RAZOLE Tablet

Rabeprazole Sodium INN 20 mg

Composition:

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

Mode of action :

Rabeprazole suppresses gastric acid secretion by inhibiting the gastric H^+/K^+-ATPase at the secretory surface of the gastric parietal cell. It blocks the final step of gastric acid secretion.

Pharmacokinetics :

Following 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 P450 3A (sulphone metabolite) and 2C19 (desmethyl Rabeprazole). Following a single 20 mg oral dose of 14 C-labeled Rabeprazole, approximately 90% of the drug is eliminated in the urine. The remainder of the dose was recovered in the faeces.

Indication :

Healing of erosive or ulcerative Gastro-Esophageal Reflux Disease (GERD), Maintenance of healing of erosive or ulcerative Gastro Esophageal Reflux Disease (GERD), Healing of duodenal ulcer, Benign gastric ulcer, Treatment of pathological hypersecretory conditions including Zollinger- Ellison Syndrome.

Dosage and administration :

Healing of erosive or ulcerative Gastro-Esophageal Reflux Disease (GERD): The Recommended dose is 20 mg daily in the morning for 4-8 weeks. For those patients who have not healed after 8 weeks of treatment, an additional 8 weeks course may be considered.
Maintenance of healing of erosive or ulcerative Gastro Esophageal Reflux Disease (GERD): The recommended dose is 20 mg daily in the morning for 4 weeks.
Benign gastric ulcer : The recommended dose is 20 mg daily in the morning for 6 weeks.
Treatment of pathological hypersecretory conditions, including Zollinger-Ellison Syndrome: The recommended starting dose is 60 mg once day.
Dose should be adjusted to individual patients need and continued as long as clinically indicated. Some patients may require divided doses.

Contraindication :

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

Side effects :

Dry mouth, gastro-intestinal disturbances (including diarrhoea, nausea and vomiting, constipation, flatulence, abdominal pain), liver dysfunction, hypersensitivity reactions (including rash, urticaria, angioedema, bronchospasm, anaphylaxis), peripheral oedema, depression, dizziness, drowsiness, headache, insomnia, fever, muscle and joint pain, blurred vision, pharyngitis, rhinitis, asthenia, sinusitis, nervousness, rarely stomatitis, encephalopathy in severe liver disease, anorexia, weight gain.

Caution and warnings :

No dosage adjustment is necessary in elderly patients, in patients with renal disease or in patients with mild to moderate hepatic impairment. Due to the lack of clinical data on Rabeprazole, in patients with severe hepatic impairment, caution should be exercised.

Pregnancy and lactation :

No adequate and well-controlled studies in pregnant women. Animal studies have revealed no evidence of impaired fertility or harm to the fetus due to Rabeprazole. Since many drugs are excreted in the milk and there are 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. The safety and effectiveness of Rabeprazole in paediatric patients have not been established.

Drug interaction :

Rabeprazole is metabolized by the cytochrome P450 drug metabolizing enzyme system but it does not have clinically significant interactions with other drugs metabolized by the CYP 450 enzyme system such as warfarin, theophylline, diazepam, phenytoin, etc.

Storage :

Keep in cool and dry place, away from light.

Commercial pack :

Each box contains 5 x 10 tablets in blister pack.

Manufactured by :

KEMIKO PHARMACEUTICALS LTD.
BANGLADESH