龍杏" 克樂樂軟膏

Chloramphenicol(C.M.) oint 1% 15g/tube

Dosage: 1常備品 29331

Adult
· Skin infections: topical, tid-qid

Pediatric
· Skin infections: topical, tid-qid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap: 250mg (20930), Oint: 1% 15g/tube (29331), Oph soln: 0.25% 10mL/bot (29187), Inj:1g vial (30930)

ADR:

NOTE: 儲存25℃以下

藥名相似:

外觀相似:

外觀描述: 15克藥膏，黑蓋軟管，黃底黑字，有紙盒包裝

44.04A Antibiotics

29467 **B / Infant risk can**

KOLINCIN* GEL 10MG/G 可立信凝膠10毫克/公克

Clindamycin phosphate 1% gel, 20g/tube

Dosage: 1常備品 29467

Adult
· Acne vulgaris: topical, bid

Pediatric:≧12 yrs
· Acne vulgaris: topical, bid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap:150mg (21060), Gel:1% 30g (29466),1% 20g (29467) Topical Soln:1% 30mL (29457), Inj:300mg/2mL Amp (31060)

ADR:

Abdominal pain, gastrointestinal discomfort, folliculitis, eye pain and contact dermatitis.

NOTE: 室溫儲存

外用時曾有出現腹痛、腸胃不適、毛囊炎、眼痛及接觸性皮膚炎的報告。

藥名相似:

外觀相似:

外觀描述: 白色軟管，白色上蓋，有黑色字樣

44.04B Antifungals

29312 **C / Caution**

ZALAIN CREAM 2% 達來乳膏

Sertaconazole 2% cream, 15g/tube

Dosage: 1常備品 29312

Adult & Children > = 12yrs
·Tinea pedis: topical, bid for 4 wks.

Pediatric
·Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cream: 15g/tube(29312), Vag Tab: 500mg (29035)

ADR:

Dermatitis, dry skin, burning sensation (2%).

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1043847

44.04B Antifungals

29318 B / Unknown(有

MYCOSTEN CREAM 10MG/GM (CLOTRIMAZOLE) "SINPHAR" "杏輝"黴克頓乳膏10毫克/公克（克氯黴唑）

Clotrimazole 1% cream, 10g/tube

Dosage: 1常備品 29318

Adult

· Candidiasis, Pityriasis versicolor, Tinea corporis, Tinea cruris, Tinea pedis：topical, bid for up to 4 weeks.

Pediatric

· Candidiasis, Pityriasis versicolor, Tinea corporis, Tinea cruris, Tinea pedis：topical, bid for up to 4 weeks.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cream: 1%10g/Tube (29318); Vag Tab: 100mg (29022)

ADR:

Pruritus, skin irritation (topical)

NOTE: 室溫儲存

藥名相似: Cream: 1%10g/Tube (29318); Vag Tab: 100m

外觀相似:

外觀描述: 白色軟管，黑色瓶蓋

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1025136

44.04B Antifungals

29319 C / Unknown(有

EXELDERM SOLUTION (SULCONAZOLE) "台灣田邊"優足達液劑（蘇可那挫）

Sulconazole 1% soln, 10mL/bot

Dosage: 1常備品 29319

Adult

·Candidiasis, cutaneous: topical, qd-bid for 3-4 wks

·Tinea infections: topical, qd-bid for at least 3 wks; 4 wks for tinea pedis, with twice-daily application

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Soln: 1% 10mL/Bot (29319)

ADR:

Redness, irritation, allergic reactions, pruritis

NOTE: 室溫儲存

Gently massage a small amount into the affected and surrounding skin

藥名相似:

外觀相似:

外觀描述: 10mL外用藥液，綠色塑膠瓶裝，白底黑字標籤有紫色圖案

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1029790

44.04B Antifungals

29321 B / Unknown(有

MENTAX CREAM 1% "SINPHAR" 黴可舒乳膏１％〝杏輝〞

Butenafine 1% cream, 10g/tube

Dosage: 1常備品 29321

Adult

· Pityriasis versicolor, Tinea corporis,Tinea cruris: topical,qd for 2 wks

· Tinea pedis, interdigital: topical, bid for 7 days or qd for 4 wks

Pedoatric (12-18 yrs)

· Pityriasis versicolor, Tinea corporis,Tinea cruris: topical, qd for 2 wks

· Tinea pedis, interdigital: topical, bid for 7 days or qd for 4 wks

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cream: 10g/Tube (29321)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 10G軟管，有藍色線條，黑色瓶蓋

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044012

44.04B Antifungals

29323 ɔt be ruled out / Infant risk can

PASCA GEL "SHIONOGI" "鹽野義"保溼康凝膠

Methyl salicylate 20mg/g, Tolnaftate 20mg/g gel, 10g/tube

Dosage: 1常備品 29323

Adult
· Tinea, Superficial: topical, bid

Pediatric (≧2 yrs)
· Tinea, Superficial: topical, bid

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Gel: 10g/tube, each g contains: Methyl salicylate 20mg, Tolnaftate 20mg (29323)

ADR:

NOTE: 室溫儲存

·下列情形時需慎用：(1)有深部皮膚組織感染者；(2)3歲以下；(3)孕婦、可能懷孕婦女及哺乳婦；(4)患部在臉上；(5)患部化膿。
·下列情形不建議使用：(1)長期大面積使用(超過兩手掌面積)，以免引起水楊酸中毒症狀[如呼吸困難、發汗、體溫過高、面色潮紅、持續耳鳴、據列或持續頭痛]。(2)眼睛四周或黏膜(如口腔、鼻腔、陰道、陰囊、外陰部等)，潰爛、龜裂或嚴重外傷之患部。
·保持塗抹部位透氣，勿密封，以免增加副作用。
·萬一誤入眼睛，請立即以水或溫水沖洗，並立即前往眼科就醫。

藥名相似:

外觀相似:

外觀描述: 10公克微黃色透明凝膠，『淺黃』色上蓋，金屬軟管，『淺黃』底『綠』色字，有綠色線條區塊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1023336

44.04B Antifungals

29325 b3 / Unknown(有

Amocoat Nail Lacquer " H.S " "黃氏"雅舒安抗甲癬油劑

Amorolfine HCl Nail Lacquer 5% 3mL/bot

Dosage: 1常備品 29325

Adult
·Onychomycosis due to dermatophytes, yeasts, or molds: Topical, apply to the affected nails once or twice weekly. Treatment may be needed for about 6 months for fingernails or 9-12 months for toenails.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Nail lacquer: 5% 3mL/Bot (29325)

ADR:
Transient periungual burning sensation

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 5mL外用油劑

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048884

44.04B Antifungals

29330 C / Caution

Zalain External Gel 2% 達來外用凝膠2%

Sertaconazole 2% gel, 30mL/bot

Dosage: 1常備品 29330

Adult & Children > = 12yrs
·Tinea pedis: topical, bid for 4 wks.

Pediatric
·Same as adult

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Cream: 15g/tube(29312), Gel: 30mL/bot(29330), Vag Tab: 500mg (29035)

ADR:
Dermatitis, dry skin, burning sensation (2%).

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 外盒印有藍底白色"ZALAIN"橘底白色"達來"字樣

44.04D Gynecological Preparations

29019 /

SUTROL GEL-VAGINAL 素女潔陰道用凝膠

Metronidazole Vag gel 0.75% 25g/tube

Dosage: 1常備品 29019

Adult
·Bacterial vaginosis: Intravaginal, 5g qhs or bid for 5 days

Pediatric(>13yr)
·Bacterial vaginosis: Intravaginal, 5g qhs or bid for 5 days

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 250mg(20834); Dental Gel: 25%, 0.3g/Tbe(29162); Vaginal Gel: 0.75%, 25g/Tube(29019); Inj: 500mg/100mL(30831)

ADR:

Vaginal discharge, candida vaginitis, vaginal irritation, gastrointestinal discomfort

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白蓋，25公克鋁管裝

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1045386

44.04D Gynecological Preparations

29021 ɔt be ruled out / Unknown(有

LOMEXIN VAGINAL SUPPOSITORY 200MG 洛徽欣陰道軟膠囊

Fenticonazole 200mg Vag supp

Dosage: 1常備品 29021

Adult
· Vaginal candidiasis: vaginal, 200mg qhs for 3 days or single nithgttime dose of 600mg

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Vag Supp: 200mg (29021)

ADR:

Local burning

NOTE: 冰箱儲存

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2020053

44.04D Gynecological Preparations

29022 B / Unknown(有

CAMAZOLE VAGINAL TABLET 100MG (CLOTRIMAZOLE) "PURZER" 〝瑞安〞祛黴陰道錠100毫克（克催瑪汝）

Clotrimazole 100mg vag tab

Dosage: 1常備品 29022

Adult
· Candidal vulvovaginitis: vaginal, 100 mg for 7 days or 200 mg for 3 days

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cream: 1% 20g/tube (29320); Vag Tab: 100mg (29022)

ADR:

N/V, contact dermatitis, pruritus

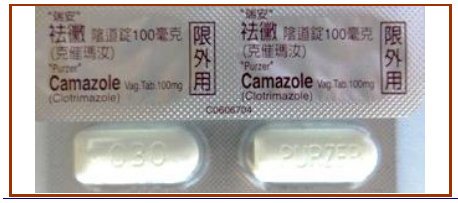
NOTE: 室溫儲存

The vaginal tablet should be inserted as deeply as possible into the vagina in the evening. Insertion is best achieved when lying back with the legs slightly drawn up.

藥名相似:

外觀相似:

外觀描述: 白色長形錠陰道塞劑，一面有"030"，另一面有"PURZER"字樣



44.04D Gynecological Preparations

29028 C / Infant risk can

NYSTATIN VAGINAL TABLETS "YUNG SHIN" 寧司泰定陰道錠

Nystatin 100,000 IU Vag tab

Dosage: 1常備品 29028

Adult
· Vaginal candidiasis: vaginal, 1 vag tab (100,000 IU) qd-bid for 2 wks

Pediatric
·Vaginal infections: Adolescents : Vaginal tablets: qhs for 2 weeks

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 500,000 IU(21102); Pow: 100,000 IU/ds, 5ds/pk(28485); VT: 100,000 IU(29028)

ADR:

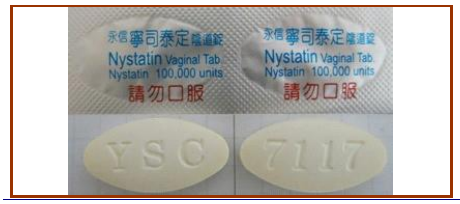
Skin irritation, hypersensitivity reaction, stevens-Johnson syndrome

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 淺黃色橢圓形塞劑，一面有7117字樣，另一面有YSC字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=114596

44.04D Gynecological Preparations

29035 C /

ZALAIN VAGINAL TABLET 達來陰道錠

Sertaconazole nitrate 500mg Vag tab

Dosage: 1常備品 29035

Adult
·Vaginal candidiasis: Vaginal, 500mg as a single dose, may repeat 1-2 weeks later in cases with residual symptoms

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Vag Tab: 500mg(29035)

ADR:

Genitourinary alterations(feeling of urethral burning), vaginal pruritus, vaginitis, urinary continence, cystitis

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 橢圓型粉質陰道塞劑，一面刻有"E01"字樣；鋁箔單顆片裝，銀色底，紅色字印刷，另一面透明塑膠

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1044451

44.04D Gynecological Preparations

29038 /

Polinin vaginal suppositories "P.L." "培力" 保理寧陰道栓劑

Policresulen 90mg(m-Cresolsulfonic acid & Formaldehyde) Vag Supp

Dosage: 1常備品 29038

Adult
· Vaginitis: vaginal, 1 tab qod for 1-2 wks

Pediatric
·NDA

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Vag supp: POLININ* Vag Supp(29038)

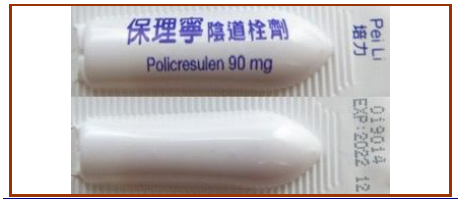
ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 子彈型黃色臘質栓劑，外有白色塑膠膜、印有中英文藥品名稱



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1055238

44.04E Scabicides and Pediculicides

29341 C / Unknown(有

ULEX LOTION 10%(CROTAMITON) "杏輝"悠力素劑液１０％（丁烯醯苯胺）

Crotamiton 10% Lotion, 30g/bot

Dosage: 1常備品 29341

Adult
·Scabies: topical, once daily, up to 5 days
·Pruritus: topical, repeated as needed

Pediatric
·Scabies: topical, once daily for 2 days followed by a cleansing bath 48 hours after the last application; repeated after 7-10 days if mites appear
·Pruritus: topical, repeated as needed

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Lotion: 10% 30g/Bot (29341)

ADR:

Dermatitis, skin irritation

NOTE: 室溫儲存

藥名相似: Lotion: 10% 30g/Bot (29341)

外觀相似:

外觀描述: 白色塑膠瓶，有黑色字體及綠色線條

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1028952

44.04E Scabicides and Pediculicides

29342 b2 / Unknown(有

JALINE LOTION 250MG/ML "GCPC" (BENZYL BENZOATE) "人人"疥寧洗液２５０毫克/毫升（苯甲醯苄酯）

急用Benzyl benzoate 120mL/bot

Dosage: 2急用藥 29342

Adult

·Scabies: topical, left on the skin for 24 hours, then washed the off. Repeat applications may be necessary.The first repeat application should be within 5 days of the initial application. Some sources suggest nightly applications on 3 consecutive nights.

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Lotion: 120mL/bot (29342)

ADR:

Skin irritation, burning, redness, exsiccation, contact dermatitis

NOTE: 室溫保存

藥名相似:

外觀相似:

外觀描述:

44.04E Scabicides and Pediculicides

29343 UK / Unknown(有

SOOLANTRA* 10mg/g Cream 舒利達乳膏

Ivermectin 1% cream, 30g/tube

Dosage: 1常備品 29343

Adult

·Rosacea, Inflammatory lesions:Apply thin film TOPICALLY to affected areas of the face,QD.

Pediatric

·Safety and efficacy have not been established in patients less than 18 yrs .

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Gel: 1% 30g/Tube (29343)

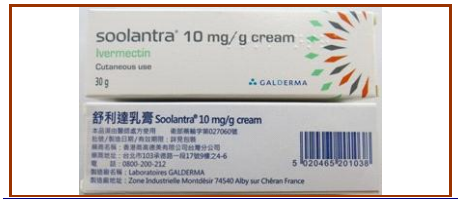
ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述:



44.04E Scabicides and Pediculicides

29804 C / Unsafe

DELICE MEDICAL HAIR EMULSION 1.0% "KINGDOM" 必去蝨藥用乳劑

Gamma-Benzene Hexachloride (r-BHC) 1% Emulsion, 10mL/PK

Dosage: 1常備品 29804

Adult

·Pediculosis capitis/phthirus pubis: 10mL of emulsion is applied and rubbed in thoroughly for 4-5 min; rinse hair thoroughly and comb with a fine tooth comb to remove nits; repeat treatment in 7 days if lice or nits are still present; Max. 2 times/wk

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Emulsion: 1% 10mL/PK (29804)

ADR:

Anemia, leukopenia, dermatitis

NOTE: 室溫儲存

Sexual partners and other persons in close contact or living in the same household should be checked for infection and treated if necessary

藥名相似:

外觀相似:

外觀描述: 10mL乳白色藥液，塑膠軟袋裝，白底綠字印刷

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1010292

44.04F Miscellaneous

29010 C / Infant risk can

Betadine Mouthwash and Gargle 必達定殺菌漱口藥水

Povidone-Iodine 10mg/mL (available iodine 0.1%) Gargle, 250mL/bot

Dosage: 1常備品 29010

ADULT
·Antiseptic: use undiluted or diluted with an equal volume of water. Gargle or rinse with up to 10-15mls for up to 30 seconds without swallowing. Repeat up to four times daily as needed.

Pediatric
· Do not use in children under 6 years of age.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: GARGLE: 250mL /bot(29010)

ADR:

Severe metabolic acidosis have occurred in burn patintes, contact dermatitis

NOTE: 室溫儲存

Use of this preparation may interfere with tests of thyroid function.

藥名相似:

外觀相似:

外觀描述: 250mL棕色瓶身，白色瓶蓋，藍色外盒

44.04F Miscellaneous

29119 C /

SINDINE GARGLE AND MOUTH WASH (POVIDONE-IODINE) "SINPHAR" 金碘漱口液（普威隆碘）

Povidone-Iodine 10mg/mL (available iodine 0.1%) Gargle, 180mL/bot

Dosage: 1常備品 29119

ADULT
·Antiseptic: mouth wash, use undiluted, repeated q2-4h as needed

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Gargle: 180mL/bot (29119); Aqua soln: 50mL/bot (29384); Oint: 10g/tube (29379)

ADR:

Severe metabolic acidosis have occurred in burn patintes, contact dermatitis

NOTE: 室溫儲存

·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1019686

44.04F Miscellaneous

29368 / Unknown(有

AN-FU GAUZE DRESSING 0.2% (NITROFURAZONE) "ROYAL" 安膚石蠟紗布（耐挫敷隆）

Nitrofurazone 0.2% gauze dressing (10cm X 10cm)

Dosage: 1常備品 29368

Adult
· Wound care: topical, use as needed

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Dressing:AN-FU*(29368)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述:

44.04F Miscellaneous

29370 / Unknown(有

MEIDINE GAUZE PADS 10% (POVIDONE-IODINE) "JENSHENG" 美碘紗布劑１０％（普威隆碘）

Povidone-iodine gauze dressing 10% (10cm X 17.42cm)

Dosage: 1常備品 29370

Adult
· Wound care: topical, use as needed

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Pads:MEIDINE*(29370)

ADR:

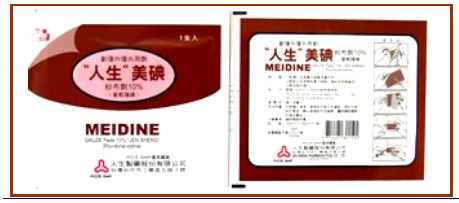
NOTE: 室溫儲存

Avoid contact with eyes.

藥名相似:

外觀相似:

外觀描述:



44.04F Miscellaneous

29379 C / Unknown(有

BIODYNE OINTMENT (POVIDONE IODINE) "施美" 百潔碘軟膏

Povidone-Iodine 10% (available iodine 1%) oint, 10g/tube

Dosage: 1常備品 29379

Adult
· Antiseptic: topical, apply directly to affected area as needed

Pediatric
·Same as adult.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Gargle: 180mL/Bot(29119); Aqua Soln: 50mL/Bot (29384); Oint:10g/Tube (29379)

ADR:

SERIOUS
Hypernatremia, Metabolic acidosis, Gastrointestinal necrosis, Functional visual loss.

NOTE: 室溫儲存

·3歲以下、有深部皮膚組織感染或大面積傷口、動物咬傷、嚴重燒燙傷，請洽醫師診治後使用。
·患部使用後保持塗抹部位透氣，勿密封，以免增加副作用.

藥名相似:

外觀相似:

外觀描述: 10克褐色外用藥膏，白色鋁管黑字有黃/褐色圖案與深藍色區塊

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1029286

44.04F Miscellaneous

29380 /

IODOSORB POWDER "普斯特" 愛得寶外用撒布散

Cadexomer iodine 3g (available iodine 0.9%) Powder

Dosage: 1常備品 29380

Adult
· Wound disinfection (absorbent & antiseptic): topical, qd-bid, applied to affected area to form a layer about 3 mm thick

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Pow: 3g/PK (29380)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 3g外用粉末 紙袋包裝，一面印有"Smith" "Nephew" "#66001286"

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2017039

44.04F Miscellaneous

29382 c / Unknown(有

SINDINE SOLUTION (POVIDONE-IODINE) "SINPHAR" 金碘藥水（普威隆碘）

Povidone-Iodine 100mg/mL (available iodine 1%) Aqua soln, 120mL/bot

Dosage: 1常備品 29382

ADULT
· Antiseptic: topical, apply directly to affected area as needed

Pediatric
·Same as adult.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Gargle:180mL/Bot (29119); Oint: 10g/Tube (29379),

Lugol's soln: (28680)

ADR:

Severe metabolic acidosis have occurred in burn patients, contact dermatitis

NOTE: 室溫儲存25℃以下

藥名相似:

外觀相似:

外觀描述: 120mL深褐色溶液，白色塑膠瓶，白色瓶蓋，白底黑字標籤，有藍色區塊

44.04F Miscellaneous

29391 B /

"SINPHAR" SILIVERZINE CREAM 10MG/GM (SULFADIAZINE SILVER) "杏輝" 燙膚舒乳膏10毫克/公克 (達淨磺胺銀)

Silver sulfadiazine cream 1% 500g bot

Dosage: 1常備品 29391

ADULT

· Burns: topical, qd-bid until healing or skin grafting

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cream: 50g/bot (29393), 500g/bot (29391)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1032571

44.04F Miscellaneous

29393 B / Infant risk can

SILVER SULFADIAZINE CREAM 皮復健乳膏

Silver sulfadiazine 1% cream, 50g/bot

Dosage: 1常備品 29393

Adult

· Burns: topical, qd-bid until healing or skin grafting

--

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cream: 50g/Bot (29393), 400g/Bot (29394)

ADR:

COMMON
Itching,local skin irritation,skin rash;
SERIOUS
Blood dyscrasias (rare), leukopenia (rare).

