

Composition:

Xeridon™ 10 mg Tablet: Each film coated tablet contains Domperidone Maleate BP equivalent to Domperidone 10 mg.

Xeridon™ 5 mg/5 ml Suspension: Each 5 ml suspension contains Domperidone BP 5 mg.

Pharmacology:

Domperidone is a selective peripheral dopamine D₂ receptor antagonist that principally blocks the dopamine receptors located in the Chemoreceptor Trigger Zone (CTZ) and stomach. Its gastroprokinetic action is based on its blocking effect of dopamine receptors that have an influence on the motility of gastro-intestinal tract. Due to its weak penetration across the blood-brain-barrier, Domperidone has almost no effect on the dopaminergic receptors in the brain, therefore excluding psychotropic and neurologic side effects. Domperidone restores normal motility and tone of the upper gastro-intestinal tract, facilitates gastric emptying, enhances antral and duodenal peristalsis and regulates contraction of the pylorus. Domperidone also increases esophageal peristalsis and lower esophageal sphincter pressure and thus prevents regurgitation of gastric content.

Indications:

1. Stimulation of gut motility in Dyspeptic symptom complex
 - Non-ulcer dyspepsia
 - Delayed gastric emptying, gastro- esophageal reflux, reflux esophagitis and gastritis
 - Epigastric sense of fullness, feeling of abdominal distension, upper abdominal pain
 - Eructation, flatulence, early satiety
 - Nausea and vomiting
 - Heartburn with or without regurgitations of gastric contents in the mouth
 - 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 treatment of migraine.

Dose and administration:

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

The recommended oral dose for-

Adults: 10-20 mg every 4-8 hours daily. Maximum dose of Domperidone is 80 mg daily.

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

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

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

Contra-indications:

Domperidone is contraindicated to patients having known hypersensitivity to this drug and in case of neonates. Domperidone should not be used whenever gastro-intestinal stimulation might be dangerous, like in the case of gastro-intestinal hemorrhage, mechanical obstruction or perforation. It is also contraindicated in patients with prolactin-releasing pituitary tumor (prolactinoma).

Warning & precaution:

Domperidone should be used with absolute caution in case of children because there may be increased risk of extra-pyramidal reactions in young children because of an incompletely developed blood-brain barrier. Since Domperidone is highly metabolized in liver, it should be used with caution in patients with hepatic impairment.

Side effects:

Domperidone may produce hyperprolactinemia (1.3% frequency). This may result in galactorrhea, breast enlargement and soreness, and reduced libido. Dry mouth (1.9%), thirst, headache (1.2%), nervousness, drowsiness (0.4%), diarrhea (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 fetus.

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

Drug interaction:

Domperidone may reduce the hypoprolactinemic effect of Bromocriptine. Anti-muscarinics and opioid analgesics may antagonize the action of Domperidone on GI function. Care should be taken when Domperidone is administered in combination with MAO (Monoamine oxidase) inhibitors.

Overdose:

There is no reported case of overdosage.

Storage:

Do not store above 30°C, protect from light & moisture. Keep out of reach of children.

Packing:

Xeridon™ 10 mg Tablet: Each box contains 100 tablets in blister pack.

Xeridon™ 5 mg/5 ml Suspension: Each bottle contains 60 ml suspension.