

Ridon®

Domperidone Film Coated Tablet / Suspension / Paediatric Drops /
Effervescent Granules / Orally Dispersible Tablet

DESCRIPTION

Ridon® is a preparation of Domperidone. It is a dopamine antagonist with anti-emetic properties. Domperidone does not readily cross the blood-brain barrier. In Domperidone users, especially in adults, extrapyramidal side effects are very rare, but Domperidone promotes the release of prolactin from the pituitary gland. Its anti-emetic effect may be due to a combination of peripheral (gastrokinetic) effects and antagonism of dopamine receptors in the chemoreceptor trigger zone.

INDICATIONS

1. Prevention and symptomatic relief of acute nausea and vomiting in adults from any cause including cytotoxic therapy, radiotherapy and anti-parkinsonism therapy.
2. Stimulation of gut motility
 - a) Non-ulcer dyspepsia
 - b) Esophageal reflux, reflux esophagitis and gastritis
 - c) Diabetic gastroparesis
 - d) Functional dyspepsia
 - e) Speeding barium transit in 'follow-through' radiological studies
3. Relieves nausea associated with migraine attack.

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

DOSAGE AND ADMINISTRATION

Adults: 10-20 mg (1-2 tablet or 10-20 mL suspension or 1-2 sachets) 3 to 4 times daily, before meal.

Children: Nausea and vomiting following cytotoxic therapy or radiotherapy only; 200-400 µg/m² / Kg (2-4mL suspension / 10 Kg or 0.4-0.8 mL drops / 10 Kg) body weight 3 to 4 times daily.

(**Ridon®** should be taken 15-30 minutes before meal. Maximum period of treatment is 12 weeks.)

CONTRAINDICATIONS

Domperidone is contraindicated in the following situations:

- Known hypersensitivity to Domperidone or any of the excipients
- Prolactin-releasing pituitary tumour (prolactinoma).
- Patients with severe renal insufficiency.

SIDE-EFFECTS

- Immune System Disorder: Very rare; Allergic reaction
- Endocrine disorder: Rare; increased prolactin levels
- Nervous system disorders: Very rare; extrapyramidal side effects
- Gastrointestinal disorders: Rare; gastro-intestinal disorders, including very rare transient intestinal cramps
- Skin and subcutaneous tissue disorders: Very rare; urticaria
- Reproductive system and breast disorders: Rare; galactorrhoea, gynaecomastia, amenorrhoea.

USE IN PREGNANCY AND LACTATION

Use in pregnancy: The potential risk of Domperidone in pregnant women is unknown. Therefore, **Ridon®** should only be used during pregnancy when justified by the anticipated therapeutic benefit.

Use in lactating mother: Domperidone concentrations in breast milk of lactating women are 10 to 50% of the corresponding plasma concentrations and expected not to exceed 10 ng/mL. The total amount of Domperidone excreted in human breast milk is expected to be less than 7µg per day at the highest recommended dosing regimen. It is not known whether this is harmful to the newborn. Therefore breast-feeding is not recommended for mothers who are taking Domperidone.

OVERDOSE

Symptoms of overdose may include drowsiness, disorientation and extrapyramidal reactions, especially in children. There is no specific antidote to Domperidone, but in the event of overdose, gastric lavage as well as the administration of activated charcoal, may be useful. Close medical supervision and supportive therapy is recommended. Anticholinergic, anti-parkinson drugs may be helpful in controlling the extrapyramidal reactions.

PHARMACEUTICAL PRECAUTIONS

Keep away from light and wet place. Store at or below 30 °C temperature. Keep out of reach of children.

PACKAGING

Ridon® FCT : Box containing 10 strips of 10 tablets each. Each film-coated tablet contains Domperidone maleate BP equivalent to 10 mg Domperidone.

Ridon® Suspension : Amber glass bottle containing 60mL/100mL suspension. Each 5 mL suspension contains Domperidone BP 5 mg.

Ridon® Paediatric Drops : Bottle containing 15 mL paediatric drops. Each 1 mL drop contains Domperidone BP 5 mg.

RIDON FAST® Tablet : Box containing 10 strips of 10 tablets each. Each tablet contains Domperidone BP 10 mg.

Ridon EG® PFS : Box containing 30 sachets. Each sachet contains Domperidone BP 10 mg as effervescent granules.

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Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

RUPGANJ, NARAYANGANJ, BANGLADESH

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