NOTE: 室溫儲存

藥名相似: Cream: 50g/Bot (29393), 400g/Bot (29394)

外觀相似: Cort S* Oint 50G/Box (29495)

外觀描述: 白色上蓋，白色鋁軟管瓶身，50g乳膏

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=116402

44.06A Topical Corticosteroids

29408 ɔt be ruled out / Infant risk can

SEPTON SOL (BETAMETHASONE DIPROPIONATE) "SHIONOGI" 舒膚通膠液 (貝他每松二丙酸鹽)

Betamethasone dipropionate 0.064% soln, 10g/bot

Dosage: 1常備品 29408

Adult

· Dermatoses: topical, bid

Pediatric

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph Oint: Rinderon*-A 0.1% 3g/Ttube (29180); Oph Soln: Rinderon*-A 0.1% 5mL/B (29182); Eye drop: Garasone* 0.1% 5mL/B (29186); Soln: 0.064% 10g/B (29408); Cream: Rinderon*-VA 0.06% 5g/Tube (29411);Inj: 4mg/amp(35205), 1mL/amp(35203)

ADR:

COMMON
Atrophic condition of skin, Erythema, Folliculitis, O/E - vesicles present, Pruritus, Stinging of skin.
SERIOUS
Allergic contact dermatitis, Hypothalamic-pituitary-adrenal axis dysfunction, Suppression, Glaucoma, Posterior subcapsular cataract.

NOTE: 儲存30℃以下

·Class III (potent)
·如使用大量或長期大範圍的密封法等時，會出現和全身性投與腎上腺皮質荷爾蒙藥品之相同的症狀，除非特殊狀況外，應避免長期大量使用密封法。

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1031086

44.06A Topical Corticosteroids

29411 / Unknown(有

RINDERON-VA CREAM 0.06% 臨得隆維膚水溶性軟膏 0．0 6 %

Betamethasone valerate 0.06% [C], Neomycin(Fradiomycin) sulfate 0.35%[D] cream, 5g/tube

Dosage: 1常備品 29411

Adult
· Dermatoses: topical, qd-qid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph Oint: Rinderon*-A 0.1% 3g/Tube(29180); Oph Soln: Rinderon*-A 0.1% 5mL/B(29182); Eye drop: Garasone* 0.1% 5mL/B(29186); Soln: 0.064% 10g/B(29408); Cream: Rinderon*-VA 0.06% 5g/Tube(29411); Inj: 4mg/amp(35205), 1mL/amp(35203)

ADR:

NOTE: 室溫儲存

Class V (low potency)
仿單注意事項：
·保持塗抹部位透氣，勿密封。
·不可使用於眼部、黏膜(如口腔、鼻腔、陰道、陰囊、外陰部等)、潰爛、龜裂或嚴重外傷之患部或內服。
·勿使用於大面積(超過使用者的兩手掌面積)之體表。
·小孩長期使用較易引起庫欣氏症候群及腎上腺功能障礙。

藥名相似:

外觀相似:

外觀描述: 5公克白色軟膏,鋁管軟管,紅色/淡淺黃色底,黑色字印刷

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1004973

44.06A Topical Corticosteroids

29412 / Unknown(有

MYCOMB CREAM "SINPHAR" 美康乳膏

Nystatin 100,000 IU/g [C], Neomycin sulfate 0.25% [D], Gramicidin 0.025% [UK], Triamcinolone acetonide 0.1% [C] cream,6g/tube

Dosage: 1常備品 29412

Adult
· Dermatoses: topical, bid-tid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cream: 6gm/Tube(29412); Inj: 40mg/Ml (35210); Nasal spray: 120puff/B (29090); Mycomb* Otic drops (29112)

ADR:

NOTE: 室溫儲存

Class V (low potency)

藥名相似: Cream: 6gm/Tube(29412); Inj: 40mg/Ml (352

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1021924

44.06A Topical Corticosteroids

29413 C / Unknown(有

USON CREAM 2.5MG/GM "S.Y." (DESOXIMETASONE) "壽元"優爽乳膏2.5公絲/公克（去氫氧迪皮質醇）

Desoximetasone 0.25% cream, 5g/tube

Dosage: 1常備品 29413

Adult
· Dermatoses: topical, bid

Pediatric
·Same as adult.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oint: 5g/Tube (29413), 6g/Tube (29442)

ADR:

Dry skin, folliculitis, pruritus, burning sensation, irritation symptom.

NOTE:

Class II (high potency)

藥名相似:

外觀相似:

外觀描述: 5公克藥膏，白色上蓋，鋁管印有白底黑字與紅底白色字樣

44.06A Topical Corticosteroids

29417 C / Unknown(有

TOPSYM CREAM (FLUOCINONIDE) 妥膚淨乳膏（氟欣諾能）

Fluocinonide 0.05% cream, 10g/tube

Dosage: 1常備品 29417

Adult
· Dermatoses: topical, qd-tid

Pediatric
· Dermatoses: topical, bid-qid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cream: 10g/Tube (29417)

ADR:

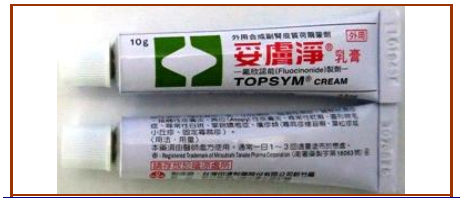
NOTE: 室溫儲存

Class II (high potency)

藥名相似:

外觀相似:

外觀描述: 白色鋁管，白色上蓋，有綠色圖形及紅色"妥膚淨"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1018063

44.06A Topical Corticosteroids

29419 / Unknown(有

URESON CREAM 優膚松乳膏

Urea 100mg/g [C], Hydrocortisone acetate 10mg/g [D] cream, 16g/tube

Dosage: 1常備品 29419

Adult
· Dermatoses: topical, bid-tid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj:100mg (35202); Cream: 1% 10g/Tube (29423); Enema: 60mL/B (29422); Oint: 50g/BX (29495), Proctosedyl Oint (29554); Proctosedyl Supp (29555)

ADR:

NOTE: 室溫儲存

Class VII (weakest)

藥名相似:

外觀相似:

外觀描述: 白色上蓋軟管

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1033377

44.06A Topical Corticosteroids

29422 D / Unknown(有

CORTEMA ENEMA 1.667MG/ML (HYDROCORTISONE) "PURZER" "瑞安"可體灌腸液１．６６７公絲/公撮（皮質醇）

Hydrocortisone Enema 100mg/60mL/bot

Dosage: 1常備品 29422

Adult
· Ulcerative colitis: rectal, 100mg qhs for 21 days; may be continued for 2 to 3 mon in severe cases

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj:100mg (35202); Cream: 1% 10g/Tube (29423); Enema: 60mL/B (29422); Oint: 50g/BX (29495), Proctosedyl Oint (29554); Proctosedyl Supp (29555)

ADR:

NOTE: 室溫儲存

藥名相似: Inj:100mg (35202); Cream: 1% 10g/Tube (294

外觀相似:

外觀描述: 「淺黃」塑膠灌注瓶，外有透明袋包裝

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1038075

44.06A Topical Corticosteroids

29423 D / Unknown(有

HYDROCORTISONE CREAM 10MG/GM "SINPHAR" "杏輝"吉舒乳膏１０毫克/公克（乙酸皮質醇）

Hydrocortisone acetate 1% cream, 10g/tube

Dosage: 1常備品 29423

Adult
· Dermatoses: topical, bid-tid

Pediatric
·Same as adult.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj:100mg (35202); Cream: 1% 10g/Tube (29423); Enema: 60mL/B (29422); Oint: 50g/BX (29495), Proctosedyl Oint (29554); Proctosedyl Supp (29555)

ADR:

NOTE: 室溫儲存

Class VII (weakest)

藥名相似:

外觀相似:

外觀描述: 10g白色軟管，有綠色字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1035883

44.06A Topical Corticosteroids

29424 C /

CLOBETASOL OINTMENT 0.5MG/GM "SINPHAR" "杏輝"可立舒軟膏0.5毫克/公克（可洛貝他索）

Clobetasol 17-propionate 0.05% oint, 7g/tube

Dosage: 1常備品 29424

Adult

· Dermatoses: topical, qd-bid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oint: 7g/Tube (29425)

ADR:

NOTE: 室溫儲存

Class I (super potent)

藥名相似:

外觀相似:

外觀描述: 7克外用藥膏，白底暗紅色字鋁管

44.06A Topical Corticosteroids

29427 C / Unknown(有

METSONE* cream 0.1% "Sinphar" (Class IV) "杏輝" 頓安膚乳膏

Mometasone cream 0.1% 5g/tube

Dosage: 1常備品 29427

Adult

·a thin film applied to affected skin areas qd use

Pediatric

·

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cream: 5g/Tube(29427)

ADR:

COMMON

Burning, pruritus, skin atrophy;

SERIOUS

Adrenal suppression,glaucoma

NOTE: 室溫儲存

Class IV (Mid-strength)

藥名相似: Cream: 5g/Tube(29427)

外觀相似:

外觀描述: 5g 白色鋁管部份印刷為紫色，黑色上蓋

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1048391

44.06A Topical Corticosteroids

29428 C / Unknown(有

FUTISONE CREAM 0.05% 膚益舒乳膏 0.05%

Fluticasone propionate 0.05% cream, 5g/tube

Dosage: 1常備品 29428

Adult

·Dermatoses: topical, apply to affected area qd-bid; rub in gently

Pediatric

·Dermatoses: (3 mon and older) topical, apply thin film to affected areas qd-bid; rub in gently

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inhalation Aerosol: Seretide 250 Evohaler 120puff/B(29091); Seretide 125 Evohaler 120puff/B(29097); Seretide 50 Evohaler 120puff/B(29113); Flixotide Evohaler: 120puff/B(29111); Nasal spray: Flixonase 120puffs/set(29059); Cream: Cutivate 0.05% 5g(29428)

ADR:

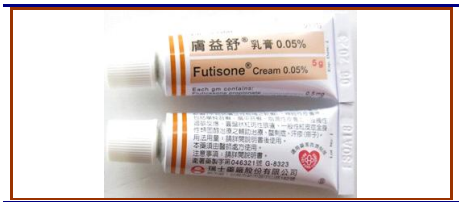
NOTE: 室溫儲存

Class V (Low potency)

藥名相似:

外觀相似:

外觀描述:



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046321

44.06A Topical Corticosteroids

29438 C /

VIMAX* foaming soln (Class I) 可易適泡沫液

Clobetasol 17-propionate 0.05% soln, 25mL/bot

Dosage: 1常備品 29438

Adult
· Disorder of skin (Corticosteroid responsive), Plaque psoriasis: topical, qd-bid. Max. duration, 4 consecutive wks.

Pediatric(>12yrs)
· Disorder of skin (Corticosteroid responsive), Plaque psoriasis: topical, qd-bid. Max. duration, 2 consecutive wks.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Oint: 5g/Tube (29425), Soln: 0.05% 25mL/Bot(29438), Shampoo: 0.05% 60mL/bot(29446)

ADR:

NOTE: 室溫儲存
Class I (super potent)

藥名相似:

外觀相似:

外觀描述: 25mL 白色填充罐

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049063

44.06A Topical Corticosteroids

29444 C / Caution

FLUCORT-F OINTMENT 0.025% 膚潤康益福軟膏 0．0 2 5 %

Fluocinolone acetonide 0.025% [C], Fradiomycin sulfate 0.35%[D] oint, 5g/tube

Dosage: 1常備品 29444

ADULT
· Dermatosis: topical, qd-qid

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Oint: 0.025% 5g/Tube(29444)

ADR:

NOTE: 請存放於陰涼處所
Class IV (low potency)

藥名相似:

外觀相似:

外觀描述: 白色上蓋 ．5g鋁管

44.06A Topical Corticosteroids

29446 C / Unknown(有

Clobex 500μg/g shampoo 柔倍絲藥用頭皮洗劑 500 μg/g

Clobetasol propionate 0.05% 60mL/bot (Class I)

Dosage: 1常備品 29446

Adult
· Scalp psoriasis: topical, qd; Max. 7.5mL/day, 50mL/wk.

Pediatric
· Scalp psoriasis
<18yr: Not recommeded
<2yr: Should be avoided

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Shampoo: 0.05% 60mL/bot(29446), Oint: 0.05% 5g/tube (29425), Soln: 0.05% 25mL/bot(29438)

ADR:

COMMON
Asteatotic eczema , atrophic condition of skin , burning sensation, skin discomfort, dry skin , pruritus , telangiectasia , nasopharyngitis , upper respiratory infection
SERIOUS
Secondary hypocortisolism ,acute intracranial hypertension

NOTE: 室溫避光

· Class I (super potent)
· It should be applied onto dry (not wet) scalp in a thin film to the affected areas only, and left for 15 mins before lathering and rinsing.
· Treatment should be liminted to 4 consecutive wks

藥名相似:

外觀相似:

外觀描述: 60CC 白色塑膠罐

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025013

44.06A Topical Corticosteroids

29495 D / Unknown(有

Cort. S. Ointment 1% "Lotus" (HYDROCORTISONE ACETATE) "美時" 皮質醇軟膏１％（乙酸皮質醇）

Hydrocortisone 1% oint 50g/box

Dosage: 1常備品 29495

ADULT

· Dermatoses: topical, bid-tid

Pediatric

· Dermatoses: topical, bid-tid

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Inj:100mg (35202); Cream: 1% 10g/Tube (29423); Enema: 60mL/B (29422); Oint: 50g/BX (29495), Proctosedyl Oint (29554); Proctosedyl Supp (29555)

ADR:

NOTE: 室溫儲存

Class VII (weakest)

藥名相似: Inj:100mg (35202); Cream: 1% 10g/Tube (294

外觀相似: Uburn* Cream (29393)

外觀描述: 白色圓罐，白底黑字標籤

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1029825

44.06B Nonsteroidal Anti-Inflammatory Agents

29401 D / Infant risk can

TORICAM GEL 10MG/G (PIROXICAM) 完疲痠痛凝膠（匹洛西卡）

Piroxicam 1%gel, 40g/tube

Dosage: 1常備品 29401

Adult

· Musculoskeletal/joint disorders: topical, bid-tid

NDA

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cream: 40g/Tube (29401)

ADR:

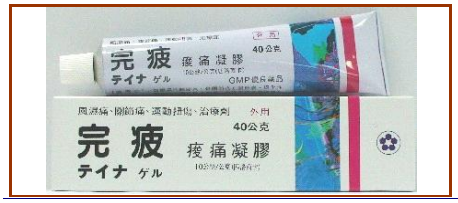
NOTE: 室溫儲存|

懷孕分類: C/D(3rd trimester)

藥名相似:

外觀相似:

外觀描述: 40克凝膠，白蓋軟管，紙盒白底黑字，有藍色區塊與紫紅色線條



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1039429

44.06B Nonsteroidal Anti-Inflammatory Agents

29403 UK / Unknown(有

TEIRIA GEL 100MG/GM (ETOFENAMATE) 思舒酸痛凝膠１００公絲/公克（伊妥芬那邁）

Etofenamate 10% gel, 40g/tube

Dosage: 1常備品 29403

ADULT

·Musculoskeletal/joint disorders: topical, bid-tid

Pediatric

·

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Gel: 10% 40g/Tube (29403)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 40克軟膏，紙盒包裝

44.06B Nonsteroidal Anti-Inflammatory Agents

29406 B / Unknown(有

FLUR DI FEN PATCH 40MG/12GM 富帝芬貼片

Flurbiprofen TTS 3.33mg/g 12g/Patch

Dosage: 1常備品 29406

Adult

·Musculoskeletal/joint disorders: topical, bid

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: TTS: 10g/Patch(29406)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 鋁箔夾鏈袋,有"富帝芬貼片"字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1040358

44.08 Antipruritics and Local Anesthetics

29133 B /

Lidopat Patch 5% 遠疼貼貼片 5%

Lidocaine patch 5% 14g/Patch

Dosage: 1常備品 29133

Adult

·Post-herpetic neuralgia: topically, apply patch to most painful area. Up to 3 patches may be applied in a single application. Patch may remain in place for up to 12 hr in any 24-hr period

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Severe hepatic disease: a dose reduction (eg, fewer patches, smaller areas of treatment, shorter application times) may be required.

Dosing adjustments in renal impairment:

Smaller areas of treatment are recommended in a patient with impaired elimination.

P: Surfance anesthesia- TTS: 5% patch(29133)；Soln: 4% 30mL/bot(29104)；Spray: 10% 500dose/bot(29109)；Jelly: 2% 30g(29101)；Cream: EMLA*(29103), 兒癒EMLA*(29902)

ADR:

COMMON

Application site reactions: blisters, bruising, burning sensation, depigmentation, dermatitis, discoloration, edema, erythema, exfoliation, irritation, papules, petechia, pruritus, vesicles, or may be the locus of abnormal sensation

SERIOUS

Allergic reactions: angioedema, bronchospasm, dermatitis, dyspnea, hypersensitivity, laryngospasm, pruritus, shock and urticaria.

Systemic (dose-related) reactions: CNS excitation and/or depression.

NOTE: 室溫儲存

1.Smaller areas of treatment are recommended in a debilitated patient, or a patient with impaired elimination.

2. Patches may be cut into smaller sizes with scissors prior to removal of the release liner.

3. If irritation or burning occurs at the application site, remove the patch(es) and do not reapply until the irritation subsides.

4. Contraindication: hypersensitivity to local anesthetics of the amide type.

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049320

44.08 Antipruritics and Local Anesthetics

29329 B / Caution

ICHDERM CREAM 50MG/GM "M.S."(DOXEPIN) 普膚乳膏（杜西平）

Doxepin cream 5% 15g/tube

Dosage: 1常備品 29329

Adult

·Pruritus (moderate), due to atopic dermatitis or lichen simplex chronicus: Topical, apply a thin film to skin 4 times a day (3-4 hr between applications) for a Max. of 8 days.

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cream: 5% 15g/tube(29329)

ADR:

COMMON

Weight gain, bloating symptom, constipation, xerostomia, dizziness, somnolence, blurred vision, urinary retention.

SERIOUS

Hypertension (rare), hypotension (rare), tachyarrhythmia (rare), agranulocytosis (rare), leukopenia (rare), pancytopenia (rare), purpuric disorder (rare), thrombocytopenia (rare), depression, worsening (rare), suicidal thoughts, suicide.

NOTE: 室溫儲存

Contraindications: glaucoma, urinary retention, hypersensitivity to doxepin.

