Prokinet

Domperidone

COMPOSITION

Prokinet Tablet: Each film coated tablet contains Domperidone Maleate BP equivalent to Domperidone 10 mg.
Prokinet Suspension: Each 5 ml suspension contains Domperidone BP 5 mg.

PHARMACOLOGY

Prokinet (Domperidone) is a dopamine receptor antagonist. It gives gastroprokinetic action by blocking dopamine receptors located in the chemoreceptor trigger zone (CTZ) and stomach. Due to its weak penetration across the blood-brain barrier, it has almost no effect on the dopaminergic receptors in the brain, therefore excluding psychotropic and neurologic side effects.

INDICATION

It is used in the following indications:
1. Stimulation of gut motility in non-ulcer dyspepsia, gastro-esophageal reflux disease, reflux esophagitis, diabetic gastroparesis & functional dyspepsia.
2. Speeding Barium transit in 'follow through' radiological studies.
3. Prevention and symptomatic relief of acute nausea and vomiting due to cytotoxic therapy, anti-parkinsonism therapy, radio therapy or migraine.

DOSAGE AND ADMINISTRATION

Adults: One 10 mg tablet up to three times per day with a maximum dose of 30 mg per day or 10 ml suspension up to three times per day with a maximum dose of 30 ml per day.
Children: The dose is 0.25 mg/kg. This should be given up to three times per day with a maximum dose of 0.75 mg/kg per day.
It should be taken 15-30 minutes before meal.

CONTRAINDICATION

It is contraindicated in patients with known hypersensitivity to Domperidone or any components of the preparation. Domperidone should not be used whenever gastro-intestinal stimulation might be dangerous (i.e., gastro-intestinal haemorrhage, mechanical obstruction or perforation). It is also contraindicated in prolactinoma.

WARNING AND PRECAUTION

It should be used with absolute caution in case of children because there may be increased risk of extra-pyramidal reactions. Since Domperidone is highly metabolized in liver, it should be used with caution in patient with hepatic impairment.

SIDE EFFECTS

It may produce hyperprolactinemia (1.3%). This may result in galactorrhea, breast enlargement & soreness and reduced libido. Dry mouth (1.9%), thirst, headache (1.2%), nervousness, drowsiness (0.4%), diarrhoea (0.2%), skin rash and itching (0.1%) may occur during treatment with Domperidone. Extra-pyramidal reactions are seen in 0.05% of patients in clinical studies.

USE IN PREGNANCY AND LACTATION

The safety of use of Domperidone has not been proven duing pregnancy; it is therefore not recommended during pregnancy. Animal studies have not demonstrated teratogenic effects on the fetus. Domperidone may precipitate galactorrhea and improve post-natal lactation. It is secreted in breast milk in very small quantities which is insufficient to be considered harmful.

USE IN CHILDREN AND ADOLESCENTS

Neonates/infants, children (less than 12 years of age) and adolescents weighing less than 35 kg should use Prokinet suspension.

DRUG INTERACTION

The action of Domperidone on gastro-intestinal function may be antagonized by antimuscarinics and opioid analgesics. Care should be exercised when Domperidone is administered in combination with MAO (monoamine oxidase) inhibitors.

OVERDOSAGE

In the event of overdose, standard symptomatic treatment should be given immediately. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation.

STORAGE

Store below 30^{O}C temperature in a cool and dry place. Protect from light. Keep out of the reach of children.

HOW SUPPLIED

Prokinet Tablet: Each box contains 100 tablets in Alu-PVC blister pack.
Prokinet Suspension: Each amber PET bottle contains 60 ml suspension.

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NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
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