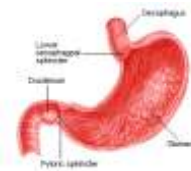
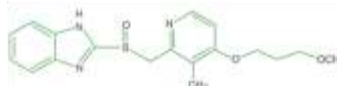


Rx RABEPRAZOLE

(Each vial contains Rabeprazole sodium20 mg As sterile freeze-dried powder for reconstitution with 5 ml of sterile water for injection IP)



GENERIC NAME: rabeprazole

DRUG CLASS AND MECHANISM

Rabeprazole is an oral drug that is used for the treatment of conditions caused by acid. It is in a class of drugs called proton pump inhibitors or PPIs which block the production of acid by the stomach. Other drugs in the same class include lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), and esomeprazole (Nexium). PPIs are used for the treatment of acid-caused conditions such as stomach and duodenal ulcers, gastroesophageal reflux disease (GERD) and Zollinger-Ellison Syndrome. Rabeprazole, like other PPIs, blocks the enzyme in the wall of the stomach that makes and secretes acid into the stomach. By blocking the enzyme, the secretion of acid into the stomach is decreased, and this allows ulcers in the stomach and esophagus to heal.

PRESCRIPTION: Yes.

PREPARATIONS: Tablets: 20 mg

PRESCRIBED FOR

Rabeprazole is used for treating ulcers of the stomach and duodenum, erosive or ulcerative gastroesophageal reflux disease (GERD) and Zollinger-Ellison Syndrome (in which there is overproduction of acid caused by tumors). It also is used with antibiotics for eradicating *Helicobacter pylori* infections of the stomach that, along with acid, are responsible for many ulcers.

DOSING

For healing ulcerative or erosive GERD, the recommended dose for adults is 20 mg daily for 4-8 weeks. If healing does not occur after 8 weeks, another 8 week course may be considered. The recommended maintenance dose is 20 mg daily. Heartburn due to GERD is treated with 20 mg daily for 4 weeks and an additional 4 weeks if symptoms do not resolve. Ulcers are treated with 20 mg daily for 4 weeks. For the management of Zollinger-Ellison Syndrome, the starting dose for adults is 60 mg daily, and the dose is adjusted based on improvement in symptoms, healing of ulcers, or the effectiveness of acid suppression. Doses of 100 mg per day and 60 mg twice daily have been used in some patients with Zollinger-Ellison Syndrome. The regimen for eradication of *Helicobacter pylori* is rabeprazole 20 mg, clarithromycin 500 mg, amoxicillin 1000 mg all given twice daily (morning and evening) for 7 days.

Tablets should be swallowed whole and should not be crushed, split or chewed. Rabeprazole can be taken with or without meals since food has little effect on its absorption.

DRUG INTERACTIONS

There have been reports of an increase in the effect of the blood thinner, warfarin, by rabeprazole which theoretically could lead to increased bleeding. Patients taking warfarin should be monitored more frequently if the begin taking rabeprazole.

Rabeprazole may reduce the elimination of cyclosporin in the liver, thereby increasing cyclosporin levels in the blood and potentially lead to cyclosporin toxicity.

The absorption of certain drugs may be affected by changes in stomach acidity. Rabeprazole and other PPIs that reduce stomach acid reduce the absorption and concentration in blood of ketoconazole (Nizoral) and increase the absorption and concentration in blood of digoxin (Lanoxin). This may lead to reduced effectiveness of ketoconazole or increased digoxin toxicity, respectively.

USES

Rabeprazole works by blocking acid production in the stomach. This medication is known as a proton pump inhibitor (PPI). It is used to treat acid-related stomach/intestinal and throat (esophagus) problems (e.g., acid reflux or GERD, ulcers, erosive esophagitis, Zollinger-Ellison syndrome). Decreasing excess stomach acid can help relieve symptoms such as heartburn, difficulty swallowing, persistent cough, and trouble sleeping. It can also prevent serious acid damage to your digestive system (e.g., ulcers,

cancer of the esophagus). This medication may also be used in combination with antibiotics to treat certain types of ulcers caused by bacterial infection.

HOW TO USE

Take this medication by mouth usually once daily, with or without food, or as directed by your doctor. Do not crush, chew, or split this medication. Swallow the medication whole. If needed, antacids may be taken along with this medication. The dosage and length of treatment is based on your medical condition and response to therapy. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time each day. Continue to take this medication for the prescribed length of treatment even if you are feeling better. Inform your doctor if your condition persists or worsens.

SIDE EFFECTS

This medication is generally well tolerated. Although uncommon, headache may occur. If this effect persists or worsens, notify your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: signs of vitamin B-12 deficiency with long-term (over 3 years) treatment (e.g., unusual weakness, sore tongue, numbness or tingling of the hands/feet). A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching/swelling (especially of the face/tongue/throat), dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS

Before taking rabeprazole, tell your doctor or pharmacist if you are allergic to it; or to similar drugs (e.g., lansoprazole, omeprazole); or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: severe liver disease, other stomach problems (e.g., tumors). Some symptoms may actually be signs of a more serious condition. Tell your doctor immediately if you have: heartburn combined with lightheadedness/sweating/dizziness, chest pain or shoulder/jaw pain (especially with trouble breathing), pain spreading to arms/neck/shoulders, unexplained weight loss. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known whether this medication passes into breast milk. Breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store the US product at room temperature 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Store the Canadian product at 59-77 degrees F (15-25 degrees C) away from moisture. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

TAJ DRUG WORLD

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