藥名相似:

外觀相似:

外觀描述: 15g白色軟管，有綠色波浪型圖樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1042214

44.08 Antipruritics and Local Anesthetics

29429 /

C.B. OINTMENT "STRONG" 強力施美藥膏

Chlorpheniramine maleate 1%[a], lidocaine HCl 3%[B], menthol 1%, methyl salicylate 1%, camphor 0.5% 5g tube

Dosage: 1常備品 29429

Adult
·Allergic skin disorders, insect bites, burns, wounds, corns: topical, apply to affected area as needed.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Oint: 5g/Tube (29429)

ADR:
· 皮膚局部灼熱、刺痛、過敏性反應、紅斑、搔癢、刺痛感。
· 水楊酸效應(耳鳴、暈眩噁心嘔吐等)。

NOTE: 室溫儲存15-30℃

Areas around the nose should be avoided in infants and chlidren <2 yrs. Menthol may cause difficulties in breathing.
仿單注意事項：
· 保持塗抹部位透氣，勿密封。
· 不可使用於眼部、黏膜(如口腔、鼻腔、陰道、陰囊、外陰部等)、潰爛、龜裂或嚴重外傷之患部或內服。
· 勿使用於大面積(超過使用者的兩手掌面積)之體表。
· 不可連續使用超過7天。
· 請勿使用於2歲以下兒童、對阿斯匹靈或水楊酸過敏者。
· 不可長期大面積使用，以免引起水楊酸中毒症狀，如呼吸困難、發汗、體溫過高、面色潮紅、持續性耳鳴、劇烈或持續頭痛。

藥名相似: Oint: 5g/Tube (29429)

外觀相似:

外觀描述: 白色紙盒，有綠色圖形、藍色區塊及紅色字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=12004550

44.08 Antipruritics and Local Anesthetics

29431 / Unknown(有

SINBABY BABY LOTION "SINPHAR" "杏輝" 金貝比嬰兒洗劑

Zinc oxide 100mg/g, Diphenhydramine 5mg/g, Dibucaine HCl 1.5mg/g, dl-Camphor 1.5mg/g, Benzalkonium chloride 2.5mg/g, Silicone oil 10mg/g Lotion, 120mL/bot

Dosage: 1常備品 29431

Adult
· Pruritus: topical, bid-tid

Pediatric
· Pruritus/diaper dermatitis: topical, bid-tid

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Lotion: 120 mL/Bot (29431)

ADR:

NOTE: 室溫儲存
·《仿單禁忌》：曾因本藥成分引起過敏。
Shake well before use

藥名相似:

外觀相似:

外觀描述: 白色塑膠瓶，有黑色字體及黃色橢圓

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1020215

44.08 Antipruritics and Local Anesthetics

29448 / Unknown(有

EMLA CREAM 5% 安麻樂乳膏 5 %

Lidocaine 25mg/g [B], Prilocaine 25mg/g [B] 5% cream, 5g/tube

Dosage: 1常備品 29448

Adult
A thick layer of cream is applied to intact skin and with an occlusive dressing
·Minor dermal procedures (eg, intravenous cannulation, venipuncture): topical, 2.5g/20-25cm(2), contact with skin for at least 1 hr
·Major dermal procedures (eg, split thickness skin graft harvesting): topical, 2g/10cm(2), conctact with skin for at least 2 hr

Pediatric
·Local anesthesia: topical; Max. doses, application areas & application times as follows
0-3 mon or <5 kg: 1 g, 10 cm(2), 1 hr
3-12 mon and >5 kg: 2 g, 20 cm(2), 4 hr
1-6 yr and >10 kg: 10 g, 100 cm(2), 4 hr
7-12 yr and >20 kg: 20 g, 200 cm(2), 4 hr

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Surfance anesthesia- Cream: EMLA*(29448),LIDIPRINE*(29103), 兒癌EMLA*(29902)；Soln: 4% 30mL/bot(29104)；Spray: 10% 500dose/bot(29109)；Jelly: 2% 30g(29101)；TTS: 5% patch(29133)；

ADR:

NOTE: 室溫儲存30℃以下

藥庫發固定數code: 37208, 37202, 37209, 29101, 38816

藥名相似:

外觀相似:

外觀描述: 白色上蓋，5g鋁管

44.08 Antipruritics and Local Anesthetics

29902 **B / Unknown(有**

EMLA CREAM 5% 安麻樂乳膏 5 %

兒癌Lidocaine 25mg/g [B], Prilocaine 25mg/g [B] 5% cream, 5g/tube

Dosage: 2兒癌基金用藥 29902

ADULT
A thick layer of cream is applied to intact skin and with an occlusive dressing
·Minor dermal procedures (eg, intravenous cannulation, venipuncture): topical, 2.5g/20-25cm(2), contact with skin for at least 1 hr
·Major dermal procedures (eg, split thickness skin graft harvesting): topical, 2g/10cm(2), conctact with skin for at least 2 hr

Pediatric
·Local anesthesia: topical, Max. doses, application areas & application times as follows
0-3 mon or <5 kg: 1 g, 10 cm(2), 1 hr
3-12 mon and >5 kg: 2 g, 20 cm(2), 4 hr
1-6 yr and >10 kg: 10 g, 100 cm(2), 4 hr
7-12 yr and >20 kg: 20 g, 200 cm(2), 4 hr

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Surfance anesthesia- Soln: 4% 30mL/bot(29104)；Spray: 10% 500dose/bot(29109)；Jelly: 2% 30g(29101)；TTS: 5% patch(29133)；Cream: EMLA*(29103), 兒癌EMLA*(29902)

ADR:

藥庫發固定數code: 37208, 37202, 37209, 29101, 38816

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述:

44.10 Antiseborreheics

29450 **C /**

ACZO GEL 50MG/GM (BENZOYL PEROXIDE) "SINPHAR" 雅若凝膠 5 0 毫克/公克（過氧化苯醯）

Benzoyl peroxide 50mg/g gel, 10g/tube

Dosage: 1常備品 29450

Adult
· Acne: topical, qd

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Gel: 10g/tube (29450)

ADR:

NOTE: 室溫儲存

藥名相似: Gel: 10g/tube (29450)

外觀相似:

外觀描述: 白色塑膠軟管,白底黑字,有橘紅色線條及商標圖樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1034127

44.10 Antiseborreheics

29465 **ɔt be ruled out / Infant risk is**

PINETARSOL* gel 松木舒敏凝膠

Pine tar gel 1.6% 100g tube

Dosage: 1常備品 29465

Adult
· Seborrhoea, psoriasis, dandruff and itching scalp: Apply to wet skin and smooth gently over affected area. Leave on 2-3 minutes. Rinse and pat skin dry.

Pediatric

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Gel: 1.6% 100g/Tube (29465)

ADR:

NOTE: 室溫儲存

·An anti-itch soap alternative with a pH of 6.
·It is used as an adjunct treatment for dermatitis, anal and genital itching, jogger' s groin rash, inflamed scaly skin and other minor skin irritations.
·It should not be used near the eyes, and should be applied with caution to the face or broken or inflamed skin.

藥名相似:

外觀相似:

外觀描述: (100克凝膠，積層鋁塑軟管裝，有綠色圖案及黑色區塊)

44.12 Cell Stimulants and Proliferants

27222 X / Unsafe

NEOTIGASON CAPSULES 10MG 新定康癬膠囊１０毫克

Acitretin 10mg cap

Dosage: 1常備品 27222

Adult
·Psoriasis: PO, initial 25-30mg once daily with food. Concomitant phototherapy dose should be decreased dependent upon patient response. ·Skin cancer; Prophylaxis - Transplant of kidney, High-risk recipients: PO, 30 mg daily was used in a clinical trial.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

severe hepatic impairment: use contraindicated.

Dosing adjustments in renal impairment:

severe renal impairment: use contraindicated.

P: Cap: 10mg (27222)

ADR:

COMMON
Alopecia, Cheilitis, Disorder of nail, Dry skin, Peeling of skin, Pruritus, Hypertriglyceridemia, Lipids abnormal, Xerostomia, Arthralgia, Hyperesthesia, Paresthesia, Dry eye syndrome, Xerophthalmia, Epistaxis, Nasal mucosa dry, Rhinitis.□
SERIOUS
Myocardial infarction, Hepatotoxicity, Increased liver aminotransferase level, Pseudotumor cerebri, Ototoxicity - deafness, Depression, Capillary leak syndrome."

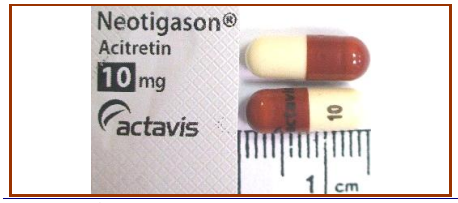
NOTE: 室溫儲存25℃以下

·《Contraindications》Chronically abnormal lipid elevations; Concomitant use with methotrexate; Concomitant use with tetracyclines; Hypersensitivity to acitretin, its excipients, or other retinoids; Pregnancy at initiation, during treatment, and for at least 3 years after treatment discontinuation; women of childbearing potential must use 2 forms of contraception, except the minipill; pregnancy tests required prior to, during, and for at least 3 years after treatment discontinuation; Severe hepatic or renal impairment；
·精神疾病(仿單副作用)-曾有全身性投予含其他retinoids藥品，及服用含acitretin成分藥品後，出現攻擊和/或自殺想法的報告。雖然因果關係尚未確立，對有精神疾病及焦慮症病史者應特別注意，應監視其是否出現相關徵兆，必要時應轉介治療。
·Pregnancy should be avoided for at least 1 month prior to initiation of acitretin therapy, during acitretin therapy, and for at least 3 years after discontinuing acitretin therapy.
·Patients should not donate blood during and for at least 3 years following acitretin therapy .
·Patients on etretinate switch to acitretin at 2/3 the dose of etretinate.

藥名相似:

外觀相似:

外觀描述: 紅褐色/乳黃色膠囊，有actavis及10字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022118

44.12 Cell Stimulants and Proliferants

27500 X / Unsafe

ROACCUTANE "ROCHE" SOFT GELATIN CAPSULES 10MG "羅氏"羅可坦軟膠囊１０毫克

Isotretinoin 10mg cap

Dosage: 1常備品 27500

Adult
·Severe recalcitrant nodular acne: PO, 0.5 to 2 mg/kg/day in 2 divided doses for 15 to 20 wks; there would be an interval of at least 8 wks before restarting treatment

Pediatric
·Nodulocystic acne (Severe), Recalcitrant: >12yr 0.5 to 1 mg/kg/day given orally with food in 2 divided doses. A normal course of treatment is 15 to 20 weeks.

Dosing adjustments in hepatic impairment:

Dosage adjustment required

Dosing adjustments in renal impairment:

NDA

P: Soft gelatin cap: 10mg (27500), 20mg (27602, 兒癌用藥)

ADR:

COMMON
Alopecia, Cheilosis, Dermatitis, Dry skin, Photosensitivity, Pruritus, Decreased HDL level, Hypertriglyceridemia, Serum cholesterol raised, Xerostomia, Anemia, Increased liver function test, Arthralgia, Backache, Hypertrophy of bone, Increased creatine kinase level, Musculoskeletal pain, Headache, Dry eye, Bleeding from nose, Nasal mucosa dry.
SERIOUS
Thrombosis of blood vessel, Vasculitis, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Gastrointestinal hemorrhage, Inflammatory bowel disease, Pancreatitis, Agranulocytosis, Neutropenia, Thrombocytopenia, Hepatitis, Anaphylaxis, Hypersensitivity reaction, Rhabdomyolysis, Cerebrovascular accident, Pseudotumor cerebri, Seizure, Syncope, Optic neuritis, Visual disturbance, Hearing loss, Aggressive behavior, Depression, Injury due to suicide attempt, Psychotic disorder,

Suicidal thoughts, Violent behavior, Bronchospasm.

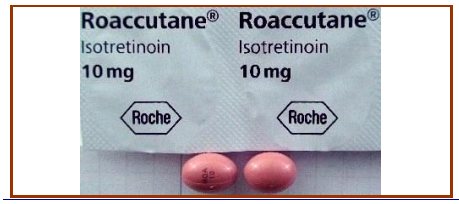
NOTE: 室溫儲存30℃以下

■具致畸胎性，禁用於懷孕或餵哺母乳的婦女。
■驗孕：具生育能力的女性，必須在開始使用前11天內、治療期間、以及治療結束5週後進行驗孕，結果必須為陰性。
■避孕：在開始治療前使用達至少1個月以上，且在治療期間與治療結束後持續使用至少達1個月以上。
・治療期間及停藥後1個月內應避免捐血。
・Preferably given with food to maximize GI absorption.

藥名相似:

外觀相似:

外觀描述: 淡紫色卵形軟膠囊，有ROA 10字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2014967

44.12 Cell Stimulants and Proliferants

29453 B / Unknown(有

SKINOREN CREAM 思麗安乳膏

Azelaic acid 20% cream 30g/tube

Dosage: 1常備品 29453

Adult
·Acne: topical, bid

Pediatric
·Acne: topical, bid

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Cream: 30g/tube (29453)

ADR:
Pruritus, tingling feeling, burning, stinging

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 30克軟膏，『白』色上蓋軟管，『橘』色紙盒有銀色圓點環繞圖案

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2019488

44.12 Cell Stimulants and Proliferants

29533 C /

TIFFORLY* GEL 蒂膚麗凝膠

Adapalene 0.1% gel 15g/tube

Dosage: 1常備品 29533

Adult
·Acne: topical, qhs

Pediatric
·Acne: > 12yr, topically, qhs

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Gel: 15g/tube (29533)

ADR:
Skin irritation, burning, dryness, erythema, pruritus, scaling

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046314

44.12 Cell Stimulants and Proliferants

29534 X /

Karac Cream 癬痘克乳膏

Tazarotene cream 0.1% 30gm/tube

Dosage: 1常備品 29534

Adult
・Plaque psoriasis/acne vulgaris: qhs

Pediatric
・Acne vulgaris: ?12 yr, topically, qhs
・Plaque psoriasis: safety and efficacy have not been established in patients less than 18 years old.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Cream: 30g/tube (29534)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 30克外用藥膏，白/綠色鋁管

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1049670

44.14A Depigmenting Agents

29580 ɔt be ruled out / Unsafe

COLOR CREAM 快樂乳膏

Hydroquinone 50mg/g [C], Tretinoin 0.3mg/g [C], Dexamethasone 0.3mg/g [C] cream, 5g/tube

Dosage: 1常備品 29580

Adult

· Hyperpigmentation, melanin: topical, qd-bid

--

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cream: each g contains: hydroquinone 50 mg, tretinoin 0.3 mg, dexamethasone 0.3 mg, 5g/tube (29580)

ADR:

(仿單副作用)
短期使用
局部輕微皮膚炎。
長期使用
可能引起皮膚萎縮、毛細血管擴張、粉刺。

NOTE: 室溫保存

·《Contraindications》
1. Hydroquinone: hypersensitivity to hydroquinone or any component of hydroquinone products; pregnancy, safety not established; children 12 years of age and under; safety not established；
2. Tretinoin: hypersensitivity to tretinoin or any component of the product；
·《仿單注意事項》如下列情形，請勿使用本劑：懷孕婦女、非黑色素引起的色素沉澱、白斑、黑色素瘤、疑似黑色素瘤症狀、皮膚結核病、濾過性病毒引起的皮膚病。

藥名相似:

外觀相似:

外觀描述: 5克軟膏，紙盒包裝

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1035826

44.16 Emollients, Demulcents and Protectives

29519 / Unsafe

ZINC OXIDE OINTMENT "WST" 氧化鋅軟膏

Zinc oxide 200mg/g oint, 28.4g/tube

Dosage: 1常備品 29519

Adult

· Soothing and protective application in skin disorders: topical, bid-tid

Pediatric

· Apply several times daily to affected area.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oint: 28.4g/tube (29519)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 28.4G軟管,紙盒,有藍色區塊及白色字體

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1014238

44.18 Enzyme

29572 /

CIVIDOID GEL (HEPARINOID) "SINPHAR" "杏輝 " 喜美凝膠（喜普理諾）

Heparinoid Natural 250 IU/g gel, 20g/tube

Dosage: 1常備品 29572

Adult

· Anticoagulation/alleviation of inflammation: topical, tId-qid

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Gel: 20g/tube (29572)

ADR:

NOTE: 室溫儲存

1.Each g contains: Heparinoid Natural (Mucopolysaccharide polysulfate) 3mg(=250 IU activity), Propylene glycol 40mg, Alcohol 95% 120mg, Chloroxylenol 8mg, Sodium EDTA 0.25mg

藥名相似:

外觀相似:

外觀描述: 白色軟管，黑色瓶蓋

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1023231

44.20 Keratolytic Agent

29492 UK / Caution

WINSOLVE UREA CREAM 允消優膚乳膏

Urea cream 10%, 20g/tube

Dosage: 1常備品 29492

Adult
· Dermatoses: topical, qd-bid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Cream: 10% 20g/tube (29492), Ueraly(29419)

ADR:
Skin irritation, temporary burning, stinging, itching

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 20克軟膏,白色蓋,有粉紅色/紅色區塊

44.20 Keratolytic Agent

29531 C / Unknown(有

SALIC OINTMENT (SALICYLIC ACID)"STANDARD" "生達" 速立康軟膏

Salicylic acid 2.5% oint, 10g/tube

Dosage: 1常備品 29531

Adult
·Keratolysis: topical, qd-bid

Pediatric
·Same as adult.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Oint: 10g/tube (29531)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色鋁管，白色上蓋，有"紫"色區塊及粉紅色圖樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1030530

44.20 Keratolytic Agent

29535 / Unknown(有

Salicylic acid 16.7% [C], Lactic acid 16.7% [UK] soln, 15mL/bot

Dosage: 1常備品 29535

Adult
· Warts: topical, 2-4 drops qd

NDA

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Soln: 15mL/bot (29535)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 棕色瓶身，白色瓶蓋

44.24 Miscellaneous

29361 / Unknown(有

L.G.T CREAM 10MG/GM "S.C."(CENTELLA ASIATICA) 雷公草乳膏（老公根）

Extract of Centella asiatica 1% cream, 10g/tube

Dosage: 1常備品 29361

Adult
· Wound management: topical, qd-tid

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Cream: 10g/tube (29361)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 10克外用乳膏

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1041934

44.24 Miscellaneous

29407 UK /

SILKIS OINTMENT 施革欣軟膏

Calcitriol 0.0003% oint, 30g/tube

Dosage: 1常備品 29407

Adult

· Plaque psoriasis: Topical, bid; Max. 30g/day

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: 0.25mcg(26815); Oint: 30g/tube(29407); Inj: 1mcg/1mL Amp(36801)

ADR:

Temporary skin irritation(reddening, itching)

NOTE: 室溫儲存

· It should not be applied to the eyes and lips

· Not recommend for treatment of more than 35% of body surface area

藥名相似:

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023403

44.24 Miscellaneous

29409 C / Infant risk can

DAIVONEX OINTMENT 得膚寧軟膏

Calcipotriol ointment 0.005% oint, 30g/tube

Dosage: 1常備品 29409

ADULT

· Plaque psoriasis: topical, bid; Max. 100g/wk

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oint: 30g/tube (29409); Soln: 0.005%, 30mL/B(29421)

ADR:

COMMON

Burning sensation, Dermatitis, Dry skin, Peeling of skin, Worsening of Plaque psoriasis, Pruritus, Rash, Skin irritation.

SERIOUS

Reversible transient Raised serum calcium level.

NOTE: 室溫儲存

·《Contraindications》facial application; hypercalcemia; hypersensitivity to calcipotriene or any ingredient; vitamin D toxicity；

·It should not be applied to the facial area.

