

with an ticholineric properties may be helpful in controlling the extrapyramidal reactions. There is no specific antidote to domperidone but in the event of overdosage, gastric lavage as well as the administration of activated charcoal may be useful. Close observation and supportive therapy are recommended.

Presentation:

Emiset tablet 10 mg are available in blister pack of 30's.
Emiset suspension 1mg / ml 120 ml is available in glass bottle.

Storage conditions:

Store below 30°C in a dry place, protect from light.
To be dispensed on the prescription of a registered medical practitioner only.
Keep out of the reach of children.

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے پر فروخت کریں۔

Emiset® (Domperidone)

ایمیسٹ (ڈومپیری ڈون)

Tablets / Suspension

گولیاں / سسپنشن

Description:

Emiset contains (as an active ingredient) domperidone, a synthetic gastrokinetic and anti-nauseant for oral use. Domperidone is chemically identified as 5-chloro-1-[1-[3-[2,3-dihydro-2-oxo-1 H-benzimidazol-1-yl) propyl]-4-piperidinyl]-1,3-dihydro-2H-benzimidazol-2-one.

Each film coated tablet contains:
Domperidone maleate(B.P.)
eq. to Domperidone 10 mg.
Product complies B.P. Specs.

Each ml contains:
Domperidone (B.P.)....1 mg.
Product complies Platinum Specs.

Properties:

pharmacology:

Emiset contains domperidone, a dopamine antagonist with anti-emetic properties. Unlike other dopamine antagonists, domperidone does not readily cross the blood-brain barrier. In domperidone users, especially in adults, extrapyramidal side effects are very rare, but domperidone promotes the release of prolactin from the pituitary. Its anti-emetic effect may be due to a combination of peripheral (gastrokinetic) effects and antagonism of dopamine receptors in the chemoreceptor trigger zone, which lies outside the blood-brain barrier in the area postrema animal studies, together with low concentrations found in the brain, indicate a predominantly peripheral effect of domperidone on dopamine receptors. Studies in man have shown oral domperidone to increase the duration of antral and duodenal contractions, to increase the gastric emptying of liquids and semi-solids in healthy subjects and of solids in patients in whom it was delayed, and to increase lower esophageal sphincter pressure in healthy subjects. It has no effect on gastric secretion.

Metabolism and Pharmacokinetics:

In fasting subjects, domperidone is rapidly absorbed after oral administration, with peak plasma concentrations at approximately 1 hour. The low absolute bioavailability of oral domperidone (approximately 15%) is due to an extensive first-pass metabolism in the gut wall and liver. Although domperidone's bioavailability is enhanced in normal subjects when taken after a meal, patients with gastro-intestinal complaints should take domperidone 15-30 minutes before a meal. Reduced gastric acidity impairs the absorption of domperidone. Oral bioavailability is decreased by prior administration of cimetidine or sodium bicarbonate.

The time of peak absorption is slightly delayed and the AUC somewhat increased when the oral drug is taken after a meal. Oral domperidone does not appear to accumulate or to induce its own metabolism; a peak plasma level after 90 minutes of 21 ng/ml after two weeks oral administration of 30 mg per day was almost the same as that of 18 ng/ml after the first dose. Domperidone is 91-93% bound to plasma proteins. Distribution studies with radiolabelled drug in animals have shown wide tissue distribution, but low brain concentration. Small amounts of drug cross the placenta in rats. Domperidone concentrations in breast milk of lactating women are 4 times lower than corresponding plasma concentrations. Domperidone undergoes rapid and extensive hepatic metabolism by hydroxylation and N-dealklation. Urinary and faecal excretions amount to 31 and 66% of the oral dose

Manufactured by:

Platinum
Pharmaceuticals (Pvt) Ltd.
A-20, North Western Industrial Zone,
Bin Qasim, Karachi-75020, Pakistan.

QAR No.AW12-0710

D1A

PGL -1418 (359)

Platinum
Pharmaceuticals (Pvt.) Ltd.

Product : Emiset
Components : Emiset Leaflet

Dimension : 170 mm x 145 mm
Modified Date : 31-07-2012
Concepts By : Farooq Sami
Design By : Rahil Ali Rahim
QAR No. AW12-0710
Supersedes : 031027

Colors

Pantone black C

Department	Marketing	Regulatory	Quality Control	Quality Control Head	Procurement
Remarks					
Signature					
Date / Time					

respectively. The proportion of the drug excreted unchanged is small (10% of faecal excretion and approximately 1% of urinary excretion). The plasma half-life after a single oral dose is 7-9 hours in healthy subjects but is prolonged in patients with severe renal insufficiency.

Indications:

a) The dyspeptic symptom complex is often associated with delayed gastric emptying gastro-oesophageal reflux and oesophagitis.

- epigastric sense of fullness, early satiety, feeling of abdominal distension, upper abdominal pain;
- bloating, eructation, flatulence;
- nausea and vomiting;
- heartburn with or without regurgitations of gastric contents in the mouth.

b) Nausea and vomiting of functional, organic, infectious or dietetic origin or induced by radiotherapy and drug therapy. A specific Indication is nausea and vomiting induced by dopamine agonists, as used in Parkinson's disease (such as L-dopa and bromocriptine).

c) Gastroparesis due to diabetic and post surgical gastroparesis sclerodema and idiopathic gastric stasis .

Contraindications:

Emiset is contraindicated in patients with known intolerance to the drug. Emiset should not be used whenever stimulation of gastric motility might be dangerous, e.g. in the presence of gastro-intestinal haemorrhage, mechanical obstruction or perforation Emiset is also contra-indicated in patients with a pituitary tumour (Prolactinoma).

Adverse reactions:

Side effects are rare: exceptionally some transient intestinal cramps have been reported. Extrapyramidal phenomenon are rare in young children and exceptional in adults; they reverse spontaneously and completely as soon as the treatment is stopped. As the pituitary gland is located outside the blood-brain barrier, Emiset may induce an increase in the plasma prolactin level. In rare cases this hyperprolactinaemia may give rise to neuro-endocrinological phenomenon such as galactorrhea and gynaecomastia. When the blood-brain barrier is immature (as in infants) or impaired, the possible occurrence of neurological side effects cannot be totally excluded. Rare allergic reactions, such as rash and urticaria, have also been reported.

Warnings and precautions:

When antacids or antisecretory agents are used concomitantly, they should be taken after meals and not before meals. i.e. they should not be taken simultaneously with Emiset.

Use in infants:

Because the metabolic and blood-brain barrier functions are not fully developed during the first months of life, any drug should only be given to infants with great caution and under close medical supervision. Since the typical absence of neurological side effects with Emiset is mainly due to its poor penetration through the blood-brain barrier, the possible occurrence of such effects cannot be totally excluded in infants under 1 year of age.

Use in liver disorders:

Since Domperidone is highly metabolised in the liver, Emiset should be used with caution in patients with hepatic impairment.

Use in kidney disorders:

In patients with severe renal insufficiency (serum creatinine > 6 mg/100 ml i.e. > 0.6 in mol/l) the elimination half-life of domperidone was increased from 7.4 to 20.8 hours, but plasma drug levels were lower than in healthy volunteers. Since very little unchanged drug is excreted via the kidneys, it is unlikely that the dose of a single acute administration needs to be adjusted in patients with renal insufficiency. However, on repeated administration, the dosing frequency should be reduced to

once or twice daily, depending on the severity of the impairment, and the dose may need to be reduced. Patients on prolonged therapy should be reviewed regularly.

PREGNANCY AND LACTATION:

Use during pregnancy;

Even though no teratogenic effects have been observed in animal studies and autoradiographic studies in rats have shown that the drug does not reach the fetus, the possible risks should be weighed against the benefits before this drug is administered during pregnancy. Experience in humans is hitherto insufficient.

Use during lactation: The drug is excreted in breast milk of lactating rats (mostly as metabolites; peak concentration of 40 and 800 ng/ml after oral and i.v. administration of 2.5 mg/kg respectively). In women domperidone concentrations in breast milk is 4 times lower than corresponding plasma concentrations. It is not known whether this is harmful to the newborn. Therefore nursing is not recommended for mothers who are taking Emiset, unless the expected benefits outweigh any potential risk.

Interactions:

Concomitant administration of anticholinergic drugs may antagonise the antidyspeptic effect of Emiset. Antacids and antisecretory drugs should not be given simultaneously with Emiset as they lower its oral bioavailability (see also "Warnings and Precautions"). Theoretically, since Emiset has gastro-kinetic effects it could influence the absorption of concomitantly orally administered drugs, particularly those with sustained release or enteric coated formulations. However, in patients already stabilised on digoxin or paracetamol, concomitant administration of domperidone did not influence the blood levels of these drugs.

Emiset may also be associated with:

- neuroleptics, the action of which it does not potentiate
- dopaminergic agonists (bromocriptine, L-dopa), whose unwanted peripheral effects such as digestive disorders, nausea and vomiting is suppressed without counteracting its central properties.

Dosage and Administration:

1. chronic dyspepsia (mainly oral administration)

Adults: 10 mg (1 tablet, or 10 ml) 3 times daily, 15-30 minutes before meals and, if necessary, once more before retiring.

Children: Oral suspension: 2.5 ml per 10 kg body weight, 3 times daily before meals and, if necessary, once more in the evening.

When results are not satisfactory, the above dosage may be doubled in adults and children over 1 year of age.

2. Acute and subacute conditions (particularly nausea and vomiting)

Adults: 20 mg (2 tablets, or 20 ml) 3-4 times daily before meals and before bedtime.

Children: Oral: 5 ml per 10 kg body weight, 3-4 times daily before meals and before bedtime.

Remarks:

- Oral Emiset is recommended to be taken before meals. If taken after meals, absorption of the drug is somewhat delayed.
- The tablets are not intended to be administered to children below the age of 5 years.
- In patients with renal insufficiency, the dosing frequency should be reduced (see "Warnings and Precautions").

Overdosage:

Symptoms of overdosage may include drowsiness, disorientation and extrapyramidal reactions, especially in children. Anticholinergic, antiparkinson drugs or antihistamines