

COMPOSITION :

Each enteric coated tablet contains:

Rabeprazole sodium IP		
Equivalent to Rabeprazole	20 mg
Excipients	q.s
Colour: Titanium Dioxide I.P.		



DESCRIPTION :

Rabeprazole is an antiulcer drug in the class of proton pump inhibitors.

Rabeprazole sodium (RAZOCER TABLETS) is a drug used to treat gastro esophageal reflux disease, or GERD, which is a common digestive problem. In GERD, acid from the stomach flows backward into the esophagus, and irritates the lining of the esophagus. A muscle usually keeps stomach acid from flowing back into the esophagus, but in GERD, this muscle allows acid from the stomach into the esophagus.

A peptic ulcer is a sore in the stomach or small intestine. It happens when the acid and enzymes that help break down food damage the lining of the stomach or intestine. Ulcers usually affect people who are 25 to 64 years of age. The two main causes are a bacteria called helicobacter pylori and anti-inflammatory pain medicines like aspirin ibuprofen (Motrin or Advil), or naproxen (Aleve and others in prescription strengths). Steroids and medicines for osteoporosis also may cause ulcers.

MODE OF ACTION :

Rabeprazole is a selective and irreversible proton pump inhibitor. Rabeprazole suppresses gastric acid secretion by specific inhibition of the hydrogen-potassium adenosine triphosphatase (H⁺, K⁺-ATPase) enzyme system found at the secretory surface of parietal cells. It inhibits the final transport of hydrogen ions (via exchange with potassium ions) into the gastric lumen. Since the H⁺, K⁺-ATPase enzyme system is regarded as the acid (proton) pump of the gastric mucosa, rabeprazole is known as a gastric acid pump inhibitor. Rabeprazole does not have anticholinergic or histamine H₂-receptor antagonist properties.

INDICATIONS & USES :

Short-term treatment in healing and symptomatic relief of duodenal ulcers and erosive or ulcerative gastro esophageal reflux disease (GERD); maintaining healing and reducing relapse rates of HEARTBURN symptoms in patients with GERD; treatment of daytime and nighttime 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.

- Gastric ulcer (GU)
- Peptic ulcer disease (PUD)
- Maintenance of healing of erosive or ulcerative GERD
- Healing of erosive and ulcerative GERD
- Healing of duodenal ulcers.
- Treatment of symptomatic GERD
- Treatment of pathological hypersecretory conditions (Zollinger-Ellison syndrome)
- Helicobacter pylori eradication to reduce risk of duodenal ulcer recurrence.

INTERACTIONS :

Proton-pump inhibitors (PPIs) in general may inhibit the absorption of drugs such as:

- Some antifungal, such as Griseofulvin (Grisactin), Ketoconazole, Itraconazole,
- iron salts
- Vitamin b12
- cefpodoxime (Vantin)
- Enoxacin (Penetrex).

PPIs are metabolized (broken down) to varying degrees by an enzyme system in the liver called the cytochrome p450 system. They may speed up or slow down the metabolism of other drugs by increasing or decreasing the effects of the cytochrome P450 enzymes. This is important in patients taking medications in which a small difference in dose can be important to its safety, such as:

- Diazepam (valium)
- Phenytoin (Dilantin)
- Warfarin (Clinical: Coumadin (WARFARIN SODIUM) Coumadin (WARFARIN SODIUM) Coumadin).

Rabeprazole is less likely to have some of these interactions as compared to some other drugs in the proton-pump inhibitor class. Still, possible interactions need to be kept in mind.

PRECAUTIONS :

Rabeprazole does not work for everyone. Improvement in symptoms does not prevent other stomach-related medical conditions. Rabeprazole should be used with caution in patients with severe liver impairment. Rabeprazole is a pregnancy category B drug, meaning there are no studies to determine whether it is safe in pregnancy. It is unknown whether Rabeprazole is distributed in breast milk; therefore, depending on the circumstances, either breast feeding or the drug should be discontinued. Rabeprazole is contraindicated for use in any patient that is sensitive to any of its active or inactive ingredients.

SIDE- EFFECTS :

In clinical trials the most common side effect assessed as possibly or probably related to Razocer, was headache in 2.4% of patients vs. 1.6% taking placebo. Diarrhea, vomiting, nausea, abdominal pains, constipation, meteorism, dry mouth, increased or decreased appetite, asthenia, headache, anxiety, sleeplessness, vertigo, thrombocytopenia, granulocytopenia, leukocytopenia, skin eruption, erythema, myalgia, arthralgia, muscle or bone pain. Rabeprazole is generally well tolerated. Side effects affect less than 5% of individuals taking drugs of this class. Some of the more common side effects are:

- headache
- diarrhea
- abdominal pain
- nausea

PACKAGING INFORMATION :

RAZOCER Tablet is available in a strip of 10 Tablets.