·成人最大劑量：100g(= calcipotriol 5mg)/每週。併用其他含calcipotriol藥品時，每週最大總劑量：calcipotriol 5mg)/每週。

·鈣代謝-超過每週最大劑量可能發生高血鈣症。血清鈣濃度會在停止治療後恢復正常。高血鈣的症狀包括多尿、便祕、肌肉無力、意識混淆與昏迷。

·局部不良反應-不應使用於臉部。慎用於皮膚皺摺處，可能會增加不良反應的風險。

·〔特別警語及使用注意事項〕(仿單)：尚未評估的使用-沒有使用於滴狀牛皮癬、紅皮病型牛皮癬及膿皰狀牛皮癬的經驗。本藥含有propylene glycol為賦形劑，可能會引起皮膚刺激。

藥名相似: Oint: 30g/tube (29409); Soln: 0.005%, 30mL/B

外觀相似:

外觀描述: 30克白色藥膏，『藍』蓋鋁軟管，白底黑字印刷，有藍色線條，紙盒裝

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2020230

44.24 Miscellaneous

29414 C /

DAIVOBET OINTMENT 得膚寶軟膏劑

Calcipotriol 0.005% & Betamethasone 0.05% oint, 30g/tube

Dosage: 1常備品 29414

Adult

· Psoriasis vulgaris: Topical, qd; Max. 15g/day, 100g/wk

Pediatric

·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oint: DAIVOBET* 30g(29414), Gel: XAMIOL* 30g(29443)

ADR:

Pruritus, psoriasis, scaly rash, skin depigmentation, folliculitis, skin atrophy

NOTE: 室溫儲存

· It should not be applied to the face, axillae or groin

· Not recommend for treatment of more than 30% of body surface area

藥名相似: Oint: DAIVOBET* 30g(29414), Gel: XAMIOL* 3

外觀相似:

外觀描述:

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023936

44.24 Miscellaneous

29440 C /

ELIDEL 1% CREAM 醫立妥乳膏 1 %

Pimecrolimus cream 1% 15g tube

Dosage: 1常備品 29440

Adult
·Atopic dermatitis: topical, bid

Pediatric(> 2yrs)
·Atopic dermatitis: topical, bid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cream: 1% 15g/tube (29440)

ADR:

NOTE: 室溫儲存30℃以下

藥名相似:

外觀相似:

外觀描述: 15克乳膏，白色上蓋鋁管，白底藍字印刷有黃色圖樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023645

44.24 Miscellaneous

29443 C /

Xamiol Gel 絲玫歐凝膠

Calcipotriol 0.005% & Betamethasone(as dipropionate) 0.05% gel, 30g/bot

Dosage: 1常備品 29443

Adult
· Scalp psoriasis: Topical, 1-4g qd; Max.15g/day, 100g/wk.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oint: DAIVOBET* 30g (29414), Gel: XAMIOL* 30g (29443)

ADR:

Pruritus, psoriasis, scaly rash, skin depigmentation, folliculitis, skin atrophy.

NOTE: 室溫儲存

· Shake well before use.
· Not recommend for treatment of more than 30% of body surface area.
【賦形劑】Paraffin Liquid、PPG-15 Stearyl Ether、Castor Oil Hydrogenated、Butylhydroxytoluene、all-rac-α-Tocopherol。

藥名相似:

外觀相似:

外觀描述: 30gm小瓶

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025159

44.24 Miscellaneous

29449 C / Unknown(有

PROTOPIC OINTMENT 0.1% 普特皮軟膏 0.1%

Tacrolimus oint 0.1% 5g/tube

Dosage: 1常備品 29449

Adult
· Atopic dermatitis: topical, bid

Pediatric
· Atopic dermatitis (>16 yrs): topical, bid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oint: 0.03%10g/tube (29441) · 0.03% 5g/tube (29445) · 0.1% 5g/tube (29449)

ADR:

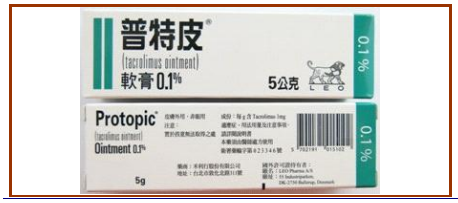
Skin burning, pruritus, erythema

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 5克軟膏，紙盒包裝，白底黑字，有『綠』色區塊



44.24 Miscellaneous

29607 C / Unknown(有

ALDARA CREAM 5% 樂得美乳膏 5 %

Imiquimod cream 5% 250mg/pk

Dosage: 1常備品 29607

Adult
·Venereal warts: topical, 3 times a week at bedtime for up to 16 wks; left on skin for 6-10 hrs

Pediatric
·Venereal warts: >12yr, same as adult.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cream: 250mg/PK (29607)

ADR:

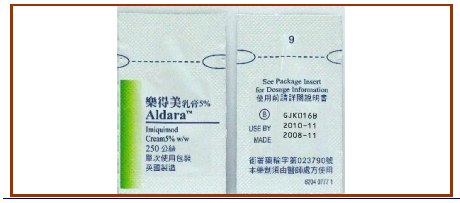
COMMON
erythema, peeling of skin, superficial ulcer of skin

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述:



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2023790

44.24 Miscellaneous

29611 C / Infant risk is

Regaine 5% Extra Strength External Solution "Canada" 落建生髮液5% (加拿大廠)

Minoxidil 5% soln, 60mL/bot

Dosage: 1常備品 29611

Adult
·Androgenetic alopecia: topical, 1mL bid; Max. 2mL/day

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 10mg (22480); Soln: 5%, 60mL/bot (29611)

ADR:

Pruritus, dryness, scaling/flaking

NOTE: 室溫保存

1. 5% topical minoxidil solution should not be used in women
2. Hair and scalp should be dry prior to topical application

藥名相似:

外觀相似:

外觀描述: 灰/黑色紙盒

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2025697

44.24 Miscellaneous

29613 UK / Unknown(有

ESECIN* GEL 1.5% "P.L." "培力"益欣凝膠 1.5%

Escin(Aesculus hippocastanum,Horse chestnut) gel 1.5% 30g/tube

Dosage: 1常備品 29613

Adjunctive treatment to relieve local swelling due to chronic venous insufficiency: topical, up to 5 times/day for 5days

Safety and efficacy have not been established in patients less than 12 years old

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Gel: 1.5% 30g/tube(29613)

ADR:

skin irritation, stinging, or contact dermatitis

NOTE: 室溫儲存

Contraindication: <30 months of age do not use

藥名相似:

外觀相似:

外觀描述: 白色上蓋 ，30g白色塑膠管

44.24 Miscellaneous

29614 ɔt be ruled out / Infant risk can

Wart Del Cream 汰疣凝 乳膏

Podophyllotoxin cream 0.15% 5g/tube

Dosage: 1常備品 29614

Adult
·External genital and perianal warts: Topical, apply twice daily (morning and evening) for 3 consecutive days and withheld for 4 days; this 7-day cycle may be repeated up to 4 times

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cream: 0.15% 5g/tube (29614)

ADR:

COMMON
Pruritus, superficial ulcer of skin, pain, burning sensation, inflammatory disorder

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述:

44.24 Miscellaneous

29616 **B / Caution**

Mirvaso 3mg/g Gel(Brimonidine) 敏立紓凝膠

Brimonidine gel 0.3% 30g/tub

Dosage: 1常備品 29616

Adult
· Persistent (nontransient) facial erythema of rosacea: topical, qd, apply a pea-size amount as a thin layer across the entire face covering the central forehead, each cheek, nose, and chin.

Pediatric
Safety and efficacy have not been established in patients less than 18 yrs old

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Gel: 0.3% 30g (29616)

ADR:

COMMON
Hypertension, contact dermatitis, erythema, flushing, sensation of burning of skin, xerostomia, somnolence
SERIOUS
Syncope

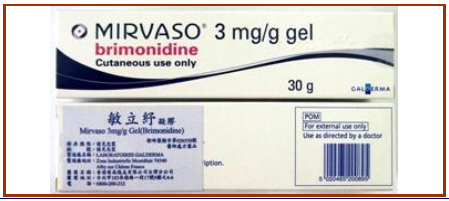
NOTE: 室溫儲存

· Do not apply to eyes or lips

藥名相似:

外觀相似:

外觀描述: 白色紙盒裝，30g凝膠



44.24 Miscellaneous

37523 **ɔt be ruled out / Infant risk can**

Stelara TM Solution for Injection "瑞士"喜達諾TM注射液

Ustekinumab inj 45mg/0.5mL prefilled syringe

Dosage: 1常備品 37523

Adult
· Moderate to severe plaque psoriasis: SC,
≦100kg: 45mg at week 0 and 4, then 45mg every 12 weeks
> 100kg: 45mg or 90mg at week 0 and 4, then 45mg or 90mg every 12 weeks

≧12 yrs
< 60 kg: 0.75 mg/kg(0.0083ml/kg)
60-100 kg: 45mg
≧100 kg: 90 mg

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 45mg/0.5mL prefilled syringe(37523), 45mg/0.5mL vial(37519, 專案捐贈)

ADR:

COMMON
Erythema at injection site, Pruritus, Vomiting, Headache, Urinary tract infectious disease, Mycosis, Bronchitis, Nasopharyngitis, Sinusitis, Upper respiratory infection, Fatigue, Infectious disease.
SERIOUS
Non-melanoma skin cancer, Anaphylaxis, Hypersensitivity reaction, Posterior reversible encephalopathy syndrome, Cryptogenic organizing pneumonia, Interstitial pneumonia, Pulmonary eosinophilia, Angioedema, Cancer,Serious Infectious disease.

NOTE: 冰箱冷藏，不可冷凍。

· It should not be given concurrently with live vaccines.
· BCG vaccines should not be given 1 year prior to, during, or 1 year following treatment.
·若治療達28週仍顯示無治療反應，應考慮停止治療。
·建議每次注射都應施打於和上次不同部位(如上臂、臀部區域、大腿、或腹部的任一四分區塊)，並且不可注入皮膚有觸痛、瘀傷、紅斑或硬化現象的區域。

藥名相似:

外觀相似:

外觀描述:

44.24 Miscellaneous

37635 **ɔt be ruled out / Infant risk can**

LUMICEF* Subcutaneous Injection 210mg Syringe 立美西膚皮下注射劑210毫克

急用 Brodalumab 210mg/1.5mL pre-filled syringe

Dosage: 2急用藥 37635

Adult

· Moderate to severe plaque psoriasis, in patients who are candidates for phototherapy or systemic therapy and have failed other systemic therapies: SC, 210 mg at week 0, 1, and 2, then every 2 weeks thereafter; if an adequate response is not seen after 12 to 16 weeks, consider discontinuation as a response is unlikely

Pediatric

· Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Inj: 210mg/1.5mL prefilled syringe(37635)

ADR:

COMMON
Diarrhea, infectious disease, mycosis, arthralgia, headache, pain in throat, fatigue
SERIOUS
Grade 3 or greater neutropenia, cryptococcal meningitis, suicidal thoughts, suicide

NOTE: 冰箱冷藏，不可冷凍

· Prior to initiation, evaluate for TB infection

藥名相似:

外觀相似:

外觀描述:

44.24 Miscellaneous

37636 ɔt be ruled out / Infant risk can

TREMFYA Solution for injection 特諾雅注射液

Guselkumab inj 100mg/1mL pre-filled syringe

Dosage: 1常備品 37636

Adult

· Plaque psoriasis, Moderate to severe disease, in patient who are candidates for systemic therapy or phototherapy: SC, 100 mg at week 0, week 4, then every 8 weeks.

Pediatric

· Safety and efficacy have not been established in pediatric patients.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 100mg/1mL prefilled syringe(37636)

ADR:

COMMON
Bronchitis, Upper respiratory infection.
SERIOUS
Anaphylaxis, Hypersensitivity reaction, Tuberculosis, Infectious disease.

NOTE: 冰箱冷藏，不可冷凍

·《Contraindications》History of serious hypersensitivity reaction to guselkumab or to any of the excipients ;
·Prior to initiation, evaluate patients for TB infection.
·開始使用本藥治療前，應檢查病人是否患有B型與C型肝炎感染症。

藥名相似:

外觀相似:

外觀描述: 預充填式針筒

44.24 Miscellaneous

37638 ɔt be ruled out / Infant risk can

TALTZ* injection 達癬治注射劑

急用IXEKIZUMAB 80mg/1mL prefilled autoinjection

Dosage: 2急用藥 37638

· Moderate-to-severe plaque psoriasis: SC,160 mg at week 0, followed by 80 mg at weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks.

· Safety and efficacy have not been established in patients less than 18 years old.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Inj: 80mg/1mL prefilled autoinjection(37638)

ADR:

Common: Injection site reaction (17%)、Neutropenia (11%)、Upper respiratory infection (14%)。

Serious:Hypersensitivity reaction、Infectious disease (27 to 57%)。

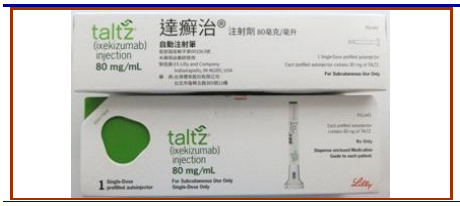
NOTE: 冰箱冷藏，不可冷凍

Prior to initiating therapy, evaluate for TB infection and if active infection, do not initiate ixekizumab. Treat latent TB prior to ixekizumab. Consider anti-TB therapy prior to initiation of ixekizumab if an adequate course of treatment cannot be confirmed in patients with a past history of latent or active TB.

藥名相似:

外觀相似:

外觀描述: 自動注射筆



44.24 Miscellaneous

37639 **ɔt be ruled out / Infant risk can**

DUPIXENT* solution for injection 300mg 杜避炎注射劑 300毫克

急用Dupilumab inj 300mg/2mL prefilled syringe

Dosage: 2急用藥 37639

Adult
· Atopic dermatitis, Moderate to severe, not adequately controlled with topical therapies or when those therapies are inadvisable: Initial, 600 mg SC, divided in 2 different injection sites, then 300 mg SC every other week.

Pediatric
· Safety and efficacy have not been established in patients less than 18 years old.

Dosing adjustments in hepatic impairment:

No dosage adjustment needed

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Inj: 300mg/2mL prefilled syringe(37709, 專案捐贈; 37639, 急用)

ADR:

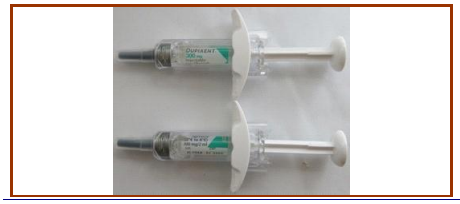
Injection site reaction, Oral herpes simplex infection , Herpes simplex, Excluding oral and ophthalmic herpes simplex , Blepharitis, Conjunctivitis , Dry eyes , Itching of eye , Keratitis .

NOTE: 冰箱冷藏，不可冷凍。

藥名相似:

外觀相似:

外觀描述: 2mL注射液，預填注射器，白色推注器灰色蓋



44.24 Miscellaneous

37989 **B / Caution**

Cosentyx 150mg/mL Solution for Injection 可善挺注射液劑150毫克/毫升

Secukinumab inj 150mg/1mL prefilled syringe

Dosage: 1常備品 37989

Adult: (SC, dosage may be given with or without LD)
· Moderate to severe plaque psoriasis:
LD, 300 mg at wks 0, 1, 2, 3 and 4 then followed by MD 300 mg q 4 wks. Dose of 150 mg may be acceptable for patients with BW ≦ 60Kg or less severe disease.
· Psoriatic arthritis:
LD, 150 mg at wks 0, 1, 2, 3 and 4 then followed by MD 150 mg q 4 wks. Consider a dosage of 300 mg if active disease persists. If coexistent with moderate to severe plaque psoriasis, use the dosage for plaque psoriasis.
· Ankylosing spondylitis:
LD, 150 mg at wks 0, 1, 2, 3 and 4 then followed by MD 150 mg q 4 wks

Pediatric
·Safety and efficacy not established in pediatric patients.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Inj: 150mg/mL prefilled syringe(37989)

ADR:

COMMON
Diarrhea, nasopharyngitis, upper respiratory infection
SERIOUS
Crohn's disease, Crohn's disease exacerbation, inflammatory bowel disease, ulcerative colitis, ulcerative colitis exacerbation, anaphylaxis, infectious disease

NOTE: 冰箱冷藏2-8℃，不可冷凍

· Patient should not receive live vaccines while using this medicine.

藥名相似:

外觀相似:

外觀描述: 預充式針筒注射劑

46.02 Pulmonary Surfactants

32136 UK / No report(毫

SURVANTA 200MG/8ML/VIAL INTRATRACHEAL SUSPENSION 守肺佳氣管吸入懸浮液

Beractant 200mg phospholipids/8mL vial Intratracheal susp

Dosage: 1常備品 32136

NDA·

Pediatric
·Neonates with respiratory distress syndrome (RDS) : Intratracheal, 100mg (or 4mL/kg) 4 doses during first 48hrs of life, no more frequently than 6 hrs apart, by instillation through a 5 French end-hole catheter inserted into the infant's endotracheal tube
·Prophylactic treatment : 100mg (4ml/kg) ; 4 doses during the first 48hrs of life, no more frequently than 6 hrs
·Rescue treatment : 100mg (4ml/kg) as soon as the diagnosis of RDS is made

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Intratracheal susp: 200mg/8ml/vial(32136)

ADR:

SERIOUS
bradycardia, transient, decreased oxygen saturation, endotracheal tube reflux, endotracheal tube blockage.

NOTE: 冰箱冷藏，不可冷凍。

for intratracheal administration only

藥名相似:

外觀相似:

外觀描述: 每小盒1支,8mL『灰白』色混濁氣管吸入懸浮液『紅』蓋玻璃瓶，蓋上有FLIP及OFF字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2019595

46.04B Interferon Beta

31136 C / Unknown(有

REBIF 44 MICROGRAMS 立比扶注射劑 44MCG

急用Interferon beta-1a 44mcg(12MIU)/0.5mL pre-filled syringe

Dosage: 2急用藥 31136

ADULT
·Multiple sclerosis: SC, initial 4 wk dose titration, 8.8 mcg 3 times/wk for weeks 1-2; 22 mcg 3 times/wk for weeks 3-4. MD 44 mcg 3 times/wk

Pediatric
·Safety and efficacy have not been established in patients less than 18 years old.

Dosing adjustments in hepatic impairment:

SGPT >5 times upper limit of normal: consider dose reduction
Discontinue therapy if jaundice or other symptoms of liver dysfunction appear

Dosing adjustments in renal impairment:

NDA

P: Inj: 22mcg(31131), 44mcg(31136, 急用藥)

ADR:

COMMON
flu-like symptoms (fever, chills, myalgia), headache
SERIOUS
anaphylaxis (rare), elevation of liver, enzymes, anemia, leukopenia, thrombocytopenia, psychiatric disorders
seizure, symptomatic hepatic dysfunction (rare)

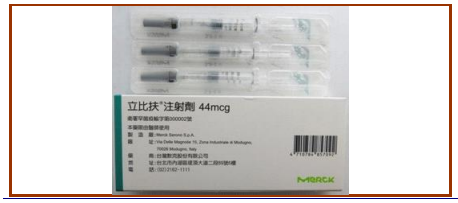
NOTE: 冰箱冷藏，不可冷凍。

Contraindications: hypersensitivity to human albumin

藥名相似:

外觀相似:

外觀描述: 0.5mL含藥透明溶液注射器 ，灰色蓋頭



46.04B Interferon Beta

37851 C / Unknown(有

BETAFERON (INTERFERON BETA-1B) 貝他費隆注射劑

急用Interferon Beta-1B inj 0.3mg(9.6M unit) pow in vial

Dosage: 2急用藥 37851

Adult
·Multiple sclerosis: SC, initial 0.0625 mg every other day, increased by 25% every 1-2 weeks, usual dose 0.25 mg every other day is reached after a 6-week

Pediatric
·Safety and efficacy have not been established in patients less than 18 years old.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 0.25mg(8MIU)/vial

ADR:

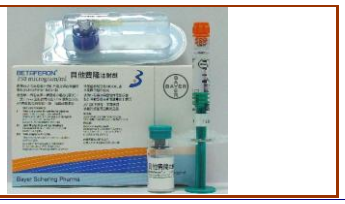
COMMON
flu-like symptoms (fever, chills, myalgia), headache, asthenia, injection site pain, local skin reactions, sweating
SERIOUS
anaphylaxis, depression, mental disorders
elevated hepatic transaminase levels, hypertension, palpitation, tachycardia, injection site necrosis, leukopenia

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色乾粉、『寶藍』蓋透明玻璃小瓶，附含1.2ml稀釋液注射器及轉接頭



46.06 Immunosuppressive Agents

26970 **D / Infant risk can**

MYFORTIC 180MG GASTRO-RESISTANT TABLETS 睦體康１８０毫克腸衣錠

Mycophenolic acid 180mg GR tab

Dosage: 1常備品 26970

Adult
·Rejection prophylaxis of renal transplant: PO, ac, 720mg bid.
·Lupus nephritis: PO, ac, 720mg bid.

Pediatric
·Safety and efficacy have not been established.

Dosing adjustments in hepatic impairment:

Kidney transplantation patients with severe hepatic parenchymal disease: No dosage adjustment needed.

Dosing adjustments in renal impairment:

Delayed graft function after kidney transplant: No dosage adjustment needed.

