

# Acifix®

Rabeprazole Sodium

Tablet

## Description

Rabeprazole Sodium (Acifix® Tablet) is an antiulcer drug in the class of proton pump inhibitors. Rabeprazole Sodium is a substituted benzimidazole which suppresses gastric acid secretion by inhibiting the gastric H<sup>+</sup>/K<sup>+</sup>-ATPase enzyme at the secretory surface of the gastric parietal cell. It is an enteric coated tablet, because of its enteric coated formulation it is highly stable in stomach and because of higher Pka value of Rabeprazole Sodium it provides faster onset of action.

## Indications

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 and in combination with amoxicillin and clarithromycin to eradicate *Helicobacter pylori*.

## Dosage and Administration

*Healing of Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD):* 20 mg to be taken once daily for four to eight 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 may require 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-Ellison syndrome have been treated continuously with Rabeprazole Sodium for up to one year.

## Contraindications

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

## Adverse Reactions

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

## Warning & Precautions

*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.

*Pediatric use:* The safety and effectiveness of Rabeprazole in pediatric patients have not been established.

## Drug Interactions

No drug interaction is reported.

## Pharmaceutical Precautions

Store in cool & dry place, away from children.

## Commercial Pack

Acifix® Tablet: Box containing 50 tablets in 5 x 10's Alu-Alu form packs. Each enteric coated tablet contains Rabeprazole Sodium INN 20 mg.



Manufactured by

**BEXIMCO PHARMACEUTICALS LTD.**

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