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Prokinin®

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Domperidone Tablets and Suspension

Composition:

Prokinin Tablets: Each tablet contains 10 mg Domperidone.
Prokinin suspension : Each 5ml contains 5 mg Domperidone.

Properties:

Domperidone is a dopamine-receptor blocking agent. Its action on the dopamine-receptors in the chemo-emetic trigger zone produces an anti-emetic effect. It does not cross the blood-brain barrier to any appreciable degree.
Domperidone increases the duration of antral and duodenal contractions to increase gastric emptying, but it does not alter gastric secretions and has no effect on intracranial pressure or in the cardiovascular system.
Domperidone is rapidly absorbed, with peak plasma concentration at approximately 1 hour after oral administration, the bioavailability is low (approximately 15%) due to first pass hepatic and intestinal metabolism, it is 91-93 % bound to plasma proteins, the plasma half life after a single oral dose is 7-9 hours in healthy patients but it is prolonged in patients with sever renal insufficiency.

Indications:

A) The dyspeptic symptom complex that 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 or 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).

Contraindications:

Prokinin is contraindicated for patients with known hypersensitivity to any of its components.
Domperidone should not be used whenever stimulation of gastric motility is to be avoided or could be harmful, eg. In case of gastro-intestinal haemorrhage, obstruction or perforation.
Domperidone is contraindicated in patients with a prolactin-releasing pituitary tumor (prolactinoma).

Precautions:

Domperidone given to animals at doses up to 160 mg/kg/day did not produce teratogenic effects.
However, as most medicines, **Prokinin** should only be used during the first trimester of pregnancy if this is justified by the anticipated therapeutic benefit.
Up to now, there has been no evidence of any increase in the risk of malformations in humans.
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 are 4 times lower than corresponding plasma concentrations. It is not known whether this is harmful to the new born.
Therefore nursing is not recommended for mothers who are taking **Prokinin**, unless the expected benefits outweigh any potential risk.

Interactions with other drugs:

Concomitant administration with Amantadine leads to extrapyramidal side effects.
Anti-muscarinic agents and opioid analgesics may antagonize the effect of **prokinin**.
Concomitant administration with Bromocriptine or Cabergoline leads to Possible antagonism of hypoprolactinaemic effect.
Concomitant administration with Paracetamol or Benorilate increases the absorption of them.

Warnings:

Generally patients on prologed therapy should be reviewd regularly.
Domperidone is highly metabolised in liver, so prokinin should be used with caution in patients with hepatic impairment (and in the elderly).
Used with caution in patients with renal impairment or in those at risk of fluid retention.

Dosage and Administration:

1. Chronic dyspepsia
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:
2 x 2.5 ml per 10 kg body weight, 3-4 times daily before meals and before bedtime.

Overdosage:

Symptoms of overdosage may include drowsiness, disorientation.
In case of overdosage gastric lavage and administration of activated charcoal may be useful.
Symptomatic and supportive treatment are recommended.

Side Effects:

Side effects are rare.
Raised prolactin concentration (possible galactorrhoea and gynaecomastia), reduced libido, rashes and other allergic reactions, acute dystonic reactions.
Consult your Pharmacist or Physician if any side effect is observed.

Pharmaceutical Precautions:

Keep at room temperature (15-30 °C).
Do not use beyond the expiry date or if the product shows any sign of deterioration.

Presentation:

Prokinin Suspension: Bottle of 180ml.
Prokinin Tablets: Pack of 30 Tablets.
Hospital packs are available.

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THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists.

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