Rabeprol

COMPOSITION:

Rabeprol 20 tablet: Each enteric-coated tablet contains Rabeprazole Sodium INN 20 mg.

DESCRIPTION:

The active ingredient in Rabeprol tablet is Rabeprazole sodium, a rapid acting proton pump inhibitor (PPI). Rabeprazole is a substituted benzimidazole which suppresses gastric acid secretion by inhibiting the gastric H+/ K+ ATPase at the secretory surface of the gastric parietal cell. This enzyme is regarded as the acid (proton) pump within the parietal cell. Rabeprazole blocks the final step of gastric acid secretion. The stability of Rabeprazole sodium depends on pH. It is rapidly degraded in acid media, and is more stable under alkaline conditions. Because of its enteric coated formulation Rabeprol is highly stable in stomach and higher pKa value of Rabeprazole provides faster action compared to other PPIs.

PHARMACOKINETICS:

Absorption: The absorption of Rabeprazole sodium is rapid and peak plasma level approximately 3.5 hours after a 20mg dose. Distribution: It is approximately 97% bound to human plasma proteins. Metabolism: It is mainly metabolized by nonenzymatic pathway. Elimination: Following a single 20 mg dose of Rabeprazole sodium, no unchanged drug was excreted in urine. Approximately 90% of the dose was eliminated in urine, the remainder of the dose was recovered in faeces.

INDICATION:

- Benign gastric ulcer
- Duodenal ulcer
- Duodenal ulcer and benign gastric ulcer associated with H. pylori infection
- Healing of erosive or ulcerative Gastroesophageal reflux disease (GERD)
- Zollinger-Ellison Syndrome
- Prevention or treatment of NSAIDs-induced ulcers
- Treatment of symptomatic GERD
- Maintenance of healing of erosive or ulcerative GERD

DOSAGE AND ADMINISTRATION:

1) Benign gastric ulcer : 20 mg daily in the morning for 8 weeks.
2) Duodenal ulcer : 20 mg daily in the morning for 4 weeks, continued for further 4 weeks if not fully healed.
3) Duodenal ulcer and benign gastric ulcer associated with H. pylori infection: Rabeprol in combination with Amoxicillin and Clarithromycin as a three drug regimen is indicated for the treatment of patients with H. pylorl lnfection and duodenal ulcer disease. Rabeprazole offer a faster therapy option than other PPIs, up to 10 to 14 days 20 mg once daiiy.
4) Healing of erosive or ulcerative Gastroesophageal reflux disease : 20 mg once daily for 4-8 weeks; maintenance 10-20 mg daily; symptomatic treatment in the absence of oesophagitis, 10 mg daily for up to 4 weeks then 10 mg daily when required.
5) Zollinger-Ellison Syndrome : Inicially 60 mg once daily adjusted according to response (maximum 120 mg daily); doses above 100 mg daily given in 2 divided doses.
6) Prevention or treatment of NSAIDs-induced ulcers: Rabeprol 20 mg tablet once daiy. In patients receiving treatment with NSAIDs.
7) Treatment of symptomatic GERD: The recommended adult oral dose of Rabeprol is 20 mg once daily for 4 weeks. lf symptoms do not resolve completely afler 4 weeks, an additional course of treatment may be considered.
8) Maintenance of healing of erosive or ulcerative GERD: Rabeprol is indicated for maintaining healing and reductron in relapse rates of heartburn symptoms in patients with erosive or ulcerative GERD maintenance. Controlled studies do not extend beyond l2 months.

CONTRAINDICATION:

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

SIDE-EFFECT:

In general, Rabeprazole is well-tolerated in both short-term and long-term studies. Rabeprazole may some times cause headache, diarrhoea, abdominal pain, vomiting, constipation, dry mouth, increased or decreased appetite, muscle pain, drowsiness, dizziness.

PRECAUTION:

Rabeprazole Sodium tablets should not be splited, chewed or crushed.

PREGNANCY AND LACTATION:

Pregnant women: Rabeprazole is FDA pregnancy category B. No data are available on administration of Rabeprazole to pregnant women. However this drug should be used during pregnancy, only if clearly needed.
Lactating mother: 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.
Paediatric use: The safety and effectiveness of Rabeprazole in pediatric patients have not been.

DRUG INTERACTION:

Rabeprazole is mainly metabolized by nonenzymatic pathway. Studies in healthy subjects have shown that 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 doses, diazepam as a single intravenous dose, and phenytoin given as a single intravenous dose.

OVERDOSAGE:

There is no experience with large overdosages with Rabeprazole. There were no clinical signs or symptoms associated with any reported overdose. Patients with Zollinger-Ellison syndrome have been treated with up to 120 mg once daily. No specific antidote for Rabeprazole is known.

PACKAGING:

Rabeprol 20 tablet: Each box contains 6 x 10 tablets in Alu-Alu blister pack with Alu-Alu sachet.