

Rabifast[®]

Rabeprazole Sodium Enteric Coated Tablet

DESCRIPTION

Rabifast[®] is enteric coated tablet which is a preparation of Rabeprazole Sodium INN. It is an antiulcer drug in the class of proton pump inhibitors (PPIs). Rabeprazole 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 **Rabifast[®]** is highly stable in stomach and higher pKa value of Rabeprazole provides faster action compared to other PPIs.

INDICATIONS

Rabifast[®] is a proton-pump inhibitor (PPI) indicated in adults for:

- Healing of erosive or ulcerative Gastroesophageal Reflux Disease (GERD)
- Maintenance of healing of erosive or ulcerative GERD
- Treatment of symptomatic GERD
- Healing of duodenal ulcers
- Helicobacter pylori eradication to reduce the risk of duodenal ulcer recurrence
- Treatment of pathological hypersecretory conditions, including Zollinger Ellison Syndrome

Rabifast[®] is a proton-pump inhibitor indicated for adolescent patients 12 years of age and above for short-term treatment of symptomatic GERD.

DOSAGE AND ADMINISTRATION

Rabifast[®] tablet should be swallowed whole. The tablet should not be chewed, crushed or split.

- Healing of erosive or ulcerative GERD: 20 mg once daily
- Maintenance of healing of erosive or ulcerative GERD: 20 mg once daily
- Treatment of symptomatic GERD: 20 mg once daily
- Healing of duodenal ulcers: 20 mg once daily after morning meal
- Helicobacter pylori eradication to reduce the risk of duodenal ulcer recurrence: **Rabifast[®]** in combination with Amoxicillin 1000 mg & Clarithromycin 500 mg as a three drug regimen twice daily with morning and evening meals for 7 days
- Treatment of Pathological Hypersecretory conditions, including Zollinger-Ellison syndrome: Starting dose 60 mg once daily then adjust to patient needs

CONTRAINDICATIONS

It is contraindicated in patients with known hypersensitivity to Rabeprazole.

PRECAUTIONS

- Symptomatic response to therapy with Rabeprazole does not preclude the presence of gastric malignancy
- Patients treated with a proton pump inhibitor and warfarin may need to be monitored for increases in INR and prothrombin time due to risk of abnormal bleeding
- Bone Fracture: Long-term and multiple daily dose PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine
- Hypomagnesemia has been reported rarely with prolonged treatment with PPIs

USE IN PREGNANCY AND LACTATION

Pregnant women:

FDA approved pregnancy category B.

Lactating mother:

It is not known if unmetabolized Rabeprazole is excreted in human breast milk.

PEDIATRIC USE

Use of Rabeprazole in adolescent patients 12 years of age and above for short-term treatment of GERD is supported. But the safety and effectiveness of Rabeprazole for the treatment of GERD patients <12 years of age have not been established. The safety and effectiveness of Rabeprazole for other uses have not been established in pediatric patients.

SIDE - EFFECTS

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 etc.

PHARMACEUTICAL PRECAUTION

Do not store above 25 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Rabifast[®] Tablet : Box containing 5 strips of 10 tablets each. Each enteric-coated tablet contains Rabeprazole Sodium INN 20 mg.

SK•F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

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