P: Tab: 180mg(26970)

ADR:

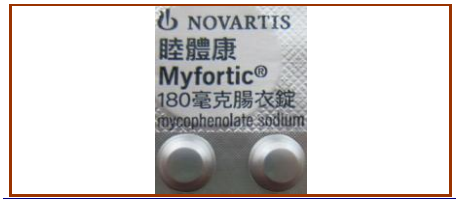
COMMON
·Gastrointestinal: Abdominal pain (less than 10% to 14%), Constipation (38%), Diarrhea (24%), Flatulence (10%), Indigestion (23%), Nausea (29%), Vomiting (23%)
·Neurologic: Insomnia (24 %)
·Renal: Urinary tract infectious disease (29%)
·Other: Cytomegalovirus infection (5% to 20%)
SERIOUS
·Gastrointestinal: Duodenal ulcer disease, Gastric ulcer, Gastrointestinal hemorrhage, Gastrointestinal perforation
·Hematologic: Anemia (22%), Leukopenia (19%), Pure red cell aplasia
·Immunologic: Malignant lymphoma (1%), Opportunistic infection
·Neurologic: Progressive multifocal leukoencephalopathy
·Renal: Kidney disease, Polyomavirus-associated
·Other: Cancer (1%), Infectious disease, Sepsis

NOTE: 儲存30℃以下

藥名相似:

外觀相似:

外觀描述: 綠色圓扁錠，一面有"C"字樣



46.06 Immunosuppressive Agents

26980 **C / Unsafe**

Certican 0.25mg tablets 卓定康錠 0.25 毫克

Everolimus 0.25mg tab

Dosage: 1常備品 26980

Adult
·Renal transplant rejection; prophylaxis: PO, 0.75mg q12h in combination with reduced-dose cyclosporine and corticosteroids
·Liver transplant rejection; prophylaxis (begin at least 30 days post-transplant): PO, 1mg q12h in combination with reduced-dose tacrolimus and corticosteroids

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild hepatic impairment (Child-Pugh class A):
Reduce initial dose by 33%
Moderate hepatic impairment (Chld-Pugh Class B):
Reduce initial dose by 50%
Severe hepatic impairment (Child-Pugh Class C):
Reduce initial dose by at least 50%

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 5mg(27579,急用)(27979,專案捐贈); 2.5mg(27569,急用)(27978,專案捐贈); 0.5mg(27567,急用); 0.25mg(26980)

ADR:

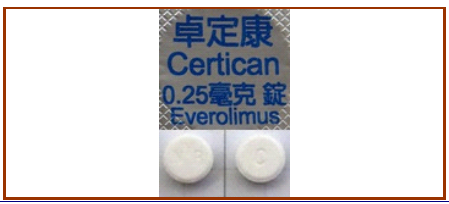
NOTE: 室溫儲存

·Swallow whole; do not crush or chew.
·Administer either consistently with food or consistently without food.
·Dosage may be adjusted every 4 to 5 days based on blood concentrations (target trough concentration: 3-8 ng/mL)
·Use of strong CYP3A4 inducers or inhibitors with CERTICAN* is not recommended.

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有" NVR"，另一面有"C"字樣



46.06 Immunosuppressive Agents

27210 D / Caution

CELLCEPT CAPSULES 250MG 山喜多膠囊 2 5 0 毫克

Mycophenolate mofetil 250mg cap

Dosage: 1常備品 27210

·Rejection prophylaxis of cardiac transplant, hepatic transplant: PO, ac, 1.5 g bid
·Rejection prophylaxis of renal transplant: PO, ac, 1g bid
·Lupus nephritis: PO, ac, Induction: 0.75-1.5 g bid; Maintenance: 0.25-1g bid

·Rejection prophylaxis of renal transplant: PO,ac
BSA 1.25-1.5 m(2): 750 mg bid
BSA > 1.5 m(2): 1g bid

Dosing adjustments in hepatic impairment:

Kidney transplantation patients with severe hepatic parenchymal disease: No dosage adjustment needed.

Dosing adjustments in renal impairment:

1. Renal transplant (GFR < 25 mL/min), who are outside of the immediate post-transplant period: < 1 g bid.
2. Delayed graft function after kidney transplant: No dosage adjustment needed.
3. Heart or liver transplantation with severe chronic renal failure: NDA

P: Cap: 250mg(27210)

ADR:

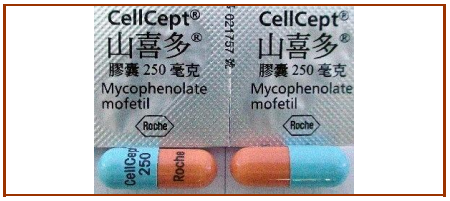
COMMON
Hypertension, Peripheral edema, Hyperglycemia, Hypokalemia, Abdominal pain, Constipation, Diarrhea, Nausea, Vomiting, Backache, Anxiety, Asthenia, Dizziness, Insomnia, Paresthesia, Tremor, Serum blood urea nitrogen raised, Serum creatinine raised, Urinary tract infectious disease, Disorder of lung, Dyspnea, Increasing frequency of cough, Respiratory tract infection, Fever, Pain
SERIOUS
Gastric ulcer, Gastrointestinal hemorrhage, Gastrointestinal perforation, Anemia, Leukopenia, Neutropenia (Severe), Pure red cell aplasia, Thrombocytopenia, Malignant epithelial neoplasm of skin, non-melanoma, Malignant lymphoma, Opportunistic infection, Sepsis, Progressive multifocal leukoencephalopathy, Disease due to Polyomavirus, Pleural effusion, Pulmonary fibrosis

NOTE: 室溫儲存

藥名相似:

外觀相似: Capecitabine 500mg tab(21613)

外觀描述: 淺藍色/土黃色膠囊，有CellCept 250及Roche字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2021757

46.06 Immunosuppressive Agents

27520 ɔt be ruled out / Infant risk can

PROGRAF CAPSULES 1MG 普樂可復膠囊1毫克

Tacrolimus 1mg cap

Dosage: 1常備品 27520

· Liver transplant rejection; prophylaxis: PO, 0.1-0.15mg/kg/day in 2 divided doses q12 hr
· Renal transplant rejection; prophylaxis: PO, 0.2 mg/kg/day in 2 divided doses q12 hr

· Liver transplant rejection; prophylaxis: PO, 0.15-0.2 mg/kg/day in 2 divided doses q12 hr

Dosing adjustments in hepatic impairment:

Use lower end of dosing range and monitor blood concentrations

Dosing adjustments in renal impairment:

Use lower end of dosing range and monitor blood concentrations

P: Cap: 1mg(27520), 5mg(27527, 急用藥), 0.5mg(27543, 急用藥); Oint: 0.1% 5g/tube (29449)

ADR:

COMMON
Peripheral edema, Alopecia, Persistent erythema of skin, Persistent erythema of skin, Pruritus, Rash, Constipation, Diarrhea, Nausea, Vomiting, Anemia, Leukocytosis, Thrombocytopenia, Headache, Insomnia, Paresthesia, Tremor, Serum creatinine raised, Increasing frequency of cough.
SERIOUS
Atrial fibrillation, Cardiac arrest, Cardiomegaly, Congestive heart failure, Hypertension, Myocardial infarction, Prolonged QT interval, Diabetes mellitus, Post-transplant, Hyperkalemia, Hypomagnesemia, Gastrointestinal perforation, Pure red cell aplasia, Hepatitis, Hepatotoxicity, Anaphylaxis, Infectious disease, Lymphoproliferative disorder, Malignant lymphoma, Opportunistic infection, Posterior reversible encephalopathy syndrome, Seizure, Acute renal failure, Hemolytic uremic syndrome, Nephrotoxicity, Acute respiratory distress syndrome.

NOTE: 室溫儲存30℃以下

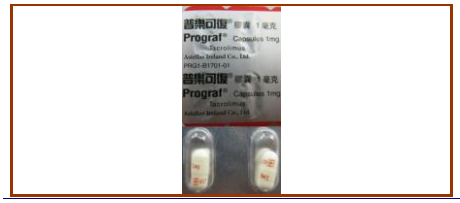
1. Liver transplantation:
· Start therapy no sooner than 6 hrs after transplant
· Trough concentration is 5-20 ng/mL at 1-12 months
2. Kidney transplantation:
· Start therapy within 24 hrs of transplantation or when renal function is recovered
· Trough concentration is 7-20 ng/mL and 5-15 ng/mL at 1-3 months and 4-12 months, respectively
3.此藥與PVC不相容。用於製備或投與本藥膠囊內容物懸浮液的管路、灌食器和其他設備不可含有PVC。
4.可能發生高鉀血症，故應常監測血清鉀值，避免同時併用保鉀型利尿劑或攝取過多的鉀。
5.可能發生心臟衰竭、心律不整、狹心症、心肌梗塞、心肌功能不全(包含心臟功能低下、心室肥大)等，使用時要做心電圖、心臟超音波、胸部 X 光檢查及其他檢查，詳細觀察病人狀態，若發現有異常時，減低劑量或暫

時停藥等處置。

藥名相似:

外觀相似:

外觀描述: 白色膠囊，有1mg及617字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2022043

46.06 Immunosuppressive Agents

27527 ɔt be ruled out / Infant risk can

PROGRAF CAPSULES 5MG 普樂可復膠囊5毫克

急用Tacrolimus 5 mg cap

Dosage: 2急用藥 27527

· Liver transplant rejection; prophylaxis: PO, 0.1-0.15mg/kg/day in 2 divided doses q12 hr
· Renal transplant rejection; prophylaxis: PO, 0.2 mg/kg/day in 2 divided doses q12 hr

· Liver transplant rejection; prophylaxis: PO, 0.15-0.2 mg/kg/day in 2 divided doses q12 hr

Dosing adjustments in hepatic impairment:

Use lower end of dosing range and monitor blood concentrations

Dosing adjustments in renal impairment:

Use lower end of dosing range and monitor blood concentrations

P: Cap: 1mg(27520), 5mg(27527, 急用藥), 0.5mg(27543, 急用藥); Oint: 0.1% 5g/tube (29449)

ADR:

COMMON
Peripheral edema, Alopecia, Persistent erythema of skin, Persistent erythema of skin, Pruritus, Rash, Constipation, Diarrhea, Nausea, Vomiting, Anemia, Leukocytosis, Thrombocytopenia, Headache, Insomnia, Paresthesia, Tremor, Serum creatinine raised, Increasing frequency of cough.
SERIOUS
Atrial fibrillation, Cardiac arrest, Cardiomegaly, Congestive heart failure, Hypertension, Myocardial infarction, Prolonged QT interval, Diabetes mellitus, Post-transplant, Hyperkalemia, Hypomagnesemia, Gastrointestinal perforation, Pure red cell aplasia, Hepatitis, Hepatotoxicity, Anaphylaxis, Infectious disease, Lymphoproliferative disorder, Malignant lymphoma, Opportunistic infection, Posterior reversible encephalopathy syndrome, Seizure, Acute renal failure, Hemolytic uremic syndrome, Nephrotoxicity, Acute respiratory distress syndrome.

NOTE: 室溫儲存

1. Liver transplantation:
· Start therapy no sooner than 6 hrs after transplant
· Trough concentration is 5-20 ng/mL at 1-12 months
2. Kidney transplantation:
· Start therapy within 24 hrs of transplantation or when renal function is recovered
· Trough concentration is 7-20 ng/mL and 5-15 ng/mL at 1-3 months and 4-12 months, respectively
3.此藥與PVC不相容。用於製備或投與本藥膠囊內容物懸浮液的管路、灌食器和其他設備不可含有PVC。
4.可能發生高鉀血症，故應常監測血清鉀值，避免同時併用保鉀型利尿劑或攝取過多的鉀。
5.可能發生心臟衰竭、心律不整、狹心症、心肌梗塞、心肌功能不全(包含心臟功能低下、心室肥大)等，使用時要做心電圖、心臟超音波、胸部 X 光檢查及其他檢查，詳細觀察病人狀態，若發現有異常時，減低劑量或暫時停藥等處置。

藥名相似:

外觀相似:

外觀描述: 淺紅色膠囊，有5mg及657字樣

46.06 Immunosuppressive Agents

27543 ɔt be ruled out / Infant risk can

PROGRAF CAPSULES 0.5MG 普樂可復膠囊0.5毫克

急用Tacrolimus 0.5mg cap

Dosage: 2急用藥 27543

· Liver transplant rejection; prophylaxis: PO, 0.1-0.15mg/kg/day in 2 divided doses q12 hr
· Renal transplant rejection; prophylaxis: PO, 0.2 mg/kg/day in 2 divided doses q12 hr

· Liver transplant rejection; prophylaxis: PO, 0.15-0.2mg/kg/day in 2 divided doses q12 hr

Dosing adjustments in hepatic impairment:

Use lower end of dosing range and monitor blood concentrations

Dosing adjustments in renal impairment:

Use lower end of dosing range and monitor blood concentrations

P: Cap: 1mg(27520), 5mg(27527, 急用藥), 0.5mg(27543, 急用藥); Oint: 0.1% 5g/tube (29449)

ADR:

COMMON
Peripheral edema, Alopecia, Persistent erythema of skin, Persistent erythema of skin, Pruritus, Rash, Constipation, Diarrhea, Nausea, Vomiting, Anemia, Leukocytosis, Thrombocytopenia, Headache, Insomnia, Paresthesia, Tremor, Serum creatinine raised, Increasing frequency of cough.
SERIOUS
Atrial fibrillation, Cardiac arrest, Cardiomegaly, Congestive heart failure, Hypertension, Myocardial infarction, Prolonged QT interval, Diabetes mellitus, Post-transplant, Hyperkalemia, Hypomagnesemia, Gastrointestinal perforation, Pure red cell aplasia, Hepatitis, Hepatotoxicity, Anaphylaxis, Infectious disease, Lymphoproliferative disorder, Malignant

lymphoma, Opportunistic infection, Posterior reversible encephalopathy syndrome, Seizure, Acute renal failure, Hemolytic uremic syndrome, Nephrotoxicity, Acute respiratory distress syndrome.

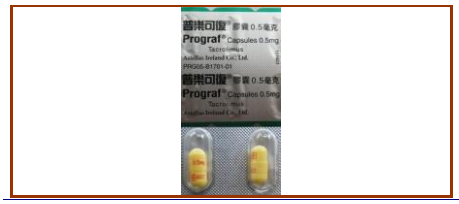
NOTE: 室溫儲存

1. Liver transplantation:
· Start therapy no sooner than 6 hrs after transplantation
· Trough concentration is 5-20 ng/mL at 1-12 months
2. Kidney transplantation:
· Start therapy within 24 hrs of transplantation or when renal function is recovered
· Trough concentration is 7-20 ng/mL and 5-15 ng/mL at 1-3 months and 4-12 months, respectively
3.此藥與PVC不相容。用於製備或投與本藥膠囊內容物懸浮液的管路、灌食器和其他設備不可含有PVC。

藥名相似:

外觀相似:

外觀描述: 淺黃色膠囊，有0.5mg及607字樣



46.06 Immunosuppressive Agents

27547 ɔt be ruled out / Unsafe

RAPAMUNE TABLETS 1MG 斥消靈錠1毫克

急用Sirolimus 1mg tab

Dosage: 2急用藥 27547

Adult
· Prophylaxis renal transplant rejection in patients at low to moderate immunologic risk: PO, ≧40kg: 6mg on day 1, followed by maintenance dose of 2mg/day starting on day 2; <40kg: 3mg/m(2) on day 1, followed by maintenance dose of 1mg/m(2) starting on day 2; Max. 40mg/day
· Prophylaxis renal transplant rejection in patients at high immunologic risk: PO, ≧40kg: 15mg on day 1, followed by maintenance dose of 5mg/day starting on day 2; <40kg: 3mg/m(2) on day 1, followed by maintenance dose of 1mg/m(2) starting on day 2; Max. 40mg/day

Pediatric (≧13 yrs)
· Prophylaxis renal transplant rejection in patients at low to moderate immunologic risk: Same as adult

Dosing adjustments in hepatic impairment:

Loading dose: No dosage adjustment needed
Mild to moderate hepatic impairment: Reduce maintenance dose by 33%
Severe hepatic impairment: Reduce maintenance dose by 50%

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 1mg(27547)

ADR:

COMMON
Chest pain, Edema, Peripheral edema, Acne, Rash, Hypercholesterolemia, Hyperlipidemia, Hypertriglyceridemia, Abdominal pain , Constipation, Diarrhea, Nausea, Stomatitis, Anemia, Thrombocytopenia, Arthralgia, Myalgia, Dizziness, Headache, Serum creatinine raised, Urinary tract infectious disease, Bleeding from nose, Nasopharyngitis, Upper respiratory infection, Fever, Pain.
SERIOUS
Coronary artery stent thrombosis, Basal cell carcinoma of skin, Malignant melanoma of skin, Squamous cell carcinoma, Deep venous thrombosis, Lymphocele, Pancytopenia, Thrombotic thrombocytopenic purpura, Venous thromboembolism, Hepatic artery thrombosis, Hypersensitivity reaction, Kidney disease, BK virus associated, Malignant lymphoma, Mycobacteriosis, Sepsis, Progressive multifocal leukoencephalopathy, Hemolytic uremic syndrome, Nephrotic syndrome, Bronchial anastomotic dehiscence, Interstitial lung disease, Interstitial pneumonia, Pulmonary embolism, Pulmonary hemorrhage, Angioedema, Cancer.

NOTE: 室溫儲存

1. Serum concentrations should be determined 3-4 days after loading dose and 7-14 days after dosage adjustments.
2. Therapeutic Drug Concentration (chromatographic assay)
· Trough concentration in patients at low to moderate immunologic risk): 16-24ng/mL for the first year; thereafter, target concentrations should be 12-20ng/mL.
· Trough concentration in patients at high immunologic risk: 10-15ng/mL from initiation of therapy until week 52.
· Ranges will vary with assay methodology and are not interchangeable.
3. Dosage should be adjusted at intervals of 7-14 days to account for the long half-life. New dosage = current dosage * (target concentration/current concentration)
4. If an estimated daily dose exceeds 40mg due to the addition of a loading dose, the loading dose should be administered over 2 days.
5. It should be taken 4 hours after cyclosporine.
6. Postmarketing:
·diabetes mellitus incidence: 3% to less than 20%
·posterior reversible encephalopathy syndrome has been reported in postmarketing experience.

藥名相似:

外觀相似:

外觀描述: 白色三角形錠，有RAPAMUNE及1mg字樣

46.06 Immunosuppressive Agents

27567 C / Unsafe

Certican 0.5mg tablets 卓定康錠 0.5 毫克

■■急用Everolimus 0.5mg tab

Dosage: 2急用藥 27567

Adult
·Renal transplant rejection; prophylaxis: PO, 0.75mg q12h in combination with reduced-dose cyclosporine and corticosteroids
·Liver transplant rejection; prophylaxis (begin at least 30 days post-transplant): PO, 1mg q12h in combination with reduced-dose tacrolimus and corticosteroids

Pediatric
Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

Mild hepatic impairment (Child-Pugh class A): Reduce initial dose by 33%
Moderate hepatic impairment (Chld-Pugh Class B): Reduce initial dose by 50%
Severe hepatic impairment (Child-Pugh Class C): Reduce initial dose by at least 50%

Dosing adjustments in renal impairment:

No dosage adjustment needed

P: Tab: 5mg(27579,急用)(27979,專案捐贈); 2.5mg(27569,急用)(27978,專案捐贈); 0.5mg(27567,急用)

ADR:

COMMON
Hypertension, peripheral edema, acne, dyslipidemia, hypercholesterolemia, hyperlipidemia, hypophosphatemia, increased glucose level, constipation, diarrhea, decrease in appetite, nausea, stomatitis, vomiting, anemia, thrombocytopenia, alkaline phosphatase raised, impaired wound healing, serum creatinine raised, urinary tract infectious disease, cough, upper respiratory infection, fatigue, fever
SERIOUS
Leukopenia, pancytopenia, thrombosis, thrombotic microangiopathy, thrombotic thrombocytopenic purpura, venous thromboembolism, infectious disease, thrombosis of renal artery, interstitial lung disease, pulmonary embolism, sepsis

NOTE: 室溫儲存

·Swallow whole; do not crush or chew.
·Administer either consistently with food or consistently without food.
·Dosage may be adjusted every 4 to 5 days based on blood concentrations (target trough concentration: 3-8 ng/mL)
·Use of strong CYP3A4 inducers or inhibitors with CERTICAN* is not recommended.

