

Rabizol

Tablet

Rabeprazole Sodium USP

Composition

Each enteric coated tablet contains Rabeprazole Sodium USP 20 mg.

Pharmacology

Rabeprazole suppresses gastric and 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.

Indications

- Healing of Erosive or Ulcerative GERD
- Maintenance of Healing of Erosive or Ulcerative GERD
- Treatment of Symptomatic GERD
- Healing of Duodenal Ulcers
- *Helicobacter pylori* Eradication to Reduce the Risk of Duodenal Ulcer Recurrence
- Treatment of Pathological Hypersecretory Conditions, Including Zollinger-Ellison Syndrome.

Dosage and Administration

Route of administration : Oral

Rabizol tablet should be swallowed whole. Rabizol tablet can be taken with or without food.

Healing of Erosive or Ulcerative GERD

The recommended adult oral dose is 1 Rabizol tablet to be taken once daily for 4 to 8 weeks. For those patients who have not healed after 8 weeks or treatment, an additional 8-week course of Rabizol tablet may be considered.

Maintenance of Healing of Erosive or Ulcerative GERD

The recommended adult oral dose is one Rabizol tablet once daily.

Treatment of Symptomatic GERD

The recommended adult oral dose is 1 Rabizol tablet once daily for 4 weeks. If symptoms do not resolve completely after 4 weeks, and additional course of treatment may be considered.

Healing of Duodenal Ulcers

The recommended adult oral dose is 1 Rabizol tablet once daily after the morning meal for a period up to 4 weeks. Most patients with duodenal ulcer heal within 4 weeks. A few patients may require additional therapy to achieve healing.

Helicobacter pylori Eradication to Reduce the risk of Duodenal Ulcer Recurrence

Rabeprazole	20 mg	Twice daily with the morning and evening meals for 7 days
Amoxicillin	1000 mg	
Clarithromycin	500 mg	

Treatment of Pathological Hypersecretory Conditions, Including Zollinger-Ellison Syndrome

The dosage of Rabizol tablet in patients with pathological hypersecretory conditions varies with the individual patient. The recommended adult oral starting dose is 60 mg once a day. Dose should be adjusted to individual patients need and should continue for as long as clinically indicated. Some patients may require divided doses. Some patients with Zollinger-Ellison syndrome have been treated continuously with Rabizol tablet for up to one year.

OR AS DIRECTED BY THE REGISTERED PHYSICIAN.

Contraindication

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

Warning & Precaution

Administration of Rabeprazole 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.

Side Effects

Rabeprazole 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.

Use in Pregnancy & Lactation

Pregnancy : Pregnancy category B. There are no adequate well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.

Lactation : Since many drugs are excreted in milk and because of the potential for adverse reactions to nursing infants for Rabeprazole, a decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Geriatric Patients

No overall differences in safety or effectiveness were observed between these subjects and younger subjects, but greater sensitivity of some older individuals can not be ruled out.

Drug Interaction

Rabeprazole like other PPIs is metabolized through Cytochrome P450 drug metabolizing enzyme system. But Rabeprazole does not have clinically significant interaction with other drug metabolized by CYP450 system, such as warfarin, theophylline, diazepam and phenytoin. Rabeprazole 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 or foods was observed.

Overdose

There has been no experience with large overdoses with Rabeprazole. In the event of overdose, treatment should be symptomatic and supportive.

Storage

Store below 30° C temperature & dry place, protect from light.
Keep all medicine out of reach of the children.

Packing

Rabizol 20 mg tablet (140's) : Each box contains 10x14 tablets in Alu-Alu blister strips.

Rabizol 20 mg tablet (70's) : Each box contains 5x14 tablets in Alu-Alu blister strips.

* Further information is available on request.



Manufactured by:

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