

EPIDOR[®]-D

(Rabeprazole & Domperidone sustained release pellets in capsule)

Composition:

Each hard gelatin Capsule Contains:

Rabeprazole Sodium IP..... 20mg

(As enteric coated pellets)

Domperidone IP..... 30mg

(As sustained release pellets)

Excipients... q.s.

Clinical Pharmacology:

Rabeprazole

Rabeprazole belongs to a class of antisecretory compounds suppress gastric acid secretion by inhibiting the gastric H⁺, K⁺ ATPase at the secretory surface of the gastric parietal cell. Because this enzyme is regarded as the acid (proton) pump within the parietal cell, Rabeprazole has been characterized as a gastric proton pump inhibitor. Rabeprazole blocks the final step of gastric acid secretion.

Domperidone

Domperidone the Dopamine A₂-receptor antagonist antagonizes the inhibitory effect of dopamine, resulting in stimulation of gastric muscle contraction. This provides a mechanism for the gastro kinetic effect of domperidone. Domperidone is a dopamine-2 receptor antagonist. It acts as an antiemetic and a prokinetic agent through its effects on the chemoreceptor trigger zone and motor function of the stomach and small intestine.

Indications:

- Gastro Esophageal Reflux Disease (GERD).
- Severe acidity associated with vomiting
- Regurgitation and dyspepsia.
- Nausea and vomiting

Contraindications:

- Patients with a history of hypersensitivity to rabeprazole
- Proton pump inhibitors, including rabeprazole delayed-release tablets, are contraindicated in patients receiving rilpivirine-containing products
- Refer to the Contraindications section of the prescribing information for clarithromycin and amoxicillin, when administered in combination with rabeprazole
- Domperidone is contraindicated for patients with moderate or severe hepatic impairment

Precautions and Warnings:

- Gastric Malignancy: In adults, symptomatic response to therapy with rabeprazole does not preclude the presence of gastric malignancy. Consider additional follow-up and diagnostic testing
- Use with Warfarin: Monitor for increases in INR and prothrombin time
- Acute Interstitial Nephritis: Observed in patients taking proton pump inhibitors
- Bone Fracture: Long-term and multiple daily dose proton pump inhibitors therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine.
- Do not use domperidone if you have moderate or severe liver failure.

Drug Interactions:

Decreased exposure of some antiretroviral drugs (e.g., rilpivirine, atazanavir, and nelfinavir) when used concomitantly with rabeprazole may reduce antiviral effect and promote the development of drug resistance. Increased exposure of other antiretroviral drugs (e.g., saquinavir) when used concomitantly with rabeprazole may increase toxicity. Do not take domperidone with medicines containing the active ingredient itraconazole, posaconazole or voriconazole which is used to treat fungal infections and with active ingredient like ritonavir or siquinavir which is used to treat HIV.

Adverse effects:

- Most common adverse reactions in adults are pain, pharyngitis, flatulence, infection, and constipation
- Most common adverse actions in adolescents are headache, diarrhea, nausea, vomiting, and abdominal pain

Overdosage:

Causes agitation, convulsion, drowsiness, altered consciousness, confusion and uncontrolled movements.

For Therapeutic use.

Route of administration: Oral.

Capsule should be swallowed as whole. Not to be opened, crushed or chewed.
Keep the medicine out of reach of children.

SCHEDULE H PRESCRIPTION DRUG CAUTION

Not to be sold by retail without the prescription of a Registered Medical Practitioner.

Dosage:

As directed by Physician.

Storage:

Store in temperature below 25°C Protect from light and moisture.

Presentation: Epidor-D Enteric coated capsules available as 10 x10 Capsules

Marketed By:

EPIONE PHARMACEUTICALS PVT.LTD.

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