Domperidone

Tablet 10 mg

Category: Dopamine antagonist, Peripheral; Gastrointestinal agents, Prokinetic

Composition: Each tablet contains 10 mg Domperidone (as maleate).

Mechanism of action:

Domperidone has peripheral dopamine receptor blocking properties and does not readily cross the blood-brain barrier. It increases esophageal peristalsis and increases lower esophageal sphincter pressure, increases gastric motility and peristalsis, and enhances gastroduodenal coordination, therefore, facilitating gastric emptying and decreasing small bowel transit time.

Pharmacokinetics:

Protein binding: 93%

Metabolism: Hepatic via CYP3A4, N-dealkylation and hydroxylation.

Half-life elimination: 7 hours (increases to ~21 hours in severe renal impairment)

Time to peak serum concentration: 30 minutes

Excretion: Feces (66%) ; urine (31%).

Indications:

Domperidone is indicated for the relief of the symptoms of nausea and vomiting.

Contraindications:

Domperidone is contraindicated in the following situations:

- Known hypersensitivity to domperidone or any of the excipients
- Prolactin - releasing pituitary tumour (prolactinoma).
- when stimulation of the gastric motility could be harmful e.g in patients with gastro - intestinal haemorrhage, mechanical obstruction or perforation.
- in patients with moderate or severe hepatic impairment.
- in patients who have known existing prolongation of cardiac conduction intervals, particularly QTc, patients with significant electrolyte disturbances or underlying cardiac diseases such as congestive heart failure .
- co - administration with QT-prolonging drugs, at the exception of apomorphine .
- co - administration with potent CYP3A4 inhibitors (regardless of their QT prolonging effects).

Drug interactions:

Antiarrhythmics (dronedarone); Antifungals, azoles (fluconazole, isavuconazole, itraconazole, ketoconazole, posaconazole, voriconazole); Aprepitant; Calcium channel blockers (diltiazem, verapamil); Cobicistat; Crizotinib; HIV-protease inhibitors; Idelalisib; Imatinib; Macrolides (clarithromycin, erythromycin); Netupitant; Nilotinib. (increases the risk of QT-prolongation when given with domperidone).

Domperidone is predicted to decrease the prolactin - lowering effect of dopamine receptor agonists (bromocriptine, cabergoline).

Precaution:

Pregnancy: There are limited post-marketing data on the use of domperidone in pregnant women. Studies in animals have shown reproductive toxicity at maternally toxic doses. Domperidone should only be used during pregnancy when justified by the anticipated therapeutic benefit.

Breast-feeding: Domperidone is excreted in human milk and breast-fed infants receive less than 0.1 % of the maternal weight-adjusted dose. Caution should be exercised in case of QTc prolongation risk factors in breast-fed infants.

Renal impairment: The elimination half-life of domperidone is prolonged in severe renal impairment. For repeated administration, the dosing frequency of Domperidone should be reduced to once or twice daily depending on the severity of the impairment. The dose may also need to be reduced.

Side/Adverse effects

Common or very common Drowsiness, dry mouth, malaise.

Uncommon Anxiety, breast pain,decreased libido, diarrhoea, galactorrhoea, headache, pruritus, rash.

Frequency not known Agitation, amenorrhoea, convulsions, extrapyramidal disorders, gynaecomastia, nervousness, oculogyric crisis, QT-interval prolongation, sudden cardiac death, urinary retention, ventricular arrhythmias.

Dosage and administration:

Domperidone should be used at the lowest effective dose for the shortest duration necessary to control nausea and vomiting.

It is recommended to take oral Domperidone before meals. If taken after meals, absorption of the drug is somewhat delayed.

Adults and adolescents (12 years of age and older and weighing 35 kg or more)

One 10mg tablet up to three times per day with a maximum dose of 30 mg per day.

Packaging:

Domperidone tablets are available in packages of 30's (3 blister of 10's).

Manufactured by Amin
Isfahan-Iran