RabemaX Tablet

Rabeprazole Sodium

Presentation

Rabemax Tablet: Each enteric coated tablet contains Rabeprazole Sodium INN 20 mg.

Properties and effects

Rabeprazole Sodium suppresses gastric acid secretion by inhibiting the gastric H+/K+ ATPase at the secretary surface of the gastric parietal cell. Because this enzyme is rctegarded as the acid (Proton) pump within the parietal cell, Rabeprazole Sodium has been characterized as a gastric proton-pump inhibitor.

Pharmacokinetic Properties

Rabeprazole Sodium is well absorbed and can be detected in plasma by 1 hour. Rabeprazole Sodium is 96.3% bound to human plasma protein. Rabeprazole Sodium is metabolized in the liver primarily by cytochromes P450 3A (CYP3A) to a sulphone metabolite and cytochrome P450 2C19 (CYP2C19) to desmethyl Rabeprazole Sodium. Approximately 90% of the drug is eliminated in the urine.

Indications

- Benign gastric ulcer
- Duodenal Ulcer
- Duodenal and benign gastric ulcer associated with Helicobacter pylori
- Gastro Esophageal Reflux Disease (GERD)
- Zollinger-Ellison Syndrome

Dosage and Administration

Rabeprazole Sodium 20 mg tablet should be swallowed whole. This can be taken with or without food.

Adult

Benign gastric ulcer:
20 mg daily in the morning for 8 weeks

Duodenal ulcer:
20 mg daily in the morning for 4 weeks

Duodenal and benign gastric ulcer associated with Helicobacter pylori:
A three drug regimen containing Rabeprazole Sodium 20 mg delayed release tablet, Amoxicillin 1000 mg capsule and Clarithromycin 500 mg tablet should be taken twice daily with the morning and evening meals for 7 days.

Gastro-oesophageal reflux disease (GERD):
20 mg once daily for 4–8 weeks; maintenance 10–20 mg daily

Zollinger–Ellison syndrome:
Initially 60 mg once daily adjusted according to response (max. 120 mg daily).

Child

Not recommended

Contraindications

Rabeprazole Sodium is contraindicated in patients with known hypersensitivity to Rabeprazole Sodium or to any component of the formulation.

Side Effects

Rabeprazole Sodium tablets are generally well tolerated. The observed undesirable effects have been generally mild/moderate and transient in nature. The most common adverse events are headache, diarrhea and nausea. The less common adverse effects are abdominal pain, asthenia, flatulence, rash, dry mouth etc.

Precautions

Administration of Rabeprazole Sodium to patients with mild to moderate liver impairment results in increased exposure and decreased elimination. Caution should be exercised in patients with severe hepatic impairment.

Drug Interactions

Like other PPIs Rabeprazole Sodium is metabolized through Cytochrome P450 drug metabolizing enzyme system. But Rabeprazole Sodium does not have clinically significant interaction with other drugs metabolized by CYP P450 system such as warfarin, theophylline, diazepam and phenytoin. Rabeprazole Sodium inhibits gastric acid secretion and may interfere with absorption of drugs where gastric pH is an important determinant of bioavailability e.g. ketoconazole, iron salts and digoxin. In studies no interaction with liquid antacid foods was observed.

Use in Pregnancy & Lactation

Pregnancy category C. This drug should be used during pregnancy only if clearly needed. It is not known whether Rabeprazole Sodium is excreted in human milk. Because many drugs are excreted in human milk, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Storage Conditions

Store in a cool (below 25^0 C) & dry place, away from light. Keep out of reach of children.

Commercial Pack

Rabemax Tablet: Each box contains 5 blister packs of 14 tablets.

Manufactured by:
general GENERAL
Pharmaceuticals Ltd.
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