Only for the use of Medical Professionals

Paricel®

Rabeprazole

Description

Paricel® 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)
- Prevention of Relapse of Gastro-Esophageal Reflux Disease (GERD)
- Treatment of Symptomatic Gastro-Esophageal Reflux Disease (GERD)
- Healing of Duodenal & Gastric Ulcers
- Helicobacter pylori eradication to reduce the risk of Duodenal & Gastric 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 **Paricel**® 20 mg to be taken once daily for 4 to 8 weeks. For those patients who have not healed after 8 weeks of treatment, an additional 8 weeks course of **Paricel**® 20 mg may be considered.

Maintenance of Healing of Erosive or Ulcerative Gastro-Esophageal Reflux Disease (GERD): The recommended adult oral dose is **Paricel**® 20 mg to be taken once daily.
Prevention of Relapse of Gastro-Esophageal Reflux Disease (GERD): The recommended adult oral dose is **Paricel**® 10 mg to be taken once daily. If needed this dose should be increased to **Paricel**® 20 mg to be taken once daily.

Treatment of Symptomatic Gastro-Esophageal Reflux Disease (GERD): The recommended adult oral dose is **Paricel**® 20 mg 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.

Treatment should commence at **Paricel**® 10 mg once daily in patients without esophagitis. If there is no response, the dose should be increased to 20 mg once daily for four weeks. If symptoms do not resolve completely after 4 weeks, the patient should be further investigated.
Once symptoms have resolved, subsequent symptom control can be achieved using an on demand regimen of 10 mg to be taken once daily, when needed.

Healing of Duodenal Ulcers and Gastric Ulcers: The recommended adult oral dose for both duodenal ulcer and gastric ulcer is **Paricel**® 20 mg to be taken once daily for a period up to 4 weeks. Most patients with duodenal ulcer heal within 4 weeks.
Some patients with duodenal ulcer may respond to **Paricel**® 10 mg once daily. A few patients may require additional therapy to achieve healing.
Most patients with gastric ulcer heal within 6 weeks. However, again a few patients may require an additional 6 weeks of therapy to achieve healing.

Helicobacter pylori eradication to reduce the risk of Duodenal or Gastric Ulcer Recurrence: Most patients with gastro-duodenal ulcer or chronic gastritis due to H. pylori infection should be treated with three drug regimen-

Rabeprazole	20 mg	Twice daily for 7 days
Amoxycillin	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.

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 once daily and 60 mg BID have been administered.

Treatment of GERD in Pediatric Patients 1 to 11 years of age: The recommended dosage of **Paricel**® for pediatric patients 1 to 11 years of age by body weight is:

- 15 kg or more: 10 mg once daily for up to 12 weeks.
- Less than 15 kg: 5 mg once daily for up to 12 weeks with the option to increase to 10 mg if there is inadequate response.

Use in children

Paricel® is indicated for treatment of GERD in children 1 to 11 years of age for up to 12 weeks.

Use in elderly

No dosage adjustment is necessary in elderly patients. No overall differences in safety and effectiveness were observed between these subjects or younger subjects, and other reported clinical experience has not identified differences between the elderly and younger patients.

Use in patients with hepatic & renal impairment

No dosage adjustment is necessary in patients with renal impairment or mild to moderate hepatic impairment. There is no information in patients with severe hepatic impairment. Avoid use of Rabeprazole in patients with severe hepatic impairment; however, if treatment is necessary, monitor patients for adverse reactions.

Use in pregnancy & lactation

No evidence of adverse developmental effects were seen in animal reproduction studies with Rabeprazole administered during organogenesis at 13 and 8 times the human area under the plasma concentration-time curve (AUC) at the recommended dose for GERD, in rats and rabbits, respectively. There are no available human data on Rabeprazole use in pregnant women to inform the drug associated risk and this drug should be used during pregnancy only if clearly needed.
Rabeprazole is excreted in rat milk. Caution should be exercised when Rabeprazole is administered to a lactating woman.

Side effects

Most common adverse reactions in adults are pain, pharyngitis, flatulence, infection & constipation and most common adverse reactions in adolescents are headache, diarrhea, nausea, vomiting, and abdominal pain.

Contraindications

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

Precautions

Symptomatic response to therapy with Rabeprazole does not prelude the response of gastric malignancy. There have been reports of increased International Normalized Ratio (INR) and Prothrombin Time (PT) 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 increase in INR and prothrombin time.

Drug interactions

Rabeprazole produces a profound and long lasting inhibition of gastric acid secretion. An interaction with compounds whose absorption is pH dependent may occur. Co-administration of Rabeprazole with Ketoconazole or Itraconazole may result in a significant decrease in antifungal plasma levels. Therefore individual patients may need to be monitored to determine if a dosage adjustment is necessary when Ketoconazole or Itraconazole are taken concomitantly with Rabeprazole.

In clinical trials, antacids were used concomitantly with the administration of Rabeprazole and, in a specific drug-drug interaction study, no interaction with liquid antacids was observed.

Co-administration of Atazanavir 300 mg/Ritonavir 100 mg with Omeprazole (40 mg once daily) or Atazanavir 400 mg with Lansoprazole (60 mg once daily) to healthy volunteers resulted in a substantial reduction in Atazanavir exposure. The absorption of Atazanavir is pH dependent. Although not studied, similar results are expected with other proton pump inhibitors. Therefore PPIs, including Rabeprazole, should not be co-administered with Atazanavir.

Concomitant administration of PPIs and Methotrexate (primarily at high dose) may elevate and prolong serum levels of Methotrexate and/or its metabolite Hydroxymethotrexate. However, no formal drug interaction studies of Methotrexate with PPIs have been conducted.

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.

Pharmaceutical precaution

Store below 25^{o}C. Protect from light & moisture.

Presentation

Paricel® 10 Tablet : Each enteric coated tablet contains Rabeprazole Sodium INN 10 mg.

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

Paricel® 20 Capsule : Each HPMC shell capsule contains Rabeprazole Sodium INN 20 mg as enteric coated pellets.

Package quantities

Paricel® 10 Tablet : Carton of 60 tablets is available in 4 alu-alu sachets and each sachet contains 15 tablets in alu-alu blister strip.

Paricel® 20 Tablet : Carton of 100 tablets is available in 10 alu-alu sachets and each sachet contains 10 tablets in alu-alu blister strip.

Paricel® 20 Capsule : Carton of 50 capsules is available in 5 alu-alu sachets and each sachet contains 10 capsules in alu-alu blister strip.

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