

Deflux[®] Meltab

Domperidone
Orally Dispersible Tablet

Description

Domperidone is a Dopamine antagonist. As it does not enter the central nervous system, its effect is confined to the periphery and acts principally at the receptor in the chemoreceptor trigger zone.

Indications

1. Stimulation of gut motility in
 - Non-ulcer dyspepsia
 - Esophageal reflux and gastritis
 - Diabetic gastroparesis
 - Functional dyspepsia
 - Speeding barium transit in follow through radiological studies
2. Prevention and symptomatic relief of acute nausea and vomiting from any cause including cytotoxic therapy, radio therapy and anti-parkinsonism therapy.
3. In the prophylactic treatment of migraine.

Dosage and Administration

The recommended oral dose for

Adults: 10-20 mg every 4-8 hours daily.

Children: 0.2-0.4 mg/kg every 4-8 hours daily.

Note: Domperidone should be taken 15-30 minutes before a meal.

For acute vomiting and nausea, maximum period of treatment is 12 weeks.

Use in children is restricted to nausea and vomiting following cytotoxic or radiotherapy.

Contraindications

Domperidone is contraindicated to the patients who have hypersensitivity to this drug and in case of neonates.

Precautions

Domperidone should be used with absolute

caution in case of children because there may be an increased risk of extra-pyramidal reactions in young children because of an incompletely developed blood brain barrier.

Side Effects

Domperidone may produce hyperprolactinemia (1.3% frequency). This may result in galactorrhoea, 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

Pregnant women: The safety of Domperidone has not been proven and it is therefore not recommended during pregnancy. Animal studies have not demonstrated teratogenic effects on the foetus.

Lactating mothers: Domperidone may precipitate galactorrhoea and improve post-natal lactation. It is secreted in breast milk but on very small quantities, insufficient to be considered harmful.

Drug Interactions

Domperidone may reduce the hypoprolactinemic effect of bromocriptine. Anti-muscarinics and opioid analgesics may antagonize the action of Domperidone on GI function.

Overdosage

There is no reported case of overdosage.

Pharmaceutical Precautions

Store in a cool and dry place. Keep out of the reach of children.

Commercial Pack

Deflux[®] Meltab: Box containing 100 tablets in 10x10's blister strips. Each orally dispersible tablet contains Domperidone BP 10 mg.



Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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