

EPIDOR[®]-20

(Rabeprazole Sodium Tablets I.P. 20 mg)

Composition:

Each Enteric coated Tablet Contains:

Rabeprazole20mg

Excipients...q.s.

Colour..... Yellow oxide of Iron & Titanium Dioxide I.P

Clinical Pharmacology:

Rabeprazole

Rabeprazole belongs to a class of antisecretory compounds that suppress gastric acid secretion by inhibiting the gastric H⁺, K⁺ ATPase enzyme 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.

Indications:

- Healing of Erosive or Ulcerative Gastro Esophageal Reflux Disease(GERD).
- Maintenance of Healing of Erosive or Ulcerative GERD
- Treatment of Symptomatic GERD
- Healing of Duodenal Ulcers
- Helicobacter pylori Eradication to Reduce Risk of Duodenal Ulcer Recurrence
- Treatment of Pathological Hypersecretory Conditions, Including Zollinger-Ellison Syndrome, in adolescent patients 12 years of age and older for: Short-term Treatment of Symptomatic GERD.

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

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.

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.

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:

There are no clinical signs or symptoms associated with any reported overdose.

For Therapeutic Use.

Route of administration: Oral.

Type of tablet: Enteric coated Tablet.

Dosage: As Directed by the Physician

Storage: Store in cool and dry place.

SCHEDULE H PRESCRIPTION DRUG-CAUTION Not to be sold retail without the Prescription of a Registered Medical Practitioner.

Tablet should be swallowed whole not to be Chewed or crushed.

Presentation:

Epidor-20 enteric coated Tablet available as 10 x10 Tablets.

Marketed By:



EPIONE PHARMACEUTICALS PVT.LTD.

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