For the use only of a Registered Medical Practitioner or a Hospital or Laboratory

Rabeprazole Sodium Enteric-Coated Tablets

REBACIP

Composition
Rebacip – 10
Each enteric-coated tablet contains
Rabeprazole
Sodium ..... 10 mg

Rebacip – 20
Each enteric-coated tablet contains
Rabeprazole Sodium ..... 20 mg

Description
Rabeprazole belongs to a class of antisecretory compounds (substituted benzimidazole proton-pump inhibitors) that do not exhibit anticholinergic or histamine H_2-receptor antagonist properties, but suppress gastric acid 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. Rabeprazole blocks the final step of gastric acid secretion. In gastric parietal cells, rabeprazole is protonated, accumulates, and is transformed to an active sulfenamide.

Indications
Healing of Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD)
Rabeprazole is indicated for short term (4 to 8 weeks) treatment in the healing and symptomatic relief of erosive or ulcerative gastroesophageal reflux disease (GERD)

Maintenance of Healing of Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD)
Rabeprazole is indicated for maintaining healing and reduction in relapse rates of heart burn symptoms in patients with erosive or ulcerative gastroesophageal reflux disease (GERD maintenance)

Healing of Duodenal Ulcers
Rabeprazole is indicated for short term (up to 4 weeks) treatment in the healing and symptomatic relief of duodenal ulcers. Most patients heal within four weeks.

Treatment of pathological hypersecretory conditions, including Zollinger-Ellison Syndrome
Rabeprazole is indicated for the long term treatment of pathological hypersecretory conditions including Zollinger-Ellison syndrome.

Dosage and administration
Healing of Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD)
The recommended adult oral dose is one Rabeprazole -20 mg tablet to be taken once daily for four to eight weeks.

Maintenance of Healing of Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD)
The recommended adult oral dose is one Rabeprazole 20 mg tablet to be taken once daily.

Healing of Duodenal Ulcers
The recommended adult oral dose is one Rabeprazole 20 mg tablet to be taken once daily after the morning meal for a period up to four weeks. Most patients with duodenal ulcer heal within four weeks.

Treatment of pathological hypersecretory conditions, including Zollinger-Ellison Syndrome
The dosage of Rabeprazole in patients with pathologic hypersecretory conditions varies with the individual patient. The recommended adult oral starting dose is 60 mg once a day. Doses should be adjusted to individual patient needs and should continue for as long as clinically indicated. Doses up to 100 mg OD and 60 mg BID have been administered.

No dosage adjustment is necessary in elderly patients, in patients with renal disease or in patients

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with mild to moderate hepatic impairment. Administration of rabeprazole to patients with mild to moderate liver impairment resulted in increased exposure and decreased elimination. Due to the lack of clinical data on rabeprazole in patients with severe hepatic impairment, caution should be exercised in those patients.

Rabeprazole tablets should be swallowed whole. The tablets should not be chewed, crushed, or split.

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

Precautions
General

Symptomatic response to therapy with rabeprazole does not preclude the presence of gastric malignancy.

Drug interactions
Rabeprazole is metabolized by the cytochrome P450 (CYP450) drug metabolizing enzyme system. Rabeprazole does not have clinically significant interactions with other drugs metabolized by the CYP450 system, such as warfarin, theophylline, diazepam and phenytoin.

Rabeprazole produces sustained inhibition of gastric acid secretion. An interaction with compounds which are dependent on gastric pH for absorption like ketoconazole may occur due to the magnitude of acid suppression observed with rabeprazole.
Therefore, patients may need to be monitored when such drugs are taken concomitantly with rabeprazole. Co-administration of rabeprazole and antacids produced no clinically relevant changes in plasma rabeprazole concentrations.

Pregnancy and Lactation
There are no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Since many drugs are excreted in milk, caution should be exercised when rabeprazole is administered to a nursing mother.

Paediatric use
The safety and effectiveness of rabeprazole in paediatric patients has not been established.

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

Side effects
Adverse events with rabeprazole are mild to moderate in intensity and included malaise, diarrhea, nausea, skin eruptions, headache and dizziness.

Abnormal laboratory findings (increased hepatic enzymes, LDH, blood urea nitrogen) observed with rabeprazole are similar in incidence and severity with comparator agents and reversible with cessation of therapy.

Overdosage
There has been no experience with large overdoses with Rabeprazole.

Patients with Zollinger-Ellison syndrome have been treated with up to 120 mg rabeprazole OD. No specific antidote for rabeprazole is known. Rabeprazole is extensively protein bound and is not readily dialyzable. In the event of overdosage, treatment should be symptomatic and supportive.

Storage : Store below 25°C

Presentation:
Rebacip-10 Strip of 15 Tablets
Rebacip-20 Strip of 15 Tablets

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