Rabesec
Tablet

DRUG INTERNATIONAL LTD.

Composition : Each enteric coated tablet contains Rabeprazole Sodium USP 20mg.

Pharmacology : Rabeprazole Sodium 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.

Indications and Uses : It is indicated for the treatment of

i) Gastric ulcer
ii) Peptic ulcer disease (PUD)
iii) Maintenance of healing of erosive or ulcerative GERD
iv) Healing of Duodenal ulcer
v) Treatment of Symptomatic GERD
vi) Zollinger-Ellison Symdrome
vii) Helicobacter pylori eradication to reduce risk of Duodenal ulcer recurrence.

Dosage and administration : Usual Adult Dose for Duodenal Ulcer : 20 mg orally once a day, after the morning meal. The usual duration of therapy is four weeks in most patients. **Usual Adult Dose for Erosive Esophagitis :** 20 mg orally once a day, after the morning meal. Therapy should be continued for 4 to 8 weeks. **Usual Adult Dose for Gastric Ulcer :** 20 mg orally once a day, after the morning meal. Therapy should be continued for 4 to 8 weeks. **Usual Adult Dose for Duodenal Ulcer Prophylaxis :** 20 mg orally once a day, after the morning meal. Studies evaluating maintenance therapy for duodenal ulcers have not extended beyond 12 months. **Usual Adult Dose for Gastroesophageal Reflux Disease :** 20 mg orally once a day, after the morning meal. Therapy should be continued for 4 to 8 weeks. **Usual Adult Dose for Helicobacter pylori Infection :** Three drug regimen: rabeprazole 20 mg, amoxicillin 1000 mg, and clarithromycin 500 mg orally two times daily with morning and evening meals for 7 days. **Usual Adult Dose for Zollinger-Ellison Syndrome:** Initial: 60 mg orally once a day, after the morning meal. Maintenance: Doses up to 100 mg orally once a day or 60 mg orally twice a day have been administered. Patients have been treated continuously for up to one year. Or, as directed by the registered physician.

Contraindications : Rabeprazole is contraindicated in patients with known hypersensitivity to Rabeprazole, substituted benzimidazoles or any of its pharmaceutical excipients.

Precautions : Rabeprazole tablet should not be chewed, crushed or split.

Side effects : In clinical trials the most common side effect of Rabeprazole is headache. Other side effects are diarrhoea, vomiting, nausea, abdominal pain, constipation, dry mouth, increased or decreased appetite, asthenia, sleeplessness, thrombocytopenia, granulocytopenia, leukocytopenia, erythema, muscle or bone pain.

Pregnancy and lactation : Rabeprazole is FDA Pregnancy Category B. No data is available on administration of Rabeprazole to pregnant women. It can be used in pregnancy if potential benefit outweigh the risk or as directed by the registered physician. 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 Child : No data available.

Drug Interactions : Rabeprazole is metabolized by cytochrome P450 drug metabolizing enzyme system. Studies in healthy subjects have shown that Rabeprazole does not have clinically significant interactions with other drugs metabolized by the CYP 450 enzyme system such as warfarin, theophylline, diazepam, phenytoin etc.

Overdose : No information provided.

Storage : Store below 30°C in a dry place.

Packing : Each box contains 4 x 14's tablet in blister pack.