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠，一面有NVR字樣，另一面有CH字樣

46.06 Immunosuppressive Agents

27890 C / Unsafe

Gilenya hard capsules 0.5mg 捷力能膠囊 0.5 毫克

急用Fingolimod 0.5mg cap

Dosage: 2急用藥 27890

Adult
·Relapsing forms of multiple sclerosis: PO, 0.5mg qd

Pediatric
.

Dosing adjustments in hepatic impairment:

Mild-to-moderate impairment: No dosage adjustment needed
Severe impairment: Use with caution

Dosing adjustments in renal impairment:

NDA

P: Cap: 0.5mg (27890)

ADR:

COMMON
Diarrhea, increased liver enzymes, backache, headache, cough, influenza
SERIOUS
Atrioventricular block, bradyarrhythmia, malignant melanoma, severe lymphocytopenia, macular retinal edema

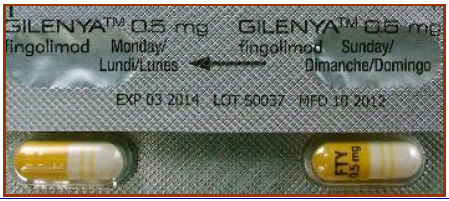
NOTE: 室溫儲存

·Observe all patients for 6 hrs for signs and symptoms of bradycardia with hourly pulse and blood pressure measurement after the first dose.
·If therapy is interrupted for ≧1 day during the first 2 weeks, for >7 days during the third and fourth weeks or for >14 days after the first month, first-dose monitoring are recommended upon reinitiation.
·Avoid live attenuated vaccines during and for 2 mons after treatment because of the risk of infection.
·Women of childbearing potential should avoid pregnancy during and for 2 mons after discontinuing treatment.

藥名相似:

外觀相似:

外觀描述: 白色/黃色膠囊，有FTY及0.5mg字樣



46.06 Immunosuppressive Agents

28701 C / Unsafe

SANDIMMUN NEORAL ORAL SOLUTION 100MG/ML 新體睦口服溶液每毫升100毫克

■急用Ciclosporin 100mg/mL 50mL/B Soln

Dosage: 2急用藥 28701

Adult
· Aplastic anemia: PO, 5 mg/kg/day in two divided doses
· Atopic dermatitis: PO, initial 2.5 mg/kg divided 2 doses; in severe cases, therapy may be started at 5 mg/kg/day. Dose may be increased by 1 mg/kg/day to a maximum of 5 mg/kg/day. After 8 weeks, slow tapering is recommended
· Organ transplant: PO, 15 mg/kg has been administered 4 to 12 hours before operation; MD: 5 to 10 mg/kg/day
· Psoriasis: PO, initial 1.25 mg/kg/day divided twice daily, Max. 4 mg/kg/day
· RA: PO, initial 2.5 mg/kg/day divided twice daily, Max. 4 mg/kg/day

Pediatric
· Organ rejection prophylaxis: PO, 15 mg/kg has been administered 4 to 12 hours before operation; MD: 5 to 10 mg/kg/day
· Bone marrow transplant: PO, 6.25 mg q12h
· Autoimmune disease: PO, 1-3 mg/kg/day; psoriasis patients may require doses up to 5-7 mg/kg/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Serum creatinine >30% of baseline: 0.5 to 0.75 mg/kg/day if remains,hold one month and reduce or discontinue other nonsteroidal antiinflammatory drugs. If serum creatinine returns to less than or equal to 15% baseline,resume cyclosporin therapy

P:

ADR:

COMMON
headache, hirsutism, N/V, diarrhea, tremor
SERIOUS
convulsion, gum hyperplasia, hepatotoxicity, hyperkalemia, hypomagnesemia, hypertension, infection, nephrotoxicity, hemolytic-uremic syndrome, pancreatitis, paresthesia, post-transplant lymphoproliferative disorder

NOTE: 室溫儲存

1.Neoral are not bioequivalent to Sandimmune
2.本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 50mL口服液,褐色透明玻璃瓶,附有保護盒之量取吸管)

46.06 Immunosuppressive Agents

37591 C / Infant risk can

Soliris 300 mg concentrate for solution for infusion 舒立瑞 濃縮靜脈輸注液 300毫克

急用Eculizumab inj 300mg/30mL vial

Dosage: 2急用藥 37591

Adult
·Paroxysmal nocturnal hemoglobinuria (PNH): IV infusion over 35 min, 600mg/wk for the first 4 wks, then 900 mg for the 5th dose, then 900 mg q 2 wks
·Atypical hemolytic uremic syndrome (aHUS): IV infusion over 35 min, 900 mg/wk for the first 4 wks, then 1200 mg for the 5th dose, then 1200 mg q 2 wks

Pediatric
·Atypical hemolytic uremic syndrome (aHUS): IV infusion over 35 min.
>=40kg: same as adult
30-40kg: 600 mg/wk for the first 2 wks, then 900mg for the 3rd dose, then 900 mg q 2 wks
20-30kg: 600 mg/wk for the first 2 wks, then 600mg for the 3rd dose, then 600 mg q 2 wks
10-20kg: 600 mg for the first wk, then 300mg at wk 2, then 300 mg q 2 wks
5-10kg: 300 mg for the first wk, then 300mg at wk 2, then 300 mg q 3 wks

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P: 300mg/30mL vial (37591)

ADR:

COMMON
Hypertension (35%), diarrhea (32%), nausea (16% to 19%), vomiting (21% to 22%), anemia (2% to 24%), backache (19%), headache (2% to 44%), nasal congestion, nasopharyngitis (23%), respiratory tract infection (7% to 35%), fever (2% to 47%)
SERIOUS
Leukopenia (16%), viral disease (2%), infectious disease (14%), meningococcal infectious disease

NOTE: 冰箱儲存2-8℃

警告: 嚴重腦膜炎球菌感染，曾有過發生危及性命與致死性腦膜炎球菌感染症的案例，可能迅速發展到危及性命或致死的程度。
· 應遵守傳染病防治諮詢委員會預防接種組(ACIP)對腦膜炎預防注射的最新建議，給予補體缺乏病人接種腦膜炎球菌疫苗。
· 除非延後給予舒立瑞療法的危險性遠大於出現腦膜炎球菌感染的危險性，否則應安排病人接種腦膜炎球菌疫苗2週
後，再施打第一劑舒立瑞。
· 監測病人是否有腦膜炎球菌感染的早期病徵，若懷疑受到感染應立即進行評估。

藥名相似:

外觀相似:

外觀描述:

46.06 Immunosuppressive Agents

37602 C / Unsafe

SANDIMMUN CONCENTRATE FOR INTRAVENOUS INFUSIO 生體睦靜脈輸注濃縮液

■Ciclosporine (cyclosporine) inj 50mg/1mL amp

Dosage: 1常備品 37602

Adult

· Organ transplant: IV infusion over 2-6 hrs, 5-6 mg/kg/day beginning 4-12 hrs prior to organ transplantation

Pediatric

· Organ transplant: >18 y/r, same as adult.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Serum creatinine >30% of baseline: 0.5 to 0.75 mg/kg/day if remains, hold one month and reduce or discontinue other nonsteroidal antiinflammatory drugs. If serum creatinine returns to less than or equal to 15% baseline, resume cyclosporin therapy

P: Soft cap: 25mg(27214)(27239, 急用藥), 100mg(27234); Inj: 50mg/1mL Amp(37602); Soln: 50mL/B (28701, 急用藥)Oph emulsion: 0.05%, 0.4mL/amp, 32amp/box(29275)

ADR:

COMMON
headache, hirsutism, N/V, diarrhea, tremor
SERIOUS
anaphylaxis, convulsion, gum hyperplasia, hepatotoxicity, hyperkalemia, hypomagnesemia, hypertension, infection, nephrotoxicity, hemolytic-uremic syndrome, pancreatitis, paresthesia, post-transplant lymphoproliferative disorder

NOTE: 避光儲存

1.Neoral are not bioequivalent to Sandimmune

藥名相似:

外觀相似:

外觀描述: 1mL透明注射液透明安瓿，頸部有藍點及1條黃色線條和1條藍色線條

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=2013049

46.06 Immunosuppressive Agents

37630 C /

Benlysta Powder for Solution for Infusion 奔麗生凍晶注射劑

急用Belimumab 120mg vial

Dosage: 2急用藥 37630

Adult

· Systemic lupus erythematosus (SLE): I.V.: Initial: 10 mg/kg every 2 weeks for 3 doses; Maintenance: 10 mg/kg every 4 weeks

Pediatric

· Safety and effectiveness not established in pediatric patients

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: P inj: 120mg vial (37630)

ADR:

COMMON
Diarrhea, nausea, infectious disease, infusion reaction, nasopharyngitis, fever
SERIOUS
Anaphylaxis, immune hypersensitivity reaction, infectious disease (serious) , infusion reaction (serious) , progressive multifocal leukoencephalopathy, depression, mental disorder, bronchitis, cancer

NOTE: Refrigerate, Protect from light

Do NOT administer as an I.V. push or bolus.

藥名相似:

外觀相似:

外觀描述:

46.06 Immunosuppressive Agents

37632 B / Infant risk has

SIMULECT LYOPHILISATE FOR INJECTION 4MG/ML 新睦樂凍晶注射劑

Basiliximab inj 20mg pow in vial

Dosage: 1常備品 37632

Adult

· Renal transplant rejection prophylaxis, in combination with cyclosporine and corticosteroids: IV, 20 mg within 2 hr before transplant surgery; then another 20 mg IV dose day 4 post-op.

Pediatric (1-17yrs)

· Renal transplant rejection prophylaxis, in combination with cyclosporine and corticosteroids: < 35 kg: IV, 10 mg within 2 hr before transplant surgery; then another 10 mg IV dose day 4 post-op. ≧35 kg: Same as adult

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Inj: 20mg vial with 5mL solvent(37632)

ADR:

COMMON
Hypertension (Adults, 10% or greater; pediatric, 49%), abdominal pain (10% or greater), Constipation (10% or greater), Diarrhea (10% or greater), Indigestion (10% or greater), Nausea (10% or greater), Vomiting (10% or greater), Urinary tract infectious disease (Adults, greater than 10%; pediatric, 46%), Rhinitis (Pediatric, 49%), Fever (Adult, greater than 10%; pediatric, 39%), Hypertrichosis (Pediatric, 49%)
SERIOUS
Thrombosis (10.7%), Allergic reaction, acute, Cytomegalovirus infection (Triple immunosuppression therapy, 11%), Lymphoproliferative disorder (Pediatric, 16.2%), Pulmonary edema

NOTE: 冰箱冷藏，不可冷凍

· Women of childbearing potential should use effective contraception before, during, and for 4 months following therapy.
· Women should not breastfeed for 4 months following the last dose.
· Reconstituted basilixmab (20 mg in 5 mL) should be diluted to a volume of 50 mL with normal saline or dextrose 5% and administered as an intravenous infusion over 20 to 30 minutes.

藥名相似:

外觀相似:

外觀描述:

46.08 Miscellaneous

22505 b2 / Caution

MERISLON* 12mg tab 敏使朗錠

Betahistine mesylate 12mg tab

Dosage: 1常備品 22505

Adult
·Meniere's disease, cerebrovascular disease and other audiovestibular disorders: PO, 8-16 mg 3 times daily.

Pediatric
.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 12mg(22505)

ADR:

NOTE: 室溫儲存

·Antihistamines may block some or all of intended effects of betahistine

藥名相似:

外觀相似: Neuquinon* 10mg Tab (26814)

外觀描述: 白色圓扁錠，一面中間有刻痕及MR12 字樣

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1029356

46.08 Miscellaneous

22568 ɔt be ruled out / Infant risk can

SYNTAM* F.C. TABLETS 1200MG 欣坦膜衣錠1200毫克

Piracetam 1200mg FC tab

Dosage: 1常備品 22568

Adult
·Potential efficacy in cerebrovascula insufficiencies and age-associated intelligence disturbace: PO, initial 4.8g/day, when the desired effect has been obtained, gradually reduce to 1.2-2.4g/day.
·Supplemental therapy in cortical myoclonus: PO, 7.2g/day increasig by 4.8g/day every 3 or 4 days. Max. 24g/day divided into 2-3 doses.

Pediatric
·Potential efficacy in dyslexia: PO, 1.65 gm bid.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 40-60 mL/min: 1/2 usual dose
Clcr 20-40 mL/min: 1/4 usual dose
Clcr <20 mL/min: Contraindiaction

P: Cap: 400mg (22602);Tab: 1.2g (22568); Soln: 200mg/mL 200mL/bot(28710); Inj:1g/5mL Amp (32202)

ADR:

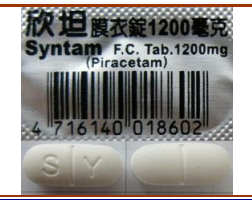
NOTE: 室溫儲存

Contraindication: Huntington's chorea, Clcr <20 mL/min

藥名相似:

外觀相似:

外觀描述: 白色長橢圓錠，兩面中央有刻痕，一面有有"S | Y"字樣



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1046681

46.08 Miscellaneous

26814 / Unknown(有

NEUQUINON S.C. TABLETS 10 MG 能淤奇朗糖衣錠 1 0 毫克

Ubidecarenone (Coenzyme Q10, Ubiquinone 10) 10mg tab

Dosage: 1常備品 26814

Adult
·Supplemental therapy in congestive heart failure: PO, 50-150mg/day divided into 2-3 times

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

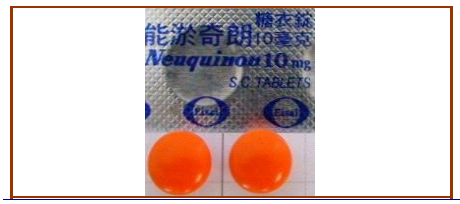
Diarrhea, nausea, heartburn, appetite suppression, headache, dizziness, irritability, agitation, mild increase in liver enzymes, skin rash, pruritus, exanthema

NOTE: 避光儲存

藥名相似:

外觀相似: Solantin* 25mg Tab(22533), Nordazepam 5m

外觀描述: 橘色圓扁糖衣錠



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1040042

46.08 Miscellaneous

27501 C /

Phenbuty 500mg Tablets 芬必提500毫克錠

急用Sodium phenylbutyrate 500mg tab

Dosage: 2急用藥 27501

·Urea cycle disorders: PO, 450 to 600 mg/kg daily in patients weighing less than 20 kilograms and 9.9 to 13 g/m(2)/day in larger patients.Tablets should be taken in divided daily doses with meals

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 500mg(27501)

ADR:

aplastic anemia, ankle or peripheral edema, arrhythmias, syncope, headache, depression, hypoalbuminemia, weight gain, anorexia, epigastric discomfort, menstrual cycle irregularities, renal tubular acidosis, hepatoxicity, skin rash, offensive body odor.

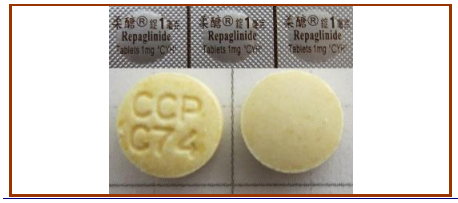
NOTE: 室溫儲存25℃以下

Contraindication: Emergency treatment of acute hyperammonemia, severe hypertension, heart failure, renal insufficiency

藥名相似:

外觀相似:

外觀描述: 白色長橢圓錠，有S 500字樣



46.08 Miscellaneous

27530 UK /

PURE SODIUM BENZOATE CAPSULES 250MG 純安息香酸鈉膠囊250毫克

急用Sodium benzoate 250mg cap

Dosage: 2急用藥 27530

Pediatric
·Non-ketotic hyperglycinemia: PO, 250mg/kg/day in 3-6 divided doses, Max 10g/day

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: 250mg(27530)

ADR:

Nausea, vomiting

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 藍色膠囊

46.08 Miscellaneous

28706 ɔt be ruled out / No report(毫

STIMOL* ORAL SOLUTION 1G/10ML 司狄摩口服溶液1公克/10公撮

急用Citrulline malate oral soln 1g/ 10mL/PK

Dosage: 2急用藥 28706

· Hyperammonemia: PO, 1pk tid with meal

· Hyperammonemia: PO, 1pk bid with meal

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P: Soln： [1g/10mL](28706)

ADR:

·At the beginning of treatment, some patients had a report of transient stomach pain.

NOTE: 室溫儲存25℃以下

·《仿單禁忌》：對不能吃含有鹽類飲食之患者應小心服用。

·Due to the acid pH, the contents of the sachets should always be diluted in a glass of water.

·本品賦形劑不含阿斯巴甜。

藥名相似: STILNOX*

外觀相似:

外觀描述: 10mL口服液，銀色鋁箔袋裝，有深紅色區塊

46.08 Miscellaneous

28710 UK /

Piracetam Oral Solution "Center" "晟德" 派卡登內服液劑

Piracetam 200mg/mL 200mL/bot

Dosage: 1常備品 28710

Adult

·Potential efficacy in cerebrovascula insufficiencies and age-associated intelligence disturbace: PO, initial 800mg tid or 1.2g bid when the desired effect has been obtained, gradually reduce to 400mg tid

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

Clcr 40-60 mL/min: 1/2 usual dose
Clcr 20-40 mL/min: 1/4 usual dose
Clcr <20 mL/min: Contraindiaction

P: Cap: 400mg (22602);Tab: 1.2g (22568); Soln: 200mg/mL 200mL/bot(28710); Inj:1g/5mL Amp (32202)

ADR:

nervousness, irritability, headache, depression, hyperstimulation, sleep disturbances, dizziness, confusion, nausea, gastric discomfort, abdominal pain, flatulence, hepatotoxicity.

NOTE: 室溫儲存

·《Contraindications》Previous hypersensitivity to piracetam; Huntington's chorea；
仿單禁忌：腦內出血，或腎疾末期(End Stage Renal Disease)病人

·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 每瓶含200mL無色優格味液劑,半透明塑膠瓶包裝,有黃色,紅色,藍色,綠色紫色條紋圖案

TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1050206

46.08 Miscellaneous

36901 UK / Unknown(有

PG2 Lyo.Injection 500mg 懷特血寶凍晶注射劑

Polysaccharides of Astragalus membranaceus inj 500mg pow in vial(黃耆多醣體)

Dosage: 1常備品 36901

Adult

·Assistance of chemotherapy or radiation therapy in cancer patients(e.g. alleviate fatigue, increase the production of blood cells): IV infusion over 2.5-3 hours, 500mg/dose, 2-5 times/week

Pediatric

.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Inj: 500mg vial(36901)

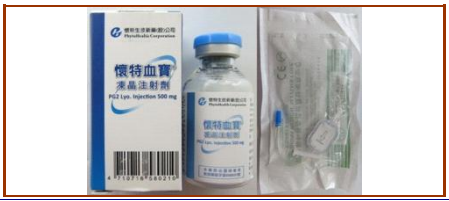
ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 『白』色注射凍晶,透明玻璃瓶,『藍』色塑膠封蓋)



TFDA許可證

http://www.fda.gov.tw/licnquery/DO8180T.asp?Type=Lic&LicId=1058837

48.02 MHF- Antidotes & Intoxication

172510 ɔt be ruled out / Infant risk can

KREMEZIN " 吳羽" 克裏美淨細粒

Spherical adsorptive carbon (AST-120) granules 2g/pk 21pk/box

Dosage: 31醫學保健品-指示藥 172510

Adult
· Hemodialysis-associated pruritus: PO, 2g/pk tid.
· Poison ingestion: PO, 50-100 g as a single dose; may repeat every 4-6 hr.

PEDIATRIC
· Poison ingestion: >12 yr, as adult ; 1-12 yr, PO, 25-50 g as a single dose, may repeat every 4-6 hr; < 1 yr, PO, 1 g/kg as a single dose, may repeat every 4-6 hr .

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Granule: 84pk/box(172511), 21pk/box(172510)

ADR:

Nausea, vomiting, black stools, GI obstruction.

NOTE: 室溫儲存

As the adsorbent properties of this product may interfere with the rates and/or levels of absorption of other substances, it is recommeded not to administer any other drug at the same time.
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 長方體紙盒包裝，有紅/黑色區塊

48.02 MHF- Antidotes & Intoxication

172511 ɔt be ruled out / Infant risk can

KREMEZIN " 吳羽" 克裏美淨細粒

Spherical adsorptive carbon (AST-120) granules 2g/pk 84pk/box

Dosage: 31醫學保健品-指示藥 172511

Adult
· Hemodialysis-associated pruritus: PO, 2g/pk tid.
· Poison ingestion: PO, 50-100 g as a single dose; may repeat every 4-6 hr.

