

Acifix®

Rabeprazole Sodium
Tablet, Capsule

Description

Rabeprazole Sodium is an antiulcer drug in the class of proton pump inhibitors. Rabeprazole Sodium is a substituted benzimidazole which suppresses gastric acid secretion by inhibiting the gastric H^+/K^+ -ATPase enzyme at the secretory surface of the gastric parietal cell. It is an enteric coated formulation, because of its enteric coated formulation it is highly stable in stomach and because of higher pKa value of Rabeprazole Sodium it provides faster onset of action.

Indications

- Short-term treatment in healing and symptomatic relief of duodenal ulcers and erosive or ulcerative Gastroesophageal Reflux Disease (GERD);
- Maintaining, healing and reducing relapse rates of heartburn symptoms in patients with GERD;
- Treatment of daytime and night time heartburn and other symptoms associated with GERD;
- Long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome and in combination with amoxicillin and clarithromycin to eradicate *Helicobacter pylori*.

Dosage and Administration

Healing of Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD): 20 mg to be taken once daily for four to eight weeks. For those patients who have not healed after 8 weeks of treatment, an

additional 8 weeks course may be considered.

Maintenance of Healing of Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD Maintenance): The recommended adult oral dose is 20 mg once daily.

Treatment of Symptomatic Gastroesophageal Reflux Disease (GERD): The recommended adult oral dose is 20 mg once daily for 4 weeks. If symptoms do not resolve completely after 4 weeks, an additional course of treatment may be considered.

Healing of Duodenal Ulcers: The recommended adult oral dose is 20 mg once daily after the morning meal for a period up to four weeks. Most patients with duodenal ulcer heal within four weeks. A few patients may require additional therapy to achieve healing.

Helicobacter pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence:

Rabeprazole Sodium	20 mg	Twice Daily for 7 Days
Amoxicillin	1000 mg	Twice Daily for 7 Days
Clarithromycin	500 mg	Twice Daily for 7 Days

All three medications should be taken twice daily with the morning and evening meals. It is important that patients comply with the full 7 days regimen.

Treatment of Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome: The starting dose is 60 mg once daily adjusted according to response.

Contraindications

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

Adverse Reactions

Rabeprazole Sodium may sometimes cause headache, diarrhoea, abdominal pain, vomiting, constipation, dry mouth, increased or decreased appetite, muscle pain, drowsiness and dizziness.

Warning & Precautions

Pregnant women: Rabeprazole Sodium is TGA pregnancy category B1. However this drug should be used during pregnancy, only if clearly needed.

Lactating mother: There are no data on the excretion of Rabeprazole Sodium into the breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the benefit of the drug to the mother.

Pediatric use: The safety of Rabeprazole Sodium have not been established for GERD in pediatric patients younger than 1 year of age.

Drug Interactions

Rabeprazole shows least drug drug interaction. Studies in healthy subjects have shown that Rabeprazole does not have clinically significant interactions with other drugs metabolized by the CYP450 system, such as warfarin and theophylline given as single oral doses, diazepam as a single intravenous dose, and phenytoin given as a single intravenous dose (with supplemental oral dosing).

Combined administration consisting of rabeprazole, amoxicillin, and clarithromycin resulted in increases in plasma concentrations of rabeprazole and 14-hydroxylclarithromycin.

Pharmaceutical Precautions

Keep in a dry place and store below 30° C. Protect from light and keep out of the reach of children.

Commercial Pack

Acifix® Tablet: Box containing 100 tablets in 10 x 10's Alu-Alu form packs. Each enteric coated tablet contains Rabeprazole Sodium USP 20 mg.

Acifix® VegeCap: Box containing 60 capsules in 6 x 10's Alu-Alu form packs. Each HPMC vegetable shell capsule contains Rabeprazole Sodium USP 20 mg as delayed release pellets.



Manufactured by

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