

Paricel[®]

Description

Paricel[®] 20mg is a preparation of Rabeprazole Sodium. It is an antisecretory compound that suppresses gastric acid secretion by inhibiting the gastric H⁺, K⁺ ATPase at the secretory surface of the gastric parietal cell.

Indications

- Healing of Erosive or Ulcerative Gastro-Esophageal Reflux Disease (GERD)
- Maintenance of Healing of Erosive or Ulcerative Gastro-Esophageal Reflux Disease (GERD)
- Treatment of Symptomatic Gastro-Esophageal Reflux Disease (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

Healing of Erosive or Ulcerative Gastro-Esophageal Reflux Disease (GERD): The recommended adult oral dose is one Paricel[®] 20mg tablet for 4 to 8 weeks. For those patients who have not healed after 8 weeks of treatment, an additional 8 weeks course of Paricel[®] may be considered.

Maintenance of Healing of Erosive or Ulcerative Gastro-Esophageal Reflux Disease (GERD): The recommended adult oral dose is one Paricel[®] 20mg tablet to be taken once daily.

Treatment of Symptomatic Gastro-Esophageal Reflux Disease (GERD): The recommended adult oral dose is one Paricel[®] 20mg tablet to be taken 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 one Paricel[®] 20mg tablet to be taken 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:
Three drug regimen-

Rabeprazole	20mg	Twice daily for 7 days
Amoxicillin	1000mg	Twice daily for 7 days
Clarithromycin	500mg	Twice daily for 7 days

All three medications should be taken twice daily with the morning and evening meals.

Treatment of pathological hypersecretory conditions including Zollinger-Ellison Syndrome: The recommended adult oral starting dose is 60 mg once daily. Doses should be adjusted to individual patient needs and should continue for as long as clinically indicated. Some patients may require divided doses. Doses up to 100 mg QD and 60 mg BID have been administered.

Use in pregnancy

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

Use in lactating mother

It is not known if unmetabolized Rabeprazole is excreted in human breast milk. Since many drugs are excreted in milk, and because of the potential for adverse reactions to nursing infants from Rabeprazole, a decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Paediatric Use

The safety and effectiveness of Rabeprazole in paediatric patients have not been established.

Geriatric use

No overall differences in safety or effectiveness were observed between these subjects and younger subjects.

Precautions

Symptomatic response to therapy with Rabeprazole does not preclude the response of gastric malignancy. There have been reports of increased INR and prothrombin time in patients receiving a proton pump inhibitor and warfarin concomitantly. Patients treated with a proton pump inhibitor and warfarin concomitantly may need to monitor for increases in INR and prothrombin time.

Side effects

Rabeprazole tablet is generally well tolerated. Most common adverse events include headache, diarrhea and nausea. Other adverse events are rhinitis, abdominal pain, asthenia, flatulence, pharyngitis, vomiting, dizziness, flu like syndrome, infection, cough, constipation and insomnia. The observed undesirable effects have generally been mild/moderate and transient in nature.

Contra-indications

Rabeprazole is contra-indicated in patients with known hypersensitivity to Rabeprazole, substituted benzimidazoles or to any component of the formulation.

Overdose

There has been no experience with large overdoses with Rabeprazole. No specific antidote for Rabeprazole is known. Rabeprazole is extensively protein bound and is not readily dialyzable. In the event of over dosage treatment should be symptomatic and supportive.

Warnings

Clarithromycin should not be used in pregnant women except in clinical circumstances where no alternative therapy is appropriate. If pregnancy occurs while taking Clarithromycin, the patient should be appraised of the potential hazards to the fetus. Amoxicillin: serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens.

Drug Interactions

Rabeprazole is metabolized by the cytochrome P450 (CYP450) drug metabolizing enzyme system. 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, diazepam and phenytoin.

Pharmaceutical precaution

Store in a cool and dry place below 30°C. Protect from light & moisture.

Presentation

Paricel® 20 Tablets: Each enteric coated tablet contains Rabeprazole Sodium INN 20mg.

Package quantities

Paricel® 20 Tablets: Carton of 60 tablets in blister.

® Registered Trade Mark



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