PEDIATRIC
· Poison ingestion: >12 yr, as adult ; 1-12 yr, PO, 25-50 g as a single dose, may repeat every 4-6 hr; < 1 yr, PO, 1 g/kg as a single dose, may repeat every 4-6 hr .

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Granule: 84pk/box(172511), 21pk/box(172510)

ADR:

Nausea, vomiting, black stools, GI obstruction.

NOTE: 室溫

As the adsorbent properties of this product may interfere with the rates and/or levels of absorption of other substances, it is recommeded not to administer any other drug at the same time.
·本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述:

48.06 MHF- Anti-infective Agents

172935 B / Caution

Jye Mei Spray "S.C." "十全" 潔之黴噴劑

Terbinafine HCl 1% spray 40mL/bot

Dosage: 31醫學保健品-指示藥 172935

Adult
· Dermal mycosis: topical, qd-bid for 1-2 wks.

Pediatric(≧12yrs)
· Dermal mycosis: topical, qd-bid for 1-2 wks.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Tab: 250mg(21105), So'n: 1% 40mL/bot(172935)

ADR:

Burning, contact dermatitis, dryness,exfoliation, irritation, pruritus, rash.

NOTE: 室溫

1.Hypersensitivity to allylamine antifungals(eg. naftifine, butenafine, terbinafine) and excipients are contraindicated.
2.Excipients: acetone, alcohol 18%, methylal, transcutol, perfume.

藥名相似:

外觀相似:

外觀描述: 白色塑膠瓶

48.18 MHF- Electrolytic, Caloric and Water Balance

172690 UK /

ABOUND* Powder 24g/pk 基速得

L-Glutamine 7g、Arginine 7g、HMB 1.2g 24g/pk

Dosage: 33醫學保健品-特殊營養品 172690

Adult
· Therapeutic nutrition for management of the wound: 2pk/day

--

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Pow: 24g/pk(172690)

ADR:

NOTE: 室溫

Eath packet contains: Arginine 7g、L-Glutamine 7g、Calcium Beta-hydroxy-beta-methylbutyrate (HMB) 1.5g (=HMB 1.2g).

藥名相似:

外觀相似:

外觀描述:

48.22 MHF- Respiratory Agents

172700 C / Infant risk has

S.S BRON SYRUP-ACE 愛斯百朗糖漿

Codeine phosphate 1 mg/mL[C], Chlorpheniramine maleate 0.4mg/mL[C], Caffeine 2.067mg/mL[C], Guaifenesin 5.67mg/mL[C]

Dosage: 31醫學保健品-指示藥 172700

Adult
·Cough, Expectoration: PO, 6mL tid

Pediatric
·Cough, Expectoration: PO,
12-14 yr: 4mL tid
>15 yr: same as adult

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Soln: 54mL/bot(172700)

ADR:

Nausea, lethargy

NOTE: 室溫儲存

·Each mL contains: Codeine phosphate 1mg、Chlorpheniramine maleate 0.4mg、Caffeine anhydrous 2.067mg、Guaifenesin 5.67mg
·Avoid using this product if you are pregnant or possibly being pregnant
·Avoid driving or operating machines
·Avoid using with other antitussive, expectorant, antihistamine or sedative
·Long term use can be habit-forming
·本品賦形劑不含阿斯巴甜

藥名相似:

外觀相似:

外觀描述:

48.24 MHF- Gastrointestinal Agents

172610 UK /

MIYARISAN BM 妙利散

Clostridium Butyricum Miyairi Powder 40mg/pk(單包)

Dosage: 31醫學保健品-指示藥 172610

Adult
· Acute or chronic enterocolitis/diarrhea: PO, 1 pk tid, or depending on the age/severity of disease.

Pediatric
· Acute or chronic enterocolitis/diarrhea: PO, >=12yrs 1 pk tid; 6-11yrs 1/2 pk tid; 3-5yrs 1/4 pk tid;<=3yrs as order.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Pow: Miyarisan* BM Powder 40mg/pk 21pk/box(172604); Miyarisan* BM Powder 40mg/pk (172610);VSL* 4.5x10(12) CFU/PK 10 PK/B(170051); TCELL* 1x10(10)/G 60G/BT(171002)

ADR:

NOTE: 室溫儲存

Each g cotains: Clostidium Butyricum Miyairi 40mg.

藥名相似:

外觀相似:

外觀描述: 白色粉末

48.24 MHF- Gastrointestinal Agents

172617 UK /

MoProbi-LR Capsules 摩舒益多膠囊

Lactobacillus rhamnosus 1x 10(9) cfu 150mg cap 30cap/box

Dosage: 31醫學保健品-指示藥 172617

Adult
· Relief of mild abdominal pain, diarrhea, constipation: 1 cap tid-qid or prn.

Pediatric
· Relief of mild abdominal pain, diarrhea, constipation: ≧12 yrs: same as adult dose

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Cap: MOPROBI-LR *(172617, 172622), 敏可立(170056);Pow: T Cell-1(171002)

ADR:
Burping, gas, constipation, flatulence and vomiting.

NOTE: 冰箱冷藏，不可冷凍。
Patients sensitive to milk should not use lactobacillus products.

藥名相似:

外觀相似:

外觀描述: 白色膠囊，有摩舒LR字樣

48.24 MHF- Gastrointestinal Agents

172618 UK /

BIO-THREE TABLETS 百賜益 錠

Streptococcus faecalis 2mg, Clostridium butyricum 10mg, Bacillus mesentericus10mg/tab 10tab/pc

Dosage: 31醫學保健品-指示藥 172618

Adult
· Diarrhea, constipation: PO, 1-2 tab tid.

Pediatric
· Diarrhea, constipation: PO, >=12yrs 1-2 tab tid; 6-11yrs 1/2-1tab tid; 3-5yrs 1/4-1/2tab tid;<=3yrs as order.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P:

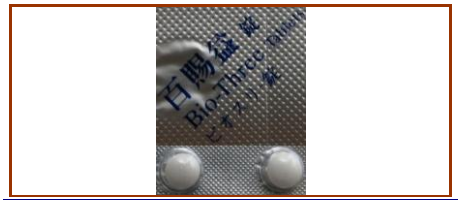
ADR:
Flatulence

NOTE: 室溫
1.Patients sensitive to milk should not use BIO-THREE* tab.
2.Each tab cotains: Streptococcus faecalis T-110 2mg、Clostridium butyricum TO-A 10mg、Bacillus mesentericus 10mg/tab (≧10(6) cfu / g ; ≧6.8x 10(5)cfu /tab)

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠



48.24 MHF- Gastrointestinal Agents

172621 /

MIYARISAN A 妙利散 - 愛錠

Clostridium Butyricum 30mg tab 90tab/bot

Dosage: 31醫學保健品-指示藥 172621

Adult
· Intestinal regulation (regulate the stool), soft stool, constipation, abdominal distension: PO, 2 tab tid.

Pediatric
· Intestinal regulation (regulate the stool), soft stool, constipation, abdominal distension: PO, ≧ 12yrs: 2 tab tid, 6-11yrs: 1 tab tid, 3-5yrs: 0.5 tab tid, < 3yrs: not recommended.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Tab: MIYARISAN-A* Tab (172621); Pow: MIYARISAN-A* BM powder 40mg/pk (172610)

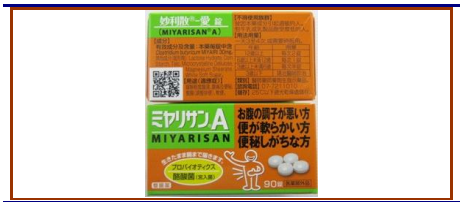
ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色圓扁錠



48.24 MHF- Gastrointestinal Agents

172622 UK /

MoProbi-LR Capsules 摩舒益多膠囊

Lactobacillus rhamnosus 1x 10(9) cfu 150mg cap(單顆)

Dosage: 31醫學保健品-指示藥 172622

Adult
· Relief of mild abdominal pain, diarrhea, constipation: 1 cap tid-qid or prn.

Pediatric
· Relief of mild abdominal pain, diarrhea, constipation: ≧12 yrs: same as adult dose

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Cap: MOPROBI-LR *(172617, 172622), 敏可立(170056);Pow: T Cell-1(171002)

ADR:

Burping, gas, constipation, flatulence and vomiting.

NOTE: 冰箱冷藏，不可冷凍。

Patients sensitive to milk should not use lactobacillus products.

藥名相似:

外觀相似:

外觀描述: 白色膠囊，有摩舒LR字樣

48.24 MHF- Gastrointestinal Agents

172624 ɔt be ruled out / Infant risk can

ANTIBIOPHILUS CAPSULES 阿德比膠囊

Lactobacillus casei variety rhamnosus 8 x 108 CFU，250mg/cap

Dosage: 31醫學保健品-指示藥 172624

ADULT
· Intestinal regulation (regulate the stool), soft stool, constipation, abdominal distension: PO, 2-8 cap /day

PEDIATRIC
· Intestinal regulation (regulate the stool),soft stool, constipation, abdominal distension: PO, ≧12yrs: 2-8 cap /day, 6-11yrs: 1-4cap /day, 3-5yrs: 0.5-2 cap /day.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Cap :Antibiopilus* cap(172624)

ADR:

NOTE: 室溫儲存

賦形劑：Potato starch, lactose, Sodium thiosulfate, Sodium Glutamate, Milk dry extract, Magnesium stearate

藥名相似:

外觀相似:

外觀描述: 白色膠囊

48.24 MHF- Gastrointestinal Agents

172720 UK / No report(毫

Alginos Oral Suspension 胃逆舒口服懸浮液

Sodium alginate 50 mg、Sodium bicarbonate 26.7 mg、Calcium carbonate 16 mg/mL 210mL/bot

Dosage: 31醫學保健品-指示藥 172720

Adult(>12yrs)
·Gastro-oesophageal reflux: PO, 10-20mL qid.

Pediatric(2-11yrs)
·Gastro-oesophageal reflux: PO, 5-10mL qid.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Tab: Topaal*(24805), Susp: Alginos*210mL/bot(172720), Gaviscon* 200mL/bot(172721)

ADR:

Flactulence

NOTE: 室溫儲存

Sodium contain of 10mL: 141mg(6.2 mmol)
本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 白色瓶裝草莓口味

48.36 MHF- Vitamins

172623 /

ALINAMIN EX PLUS 合利他命 強效錠

Fursultiamin HCl 36.39mg, Pyridoxine HCl 33.33mg, Cyanocobalamin 500μg[C],Tocopherol calcium succinate 34.53mg[A], Calcium pantothenate Type S 15.4mg,Gamma-Oryzanol 3.33mg 60tab/bot

Dosage: 31醫學保健品-指示藥 172623

Adult(>15 yrs)
·Vitamin B1, B5, B6, B12 & vitamin E deficiency : PO, 2-3 tab qd.

Pediatric
· < 15 years of age do not use.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P:

ADR:

NOTE: 室溫儲存

合併使用多種維生素B群製劑時，請注意高劑量Pyridoxine可能發生周邊神經病變。(ADR小組115次會)

藥名相似:

外觀相似:

外觀描述: 黃色圓扁糖衣錠

48.36 MHF- Vitamins

172625 UK /

VITACOMB S.C. TABLETS 維體康糖衣錠

Thiamine mononitrate 100mg、Pyridoxine HCl 100mg、Hydroxocobalamine 1000mcg/tab

Dosage: 31醫學保健品-指示藥 172625

Adult
·Peripheral neuropathy, anaemia: PO, 1 tab qd

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Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Tab: Vitacomb* Tab (172625)

ADR:

Decreased serum folic acid secretion, paresthesia, somnolence

NOTE: 室溫儲存

1.本藥不適用於孕吐.
2.合併使用多種維生素B群製劑時，請注意高劑量Pyridoxine可能發生周邊神經病變。(ADR小組115次會)

藥名相似:

外觀相似:

外觀描述: 粉紅色長橢圓形糖衣錠

48.40 MHF- Ear, Nose and Throat (ENT) Preparations

172907 UK / Unsafe

Enoxolone Gingival Paste 齒博士牙齦膏

Glycyrrhetinic acid gingival paste 1% 80g/ tube

Dosage: 31醫學保健品-指示藥 172907

Adult
·Gingivitis: Brushing followed by a massage gums after each meal for a few minutes, then rinse.bid-tid.

Pediatric
· <3 years of age do not use.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Gingival Paste: 80g/ tube (172907)

ADR:

NOTE: 室溫儲存

· Contraindication: <3 years of age do not use

藥名相似:

外觀相似:

外觀描述: 白色瓶身，藍色外盒

48.40 MHF- Ear, Nose and Throat (ENT) Preparations

172910 C / Infant risk is

Perioxidin Bioadhesive Gel 樂利口抗炎凝膠

Chlorhexidine digluconate 2mg/g Gel 50ml/tube

Dosage: 31醫學保健品-指示藥 172910

Adult
·Oral disinfection,sterilization, cleaning, halitosis elimination: bid-tid ,0.5-2g each time.□

--

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:

NDA

P: Gel: 50ml/tube(172910)

ADR:

NOTE: 儲存25℃以下

使用完本品後半小時內應避免進食及喝飲料。睡前使用效果最佳。
使用後請勿漱口及請勿吞服。
使用本品後，在進食前請先清潔口腔，以避免食入殘餘藥物。

藥名相似:

外觀相似:

外觀描述: 白色瓶蓋，白底紅字藍色條紋

48.40 MHF- Ear, Nose and Throat (ENT) Preparations

172932 C / Infant risk can

Betadine Throat Spray 必達定殺菌口腔噴液

Povidone-Iodine 0.45% w/v 50mL/bot

Dosage: 31醫學保健品-指示藥 172932

·Antiseptic: spray 2-3 times directly onto the throat ,repeated q3-4h as needed.

· Safety and efficacy have not been established in patients less than 6 years old.

Dosing adjustments in hepatic impairment:

Use with caution.

Dosing adjustments in renal impairment:

Use with caution.

P: Throat spray: 50mL/B(172932)

ADR:

Local irritation

NOTE: 室溫儲存

Contraindications:thyroid disorder,patients taking lithium.

藥名相似:

外觀相似:

外觀描述: 50mL黃色溶液，白黃色瓶身，藍色棕色外盒

48.40 MHF- Ear, Nose and Throat (ENT) Preparations

173033 UK / No report(毫

GELCLAIR Concentrated Oral Gel (Non-sterile) 捷膜漱口腔凝膠(未滅菌)

Sodium hyaluronate、Polyvinylpyrrolidone、Glycyrrhetinic acid oral gel 15mL/pk 21 pk/box

Dosage: 36醫學保健品-用藥醫材(有執照) 173033

Adult
· Mucositis/stomatitis: 3 times a day or as needed.Avoid eating or drinking for at least 30-60 minutes following treatment.

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oral gel: 15mL/pk 21 pk/box(173033) 15mL/pk 6 pk/box(173044)

ADR:

NOTE: 室溫儲存

(1)本品可能降低舌下錠藥品之吸收。
(2)若產品鋁箔包裝損毀，或效期已過，請勿使用。
(3)經存放後產品可能產生色澤稍微變深及變濃稠之現象，並不影響其功效及安全性。
(4)存放於室溫，避免陽光直射。
(5)若經過7日療程後，症狀未見改善，請諮詢醫師。療程應於連續4周後停止。

藥名相似:

外觀相似:

外觀描述: 整盒發放白底藍色

48.40 MHF- Ear, Nose and Throat (ENT) Preparations

173039 /

"GEROLYMATOS" Sinomarin Hypertonic Sea Water Nasal Spray "吉爾馬特"希諾寧海水洗鼻器

2.3%NaCl

Dosage: 36醫學保健品-用藥醫材(有執照) 173039

Adult
·Cleansing of nasal cavities, relief of nasal congestion: 1-3 sprays in each nostril, 2-3 times a day.

Pediatric (>6 yrs)
·Cleansing of nasal cavities, relief of nasal congestion: 1-2 sprays in each nostril, 2-3 times a day.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Nasal spray: 125mL/B(173039), 30mL/B(173040)

ADR:

NOTE:

NOTE
1.Wash the nasal applicator with clean water after each use.
2.Contraindications: babies under 6 mons of age, hypersensitivity to sea water.

藥名相似:

外觀相似:

外觀描述: 白色瓶

48.40 MHF- Ear, Nose and Throat (ENT) Preparations

173042 /

NanoSigma*Oral Gel (Non-Sterile) "翰強" 口內凝膠 (未滅菌)

Polyvinylpyrrolidone、Calcium chloride、Potassium sorbate、Propylene glycol、Trisodium glycyrrhizinate、EDTA、Pure water Oral Gel 250 mL/bot

Dosage: 36醫學保健品-用藥醫材(有執照) 173042

Adult
·Mouth ulcers,aphthous stomatitis, recurrent ulcerous lesions of the oral cavity and irritations of the oral cavity: Rinse with 10-15 ml of the product 4-6 times a day,or as needed .Avoid eating or drinking for at least 30-60 minutes following treatment.

Pediatric
· Safety and efficacy have not been established .

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oral gel: 15g/pk 20pk/box(173028) 250 mL/bot(173042)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色瓶蓋，白色瓶身

48.40 MHF- Ear, Nose and Throat (ENT) Preparations

173044 /

GELCLAIR Concentrated Oral Gel (Non-sterile) 捷膜漱口腔凝膠 (未滅菌)

Sodium hyaluronate、Polyvinylpyrrolidone、Glycyrrhetinic acid oral gel 15mL/pk 6 pk/box

Dosage: 36醫學保健品-用藥醫材(有執照) 173044

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Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oral gel: 15mL/pk 6 pk(173044) 15mL/pk 21 pk(173033)

ADR:

NOTE:

藥名相似:

外觀相似:

外觀描述: 整盒發放白底藍色

48.42 MHF- Ophthalmic Preparations

173001 /

BLINK CONTACTS EYE DROPS 冰藍高水份隱形眼鏡潤濕液

Sodium Hyaluronate (玻尿酸) 0.15% 10mL/bot

Dosage: 36醫學保健品-用藥醫材(有執照) 173001

Adult
· For lubricating and rewetting all contact lenses: 1-2 drops in each lens as required.

--

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Oph soln: Systane*(29276), Tears Naturale*(29281), Tears Nature* Free Lubricant(29274), Blink*(173001), GenTeal*(172801); Oph oint: Duraters*(29288)

ADR:

NOTE: 室溫儲存

1.Discard any remaining solution 45 days after

opening.
2.Not for use in lens case.
3.Each mL contains: Sodium hyaluronate 1.5mg、sodium chloride 3.9mg、boric acid 6mg、sodium borate decahydrate 0.35mg、potassium chloride 1.4mg、calcium chloride dihydrate 0.06mg、magnesium chloride 0.06mg、Purite(保存劑) 0.05mg and purified water q.s. to 1 mL.

藥名相似:

外觀相似:

外觀描述:

48.42 MHF- Ophthalmic Preparations

173026 UK /

Allergan Optive (R) Sensitive Lubricant Eye Drops 愛力根優麗舒(R)單支裝眼用點眼液

Sodium carboxymethylcelluose 5mg/mL, 0.4mL/amp 30amp/box

Dosage: 31醫學保健品-指示藥 173026

Adlut
· Relief of dry eyes: Ophthalmic, 1-2 drops if necessary.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P:

ADR:

NOTE: 室溫儲存

藥名相似: Oph soln:OPTIVE*4mL/amp 30amp/box (173

外觀相似:

外觀描述: 0.4mL單支裝,每盒30支)

48.44 MHF- Skin and Mucous Membrane Preparations

172901 UK / Caution

Borraginol-A ointment in prefilled disposable applicators 保能痔注入軟膏

Prednisolone acetate 1mg, Lidocaine 60mg, Allantoin 20mg, Vitamin E acetate 50mg 2g/pc 10pc/box

Dosage: 31醫學保健品-指示藥 172901

Adult
·Relief of pain, hemorrhage, swelling and itching due to hemorrhoids (piles) and anal fissure:
Insert the nozzle into the anus and infuse the entire ointment slowly. 1 supp. 1-2 times/day.
Apply the appropriate amount to the affect areas. 1-3 times/day, Max. 2 supp. Once use in topical application, do not use for infusion again.

Peduatric: >15yrs
Same as adult.

Dosing adjustments in hepatic impairment:
NDA

Dosing adjustments in renal impairment:
NDA

P: Oint: BORRAGINOL-A* 10pc/box(172901)

ADR:

Rash, redness, itching, swelling, irritation, purulence.

NOTE: 室溫

Each Supp. Contains: Prednisolone acetate 1mg (=0.05%)、Lidocaine 60mg (=3%)、Allantoin 20mg (=2%)、Vitamin E acetate 50mg (=5%).

藥名相似:

外觀相似:

外觀描述: 黃色塑膠管

48.44 MHF- Skin and Mucous Membrane Preparations

172906 C / Caution

Kefentech Plaster 30mg 克痛藥膠布30毫克

Ketoprofen 30mg/pc (10x7cm) 8sh/pk plaster

Dosage: 31醫學保健品-指示藥 172906

Adult
·Musculoskeletal/joint disorders: topical, bid.

--

Dosing adjustments in hepatic impairment:
No dosage adjustment needed.

Dosing adjustments in renal impairment:
Use with caution

P: TTS: KEFENTECH* 8sh/pk (172906)

ADR:

Erythroderma, photosensitivity, pruritus, rash.

NOTE: 室溫

藥名相似:

外觀相似:

外觀描述:

48.44 MHF- Skin and Mucous Membrane Preparations

172938 C / Infant risk is

Easy Antiseptic Liquid 2% 克菌寧 殺菌液2%

CHLORHEXIDINE GLUCONATE 2%[C]

Dosage: 31醫學保健品-指示藥 172938

Adult
· Handwash:wet hands, wash with 5 mL for 30 seconds, rinse and dry.
· General skin cleansing: rinse area to be cleansed with water, wash gently, then rinse and dry.

--

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Sol'n : 30mL/tube (172938)

ADR:

NOTE: 25℃以下儲存

藥名相似:

外觀相似:

外觀描述: 綠色瓶蓋, 白色瓶身

48.44 MHF- Skin and Mucous Membrane Preparations

172939 /

Conte Anti-itching Cream 康特止癢乳膏

Crotamiton 5%、Lidocaine = 2%、Diphenhydramine 1%、Tocopherol acetate 0.5%、Glycyrrhizinic acid 0.2%

Dosage: 31醫學保健品-指示藥 172939

Adult
Allergic skin disorders, insec bites, burns, wounds, corns: topical, apply to affected area as needed.

--

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

NOTE:

藥名相似:

外觀相似:

外觀描述: 綠色瓶蓋, 白色瓶身

48.44 MHF- Skin and Mucous Membrane Preparations

173019 UK / Safe

"Polyxal" Scar care silicone gel (Non-Sterile) "玻麗舒" 疤痕護理凝膠 (未滅菌)

Polysiloxane gel 15g/tube

Dosage: 36醫學保健品-用藥醫材(有執照) 173019

Adult
·Treatment and prevention of keloids and hypertrophic scars after the wound has healed and the skin surface is intact: topical, bid.

Pediatric
·Treatment and prevention of keloids and hypertrophic scars after the wound has healed and the skin surface is intact: topical, bid.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

NOTE: 室溫

Should be applied to clean, dry skin only.

藥名相似:

外觀相似:

外觀描述:

48.44 MHF- Skin and Mucous Membrane

Preparations

173020 UK /

"Froika" Scar Gel (non-sterile) "芙立康" 疤痕凝膠 (未滅菌)

Silicone, allium cepa extract, vit E, avocado oil gel 20mL tube

Dosage: 36醫學保健品-用藥醫材 (有執照) 173020

Adult
·Treatment and prevention of keloids and hypertrophic scars after the wound has healed and the skin surface is intact: topical, bid. Should be applied to clean, dry skin only.

Pediatric
·Treatment and prevention of keloids and hypertrophic scars after the wound has healed and the skin surface is intact: topical, bid. Should be applied to clean, dry skin only.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

Redness, pain, irritation.

NOTE: 室溫儲存

1.Should not be applied to open or fresh wounds.
2.Should not be placed in contact with mucous membranes, or applied too close to the eyes.
3.Should not be applied over antibiotic skin preparation or other skin treatment and /or products.

藥名相似:

外觀相似:

外觀描述:

48.44 MHF- Skin and Mucous Membrane Preparations

173021 UK /

Dermatix Ultra Gel (Non-Sterile) 倍舒痕凝膠 (未滅菌)

Cyclopentaxiloxane, ascorbyl tetraisopalmitate gel 15g tube

Dosage: 36醫學保健品-用藥醫材 (有執照) 173021

Adult
·Treatment and prevention of keloids and hypertrophic scars after the wound has healed and the skin surface is intact: topical, bid. Should be applied to claen, dry skin only.

Pediatric
·Treatment and prevention of keloids and hypertrophic scars after the wound has healed and the skin surface is intact: topical, bid. Should be applied to claen, dry skin only.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

Redness, pain, irritation.

NOTE: 室溫

1.Should not be applied to open or fresh wounds.
2.Should not be placed in contact with mucous membranes, or applied too close to the eyes.
3.Should not be applied over antibiotic skin preparation or other skin treatment and /or products.

藥名相似:

外觀相似:

外觀描述:

48.44 MHF- Skin and Mucous Membrane Preparations

173023 UK /

"Fidia" Hyalofemme Patient Lubricant (Non-Sterile) "菲迪雅" 雅若恩病患用潤滑劑 (未滅菌)

Benzyl ester of hyaluronic acid vaginal gel 30g tube

Dosage: 36醫學保健品-用藥醫材 (有執照) 173023

Adult
· Relief symptoms of vaginal dryness: 1 application every 3 days for a period of 30 days. If necessary, increase the dosage and frequency of use in patients with severe dryness.

NDA

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Gel: 30g tube(173023)

ADR:

NOTE: 室溫儲存儲存攝氏30度以下

The product can be used during menstruation.

藥名相似:

外觀相似:

外觀描述: 白底粉紅色紙盒

48.44 MHF- Skin and Mucous Membrane Preparations

173024 UK /

"M-technologies" Eurogel Plus Silicone Gel for Scar Management (Non-Sterile) "恩特科" 優潔疤痕護理凝膠 (未滅菌)

Polysiloxanes, vitamin E gel 10g/tube

Dosage: 36醫學保健品-用藥醫材(有執照) 173024

·Treatment and prevention of keloids and hypertrophic scars after the wound has healed and the skin surface is intact: topical, bid. Should be applied to clean, dry skin only.

·Treatment and prevention of keloids and hypertrophic scars after the wound has healed and the skin surface is intact: topical, bid. Should be applied to clean, dry skin only.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

NOTE: 室溫

1.Should not be applied to open or fresh wounds.
2.Should not be placed in contact with mucous membranes, or applied too close to the eyes.
3.Should not be applied over antibiotic skin preparation or other skin treatment and /or products.

藥名相似:

外觀相似:

外觀描述:

48.44 MHF- Skin and Mucous Membrane Preparations

173025 UK /

"M-technologies" Eurogel Plus Silicone Gel for Scar Management (Non-Sterile) "恩特科" 優潔疤痕護理凝膠 (未滅菌)

Polysiloxanes, vitamin E gel 20g/tube

Dosage: 36醫學保健品-用藥醫材(有執照) 173025

·Treatment and prevention of keloids and hypertrophic scars after the wound has healed and the skin surface is intact: topical, bid. Should be applied to clean, dry skin only.

·Treatment and prevention of keloids and hypertrophic scars after the wound has healed and the skin surface is intact: topical, bid. Should be applied to clean, dry skin only.

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

NOTE: 室溫

1.Should not be applied to open or fresh wounds.
2.Should not be placed in contact with mucous membranes, or applied too close to the eyes.
3.Should not be applied over antibiotic skin preparation or other skin treatment and /or products.

藥名相似:

外觀相似:

外觀描述:

48.44 MHF- Skin and Mucous Membrane Preparations

173031 UK / No report(毫

neoVIDERM Skin Emulsion 加納軟膏

Align 0.2%、betaglucan 0.1%、sodium hyaluronate 0.01% 100mL/tube

Dosage: 36醫學保健品-用藥醫材(有執照) 173031

Wound management: topical, bid.

--

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Gel: 100mL/TU(173031)

ADR:

NOTE: 室溫儲存

1.Do not use in case of infected wounds and / or bleeding.
2.Avoid contact with eyes.

藥名相似:

外觀相似:

外觀描述: 白色鋁管，白色上蓋，有藍色字樣

48.44 MHF- Skin and Mucous Membrane Preparations

173036 UK / No report(毫

"HANBIO" patient lubricant (non-sterile) "瀚醫生技" 病患用潤滑劑 (未滅菌)

大分子天然玻尿酸 Sodium hyaluronate 3mL/tube

Dosage: 36醫學保健品-用藥醫材(有執照) 173036

Adlut
· Patient lubricant: once or twice weekly.

--

Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: Gel: 3mL/tube (173036)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 3mL單支裝)

48.44 MHF- Skin and Mucous Membrane Preparations

173038 /

"VENTURE LIFE" PROCTO-EZE CREAM (NON-STERILE) "凡特萊" 普治緩保護軟膏 (未滅菌)

Dipotassium glycyrrhizate 0.1-1%, stearyl glycyrrhetinate 0.1-1% 30mL/tube

Dosage: 36醫學保健品-用藥醫材(有執照) 173038

Adult
·Anal: topical, 2 to 3 times a day.

--

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Cream: 30mL/tube(173038)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 白色鋁管，白色上蓋，有藍色字樣

48.44 MHF- Skin and Mucous Membrane Preparations

173045 /

Radiation Rescue Pain Relieving Gel (Non-sterile) 放療救援 疼痛舒解凝膠 (未滅菌)

Tea tree oil (Melaleuca alteriflolia) 236mL/tube

Dosage: 36醫學保健品-用藥醫材(有執照) 173045

Topical, Applied in a thick layer and in contact with the skin for 30-60 minutes. tid or as needed.

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Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P:

ADR:

NOTE: 室溫儲存

Purified water, Ultrez 10, Sepinov EMT10, Propylene Glycol, Chlorobutanol, Polysorbate, Melaleuca alt., TEA99

藥名相似:

外觀相似:

外觀描述: 白色上蓋，藍色瓶身

48.44 MHF- Skin and Mucous Membrane Preparations

173046 /

ISOFACE GEL (Sterile) 適痕凝膠 (滅菌)

olydimethylsiloxane (60 %), Cyclopentasiloxane (35 %), Silica (5 %),10g/Tube。

Dosage: 36醫學保健品-用藥醫材(有執照) 173046

Adult
·Treatment and prevention of keloids and hypertrophic scars after the wound has healed and the skin surface is intact: topical, bid. Should be applied to clean, dry skin only.
Pediatric
·Treatment and prevention of keloids and hypertrophic scars after the wound has healed and the skin surface is intact: topical, bid.
Dosing adjustments in hepatic impairment:
NDA
Dosing adjustments in renal impairment:
NDA
P Gel: EUROGEL* 10g/tube(173024), EUROGEL* 20g/tube(173025), FROIKA* 20mL/tube(173020), DERMATIX ULTRA* 15g/tube(173021), POLYXAL* 15g/tube(173019)

Pediatric
·Treatment and prevention of keloids and hypertrophic scars after the wound has healed and the skin surface is intact: topical, bid.
Dosing adjustments in hepatic impairment:
NDA
Dosing adjustments in renal impairment:
NDA
P Gel: EUROGEL* 10g/tube(173024), EUROGEL* 20g/tube(173025), FROIKA* 20mL/tube(173020), DERMATIX ULTRA* 15g/tube(173021), POLYXAL* 15g/tube(173019)

Dosing adjustments in hepatic impairment:
NDA
Dosing adjustments in renal impairment:
NDA

P:

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 橘色上蓋，白色瓶身

48.46 MHF- Miscellaneous

172501 **UK / Caution**

Glucosamine sulfate powder 1500mg/pk 30pk/box 骨欣口服溶液用粉劑 30pk/box

Glucosamine sulfate 1500mg/pk 30pk/box

Dosage: 31醫學保健品-指示藥 172501

·Osteoarthritis: 1pk qd with meal for 3 mons.

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Dosing adjustments in hepatic impairment:
NDA
Dosing adjustments in renal impairment:
NDA

P: Pow: 1500mg(172501)

ADR:

Common
Peripheral edema, tachyarrhythmia, constipation, diarrhea, indigestion, nausea, vomiting, headache, insomnia, somnolence.

NOTE: 室溫

1.Each sachet contains glucosamine sulfate 2NaCl 1884mg eq. to glucosamine sulfate 1500mg.
2.Each sachet contains sodium 153.8mg.
3.本品賦形劑不含阿斯巴甜。

藥名相似:

外觀相似:

外觀描述: 銀色紙盒,有橘色"骨欣"字樣

48.46 MHF- Miscellaneous

172781 **UK / Unknown(有**

Chemo young oral solution “中天生技”化療漾內服液

有機大豆發酵液(Daidzein，Glycitein) 2.7g/ml

Dosage: 31醫學保健品-指示藥 172781

Adult
·improvement of fatigue and appetite loss associated with cancer chemotherapy: PO, 4mL/bot bid.

Pediatric
· Safety and efficacy have not been established

Dosing adjustments in hepatic impairment:
NDA
Dosing adjustments in renal impairment:
NDA

P: Solusion :180ml/b (172780)，14 bot/bx(172781)

ADR:

Constipation, diarrhea, lower estrogen levels,longer menstrual cycle.

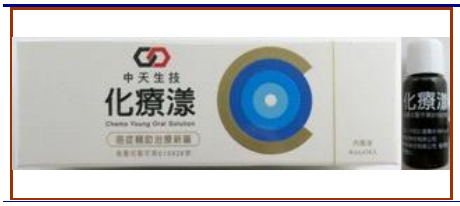
NOTE: 室溫儲存

1.本產品可能造成短暫輕微便秘或腹瀉情況，持續使用即可改善。
2.婦癌、乳癌病人請審慎評估使用。

藥名相似:

外觀相似:

外觀描述: 黑色瓶身白色瓶蓋，一盒14小瓶)整盒發放



48.46 MHF- Miscellaneous

173003 UK /

T.E.D. Thigh Length Anti-embolism stockings 頂提醫用大腿輔助襪(白色露趾)

Thigh Length Anti-embolism stockings

Dosage: 36醫學保健品-用藥醫材(有執照) 173003

穿著方式：
1.將手伸進襪子直到腳跟處。
2.抓著襪子腳跟處的中間，將襪子由內向外翻出。
3.將襪子從腳尖往腳跟緩慢套入。
4.注意確保使襪子的後跟處與腳後跟部位相吻合。
5.再將襪子拉過足踝部，然後展開至小腿部。
注意：對於膝長襪，襪子跟應位於腳踝以下1-2英吋(2.5-5 cm處)；對於腿長襪，織法變化的地方應位於膝蓋以下1-2英吋(2.5-5 cm處)，防滑帶應位於大腿跟部。

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: 依大腿圍(及長度)和小腿圍(及長度)選擇適合的型號。型號有: 3071(S), 3310(M), 3634(L), 3180(XL)四種

ADR:

NOTE: 室溫儲存

注意：對於膝長襪，襪子跟應位於腳踝以下1-2英吋(2.5-5 cm處)；對於腿長襪，織法變化的地方應位於膝蓋以下1-2英吋(2.5-5 cm處)，防滑帶應位於大腿跟部。

藥名相似:

外觀相似:

外觀描述: 此代碼含多種尺寸, 包裝袋顏色不同, 請核對型號

48.46 MHF- Miscellaneous

173008 UK /

"TRUDELL" VALVED HOLDING CHAMBER 愛治喘吸藥輔助器

Valved Holding Chamber-Child

Dosage: 36醫學保健品-用藥醫材(有執照) 173008

小兒用

使用方法
1.將此輔助器由盒子取出，並查看輔助器的透明管腔內有無阻礙物，若無則將此輔助器罩住鼻子的面罩轉向上面。
2.將噴霧劑的護蓋取下，連接在輔助器後端。
3. 將噴霧劑上下用力搖幾下，使藥物得以充分搖勻。
4.按壓噴霧劑一下劑量，並把面罩罩住病童口、鼻，輕壓勿漏氣。
5.緩慢呼吸5~6下，若呼吸短促則增至6~10下。(約罩住口、鼻20-30秒)。
6.若有第二劑量時，休息30秒後再重複第3-5步驟。

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: AeroChamber:child(173008), adult(173009)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 透明壓克力管,有「黃色」外圈

48.46 MHF- Miscellaneous

173012 UK /

"ACCUD-Med" ORAL SYRINGE (Non-Sterile) "亞科碼"口服餵藥器(未滅菌)

Oral dispenser 5mL

Dosage: 36醫學保健品-用藥醫材(有執照) 173012

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1.抽藥前需確定推藥器推到底，抽藥以黑色矽膠環底線為準確依據。
2.加蓋及貼標籤。
3.餵藥時，病患需坐直，將藥液慢慢往下推入口腔，自然吞嚥，強制灌入喉嚨可能造成窒息。

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: DIV: 5mL(173012), 10mL(173013)

ADR:

NOTE:

請勿將餵藥器置於口腔後方,以免引起咳嗽.請避免兒童接觸圓球蓋,以免誤食.

藥名相似:

外觀相似:

外觀描述:

48.46 MHF- Miscellaneous

173013 UK /

"ACCUD-Med" ORAL SYRINGE (Non-Sterile) "亞科碼"口服餵藥器(未滅菌)

Oral dispenser 10mL

Dosage: 36醫學保健品-用藥醫材(有執照) 173013

NDA

1.抽藥前需確定推藥器推到底，抽藥以黑色矽膠環底線為準確依據。
2.加蓋及貼標籤。
3.餵藥時，病患需坐直，將藥液慢慢往下推入口腔，自然吞嚥，強制灌入喉嚨可能造成窒息。

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: Div: 5mL(173012), 10mL(173013)

ADR:

NOTE:

請勿將餵藥器置於口腔後方,以免引起咳嗽.請避免兒童接觸圓球蓋,以免誤食.

藥名相似:

外觀相似:

外觀描述: 10毫升口服餵藥器，琥珀色有刻度推注筒，『白』色推進器

48.46 MHF- Miscellaneous

173014 UK /

"TRUDELL" VALVED HOLDING CHAMBER 愛治喘吸藥輔助器

Valved Holding Chamber- Adult

Dosage: 36醫學保健品-用藥醫材(有執照) 173014

1.將此輔助器由盒子取出，並查看輔助器的透明管腔內有無阻礙物，若無則將此輔助器罩住 鼻子的面罩轉向上面。
2.將噴霧劑的護蓋取下，連接在輔助器後端。
3.將噴霧劑上下用力搖十下，使藥物得以充分搖勻。
4.按壓噴霧劑一下劑量，並把面罩罩住病患口、鼻，輕壓勿漏氣。
5.自然呼吸5-6下(約20-30秒)或深吸氣後閉氣10秒即可。
6.若有第二劑量時，休息30秒後再重複第3-5步驟。

成人用

Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

P: AeroChamber:child(173008), adult(173014)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: 透明壓克力管,有「藍色」外圈

48.46 MHF- Miscellaneous

173029 UK / No report(毫

Pocket Air Portable Nebulizer 帕基艾兒攜帶式噴霧器

Dosage: 36醫學保健品-用藥醫材(有執照) 173029

1.使用噴霧器之前，請先進行藥杯組裝
2.連接電源
3.添加液體
4.正確吸入(使用咬嘴或加裝面罩)
5.清潔與消毒

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Dosing adjustments in hepatic impairment:

NDA

Dosing adjustments in renal impairment:

NDA

P: P Portable Nebulizer: Pocket Air Portable Nebulizer (173029)

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述:

48.46 MHF- Miscellaneous

173030 /

Pocket Air Portable Nebulizer(Medication Cup) 帕基艾兒攜帶式噴霧器(藥杯)

Dosage: 36醫學保健品-用藥醫材(有執照) 173030

帕基艾兒攜帶式噴霧器(173029)之藥杯

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Dosing adjustments in hepatic impairment:

Dosing adjustments in renal impairment:

48.00 醫學保健品 DIETARY SUPPLEMENT(MHF, MEDICAL HEALTH FOOD)

P:

ADR:

NOTE: 室溫儲存

藥名相似:

外觀相似:

外觀描述: