

Description

Rabeprazole is a gastric proton-pump inhibitor. It suppresses gastric acid secretion by inhibiting the gastric H+/K+ ATPase at gastric parietal cell.

Composition

Rasoz Tablet: Each enteric coated tablet contains Rabeprazole Sodium INN 20 mg.
Rasoz Capsule: Each capsule contains Rabeprazole Sodium INN 20 mg as enteric coated pellets.

Indication

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, Reduce the Risk of Duodenal Ulcer.

Dosage & Administration

Rasoz tablet should be swallowed whole. Tablet can be taken with or without food. Healing of Erosive or Ulcerative GERD: One tablet once daily for 4 to 8 weeks. If the patients do not heal after 8 weeks, additional 8-weeks course may be considered. Maintenance of Healing of Erosive or Ulcerative GERD: One tablet once daily. Symptomatic GERD: One tablet once daily for 4 weeks. If symptoms do not resolve completely, additional course may be considered. Healing of Duodenal Ulcers: One tablet once daily after the morning meal for 4 weeks. Usual Adult Dose for Helicobacter pylori Infection: Three drug regimen: Rabeprazole 20 mg, amoxicillin 1000 mg and clarithromycin 500 mg orally two times daily for 7 days. Adult Dose for Zollinger-Ellison Syndrome: Initial: 60 mg orally once a day, after the morning meal. Maintenance: Doses up to 100 mg orally once a day or 60 mg orally twice a day have been administered. Patients have been treated continuously for up to one year. Or as directed by the registered physician.

Side effect

Rabeprazole is generally well tolerated. The observed side effects are mild/moderate and transient in nature. Common side effects are headache, diarrhea and nausea, abdominal pain, asthenia, flatulence, rash, dry mouth etc.

Contraindication

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

Drug Interaction

Rabeprazole is metabolized by cytochrome P450 drug metabolizing enzyme system. Rabeprazole does not have interactions with other drugs metabolized by the CYP450 enzyme system such as warfarin, theophylline, phenytoin etc.

Precaution/Warning

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.

Use in Pregnancy & Lactation

Pregnancy category B. This drug should be used during pregnancy, only if clearly needed. There are no data on the excretion of Rebeprazole into the breast milk.

Storage

Store below 30°C, away from light and moisture. Keep out of reach of children.

How supplied

 $\it Rasoz\, Tablet: Each box contains 5x10 tablets in Alu-Alu blister within Alu-Alu pillow pack.$

Manufactured by:

