

COMPOSITION:

Rabipep™ 20 Tablet: Each enteric coated tablet contains Rabeprazole Sodium INN 20 mg.

PHARMACOLOGY:

Rabeprazole suppresses gastric acid secretion by inhibiting the gastric H⁺/K⁺ ATPase at the secretory surface of the gastric parietal cell. Because this enzyme is regarded as the acid (proton) pump within the parietal cell, Rabeprazole has been characterized as a gastric proton pump inhibitor.

INDICATION:

- Healing of Erosive or Ulcerative GERD
- Maintenance of Healing of Erosive or Ulcerative GERD
- Treatment of systematic 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

DOSAGE & ADMINISTRATION:

Rabipep™ 20 Tablet should be swallowed whole; Rabipep-20 tablet can be taken with or without food.

Healing of Erosive or Ulcerative GERD:

The recommended adult oral dose is **Rabipep™ 20 Tablet** 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 weeks course of **Rabipep™ 20 Tablet** may be considered.

Maintenance of healing of Erosive or Ulcerative GERD:

The recommended adult oral dose is one **Rabipep™ 20 Tablet** once daily.

Treatment of symptomatic GERD:

The recommended adult oral dose is one **Rabipep™ 20 Tablet** 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 one **Rabipep™ 20 Tablet** once daily after the morning meal for a period up to 4 weeks. Most patients with duodenal ulcer heal within 4 weeks. A few patients may require additional therapy to achieve healing.

***Helicobacter pylori* eradication to reduce the risk of Duodenal Ulcer recurrence:**

Rabipep™ 20	20 mg	Twice daily with the morning and evening meals for 7 days
Amoxicillin	1000 mg	
Clarithromycin	500 mg	

Treatment of pathological hypersecretory conditions, including Zollinger-Ellison Syndrome: The dosage of **Rabipep™ 20 Tablet** in patients with pathological 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. Some patients with Zollinger-Ellison syndrome have been treated continuously with **Rabipep™ 20 Tablet** for up to one year.

CONTRAINDICATION:

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

PRECAUTION:

Administration of Rabeprazole to patients with mild to moderate liver impairment results in increased exposure and decreased elimination. Caution should be exercised in patients with severe hepatic impairment.

SIDE EFFECTS:

Rabeprazole tablets are generally well tolerated. The observed undesirable effects have been generally mild/moderate and transient in nature. The most common adverse events are headache, diarrhea and nausea. The less common adverse effects are abdominal pain, asthenia, flatulence, rash, dry mouth etc.

DRUG INTERACTIONS:

Rabeprazole like other PPIs is metabolized through Cytochrome P450 drug metabolizing enzyme system. But Rabeprazole does not have clinically significant interaction with other drugs metabolized by CYP P450 system, such as warfarin, theophylline, diazepam and phenytoin. Rabeprazole inhibits gastric acid secretion and may interfere with absorption of drugs where gastric pH is an important determinant of bioavailability e.g. Ketoconazole, iron salts and digoxin. In studies no interaction with liquid antacid or foods was observed.

USE IN SPECIAL GROUP:

Pregnancy:

Pregnancy category B. There are no adequate well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.

Nursing Mother:

Since many drugs are excreted in milk and because of the 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.

Geriatric Patients:

No overall differences in safety or effectiveness were observed between these subjects and younger subjects, but greater sensitivity of some older individuals can not be ruled out.

STORAGE:

Store in a cool and dry place, protected from light. Keep out of the reach of children.

PACKING:

Rabipep™ 20 Tablet: Each box contains 5x10's tablets in Alu-Alu blister strip in Alu-Alu sachet pack.

Manufactured by:

Organic Health Care Ltd.
Gazipur, Bangladesh.

