Rabetem®

Rabeprazole Sodium 20 mg

COMPOSITION :

Rabetem® 20 Tablet: Each enteric coated tablet contains Rabeprazole Sodium USP 20 mg.

PHARMACOLOGY :

Rabeprazole Sodium (Rabetem®) is an antiulcerant 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 tablet. Because of its coated formulation it is highly stable in stomach and because of higher pka value of Rabeprazole Sodium it provides faster onset of action. It blocks the final step of gastric acid secretion. After oral administration of 20 mg, Rabeprazole is absorbed and can be detected in plasma by 1 hour. The effects of food on the absorption of Rabeprazole have not been evaluated. Rabeprazole is 96.3% bound to human plasma proteins. Rabeprazole is primarily metabolized in the liver by Cytochrome P-450 3A (Sulphone metabolite) and 2C19 (Desmethyl Rabeprazole). Following a single 20 mg oral dose of Rabeprazole, approximately 90% of the drug is eliminated in the urine.The remainder of the dose is excreted in the feaces.

INDICATION :

- 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.
- In combination with Amoxicillin and Clarithromycin to eradicate *Helicobacter pylori.*

DOSE & ADMINISTRATION :

- Healing of Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD): 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 week 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 mayrequire 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 day regimen.

Treatment of Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome: The dosage of Rabeprazole Sodium 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. Some patients may require divided doses. Doses up to 100 mg QD and 60 mg BID have been administered. Some patients with Zollinger-Ellision syndrome have been treated continuously with Rabeprazole Sodium for up to one year.

CONTRA-INDICATION :

Rabeprazole Sodium is contraindicated in patient with known hypersensitivity to Rabeprazole or to any component in the product.

WARNING AND PRECAUTION :

Administration of Rabeprazole Sodium to patients with mild to moderate liver impairment resulted in increased exposure and decreased elimination. Caution should be exercised in patients with severe hepatic impairment.

SIDE EFFECTS :

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

USE IN PREGNANCY & LACTATION :

Rabeprazole is FDA Pregnancy Category C. No data is available on administration of Rabeprazole to pregnant women. However this drug should be used during pregnancy, only if clearly needed. There are no data on the excretion of Rabeprazole 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.

USE IN CHILDREN & ADOLESCENTS :

Rabeprazole was effective and safe in 1 to 11 year old children. Rabeprazole 20 mg were well tolerated in adolescents.

DRUG INTERACTION :

Rabeprazole is metabolized by the Cytochrome P-450 (CYP-450) drug metabolizing enzyme system. Rabeprazole does not have clinically significant interactions with other drugs metabolized by the CYP-450 system,such as Warfarin and Theophylline given as single oral dose, Diazepam as a single intravenous dose, and Phenytoin given as a single intravenous dose. In normal subjects, co-administration of Rabeprazole 20 mg QD resulted in an approximately 30% decrease in the bioavailability of Ketoconazole and increase in the AUC and Cmax for digoxin of 90% and 29% respectively.

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 overdosage, treatment should be symptomatic and supportive.

STORAGE :

Store in a dry and cool place below 30^0 C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING :

Rabetem® 20 Tablets: Each box contains 5x10's tablets in Alu-Alu blister strip within Alu-Alu pillow pack.

Manufactured by

Team Pharmaceuticals Ltd.

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