

Medication Guide

Rabeprazole Sodium Delayed-Release Tablets

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Read the Medication Guide that comes with rabeprazole sodium delayed-release tablets before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or treatment.

What is the most important information I should know about rabeprazole sodium delayed-release tablets?

Rabeprazole sodium delayed-release tablets may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor.

Rabeprazole sodium delayed-release tablets can cause serious side effects, including:

- **A type of kidney problem (acute interstitial nephritis).** Some people who take proton pump inhibitor (PPI) medicines, including rabeprazole sodium delayed-release tablets, may develop a kidney problem called acute interstitial nephritis that can happen at any time during treatment with rabeprazole sodium delayed-release tablets. Call your doctor if you have a decrease in the amount that you urinate or if you have blood in your urine.
- **Diarrhea.** Rabeprazole sodium delayed-release tablets may increase your risk of getting severe diarrhea. This diarrhea may be caused by an infection (*Clostridium difficile*) in your intestines. Call your doctor right away if you have watery stool, stomach pain, and fever that does not go away.
- **Bone fractures.** People who take multiple daily doses of PPI medicines for a long period of time (1 year or longer) may have an increased risk of fractures of the hip, wrist, or spine. You should take rabeprazole sodium delayed-release tablets exactly as prescribed, at the lowest dose possible for your treatment and for the shortest time needed.
- **Certain types of lupus erythematosus.** Lupus erythematosus is an autoimmune disorder (the body's immune cells attack other cells or organs in the body). Some people who take PPI medicines, including rabeprazole sodium delayed-release tablets, may develop certain types of lupus erythematosus or have worsening of the lupus they already have. Call your doctor right away if you have new or worsening joint pain or a rash on your cheeks or arms that gets worse in the sun.

Talk to your doctor about your risk of these serious side effects if you take rabeprazole sodium delayed-release tablets.

Rabeprazole sodium delayed-release tablets can have other serious side effects. See "What are the possible side effects of rabeprazole sodium delayed-release tablets?"

What are rabeprazole sodium delayed-release tablets?

Rabeprazole sodium delayed-release tablets are a prescription medicine called a proton pump inhibitor (PPI). Rabeprazole sodium delayed-release tablets reduce the amount of acid in your stomach.

Rabeprazole sodium delayed-release tablets are used in adults:

- for up to 8 weeks to heal acid-related damage to the lining of the esophagus (called erosive esophagitis or EE) and to relieve symptoms, such as heartburn pain. If needed, your doctor may decide to prescribe another 8 weeks of rabeprazole sodium delayed-release tablets.
- to maintain the healing of the esophagus and relief of symptoms related to EE. It is not known if rabeprazole sodium delayed-release tablets are safe and effective if used longer than 12 months (1 year).
- for up to 4 weeks to treat daytime and nighttime heartburn and other symptoms that happen with Gastroesophageal Reflux Disease (GERD).

GERD happens when acid in your stomach backs up into the tube (esophagus) that connects your mouth to your stomach. This may cause a burning feeling in your chest or throat, sour taste, or burping.

- for up to 4 weeks for the healing and relief of duodenal ulcers. The duodenal area is the area where food passes when it leaves the stomach.
- for 7 days with certain antibiotic medicines to treat an infection caused by bacteria called *H. pylori*. Sometimes *H. pylori* bacteria can cause duodenal ulcers. The infection needs to be treated to prevent the ulcers from coming back.
- for the long-term treatment of conditions where your stomach makes too much acid. This includes a rare condition called Zollinger-Ellison Syndrome.

Rabeprazole sodium delayed-release tablets are used in adolescents 12 years of age and older to treat symptoms of Gastroesophageal Reflux Disease (GERD) for up to 8 weeks.

It is not known if rabeprazole sodium delayed-release tablets are safe and effective in children to:

- heal acid-related damage to the lining of the esophagus (called erosive esophagitis or EE)
- maintain the healing of the esophagus and relief of symptoms related to EE
- treat symptoms that happen with Gastroesophageal Reflux Disease (GERD)
- heal duodenal ulcers
- treat an infection caused by bacteria called *H. pylori* to reduce the risk of duodenal ulcers from coming back
- treat conditions where your stomach makes too much acid, including Zollinger-Ellison Syndrome.

Rabeprazole sodium delayed-release tablets should not be used in children under 12 years of age.

Who should not take rabeprazole sodium delayed-release tablets?

Do not take rabeprazole sodium delayed-release tablets if you:

- are allergic to rabeprazole or any of the other ingredients in rabeprazole sodium delayed-release tablets. See the end of this Medication Guide for a complete list of ingredients in rabeprazole sodium delayed-release tablets.
- are allergic to any other proton pump inhibitor (PPI) medicine.
- are taking a medicine that contains rilpivirine (Edurant®, Complera®) used to treat HIV-1 (Human Immunodeficiency Virus).

What should I tell my doctor before taking rabeprazole sodium delayed-release tablets?

Before you take rabeprazole sodium delayed-release tablets tell your doctor if you:

- have been told that you have low magnesium levels in your blood
- have liver problems
- have any allergies
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if rabeprazole sodium delayed-release tablets can harm your unborn baby. Talk to your doctor about the possible risks to an unborn baby if rabeprazole sodium delayed-release tablets are taken during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if rabeprazole sodium passes into your breast milk or if it will affect your baby or your breast milk. Talk to your doctor about the best way to feed your baby if you take rabeprazole sodium delayed-release tablets.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Rabeprazole sodium delayed-release tablets may affect how other medicines work, and other medicines may affect how rabeprazole sodium delayed-release tablets work. Especially tell your doctor if you take an antibiotic that contains clarithromycin or amoxicillin or if you take warfarin (COUMADIN®, JANTOVEN®) or methotrexate (Otrexup™, Rasuvo®, Trexall®). Know the medicines that you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take rabeprazole sodium delayed-release tablets?

- Take rabeprazole sodium delayed-release tablets exactly as prescribed. Your doctor will prescribe the dose that is right for you and your medical condition. Do not change your dose or stop taking rabeprazole sodium delayed-release tablets unless you talk to your

doctor. Take rabeprazole sodium delayed-release tablets for as long as it is prescribed even if you feel better.

- Rabeprazole sodium delayed-release tablets are usually taken 1 time each day. Your doctor will tell you the time of day to take rabeprazole sodium delayed-release tablets, based on your medical condition.
- Rabeprazole sodium delayed-release tablets can be taken with or without food. Your doctor will tell you whether to take this medicine with or without food based on your medical condition.
- Swallow each rabeprazole sodium delayed-release tablet whole. **Do not chew, crush, or split rabeprazole sodium delayed-release tablets.** Tell your doctor if you cannot swallow tablets whole.
- If you miss a dose of rabeprazole sodium delayed-release tablets, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your normal schedule. Do not take two doses at the same time.
- If you take too many rabeprazole sodium delayed-release tablets, call your doctor or your poison control center at 1-800-222-1222 right away, or go to the nearest hospital emergency room.
- Your doctor may prescribe antibiotic medicines with rabeprazole sodium delayed-release tablets to help treat a stomach infection and heal stomach (duodenal) ulcers that are caused by bacteria called *H. pylori*. Make sure you read the patient information that comes with an antibiotic before you start taking it.

What are the possible side effects of rabeprazole sodium delayed-release tablets?

Rabeprazole sodium delayed-release tablets may cause serious side effects, including:

- See “What is the most important information I should know about rabeprazole sodium delayed-release tablets?”
- **Interaction with warfarin.** Taking warfarin with a PPI medicine may lead to an increased risk of bleeding and death. If you take warfarin, your doctor may check your blood to see if you have an increased risk of bleeding. If you take warfarin during treatment with rabeprazole sodium delayed-release tablets, tell your doctor right away if you have any signs or symptoms of bleeding, including:
 - unexpected bleeding or bleeding that lasts a long time, such as:
 - nosebleeds that happen often
 - unusual bleeding from the gums
 - menstrual bleeding that is heavier than normal or unusual vaginal bleeding
 - bleeding that is severe or that you cannot control
 - red, pink or brown urine
 - bright red or black stools (looks like tar)
 - coughing up blood or blood clots
 - vomiting blood or your vomit looks like “coffee grounds”
 - headaches
 - feel dizzy or weak
- **Vitamin B-12 deficiency.** Rabeprazole sodium delayed-release tablets reduce the amount of acid in your stomach. Stomach acid is needed to absorb vitamin B-12 properly. Talk with your doctor about the possibility of vitamin B-12 deficiency if you have been on rabeprazole sodium delayed-release tablets for a long time (more than 3 years).
- **Low magnesium levels in your body.** This problem can be serious. Low magnesium can happen in some people who take a PPI medicine for at least 3 months. If low magnesium levels happen, it is usually after a year of treatment. You may or may not have symptoms of low magnesium.

Tell your doctor right away and get medical care if you have any of these symptoms:

- seizures
- dizziness
- abnormal or fast heart beat
- jitteriness
- jerking movements or shaking (tremors)
- muscle weakness
- spasms of the hands and feet
- cramps or muscle aches
- spasm of the voice box

Your doctor may check the level of magnesium in your body before you start taking

rabeprazole sodium delayed-release tablets, during treatment, or if you will be taking rabeprazole sodium delayed-release tablets for a long period of time.

The most common side effects of rabeprazole sodium delayed-release tablets in adults include:

- pain
- sore throat
- gas
- infection
- constipation

The most common side effects of rabeprazole sodium delayed-release tablets in adolescents 12 years of age and older include:

- headache
- diarrhea
- nausea
- vomiting
- stomach-area (abdomen) pain

Other side effects:

Serious allergic reactions. Tell your doctor if you get any of the following symptoms with rabeprazole sodium delayed-release tablets.

- rash
- face swelling
- throat tightness
- difficulty breathing

Your doctor may stop rabeprazole sodium delayed-release tablets if these symptoms happen.

These are not all of the possible side effects of rabeprazole sodium delayed-release tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store rabeprazole sodium delayed-release tablets?

Store rabeprazole sodium delayed-release tablets in a dry place at 20° to 25°C (68° to 77°F). Protect from moisture.

Keep rabeprazole sodium delayed-release tablets and all medicines out of the reach of children.

General Information about rabeprazole sodium delayed-release tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use rabeprazole sodium delayed-release tablets for a condition for which it was not prescribed. Do not give rabeprazole sodium delayed-release tablets to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your doctor or pharmacist for information about rabeprazole sodium delayed-release tablets that is written for health professionals.

What are the ingredients in rabeprazole sodium delayed-release tablets?

Active ingredient: rabeprazole sodium

Inactive ingredients: ammonium hydroxide, colloidal silicon dioxide, croscarmellose sodium, ethylcellulose, FD&C Blue No. 2 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake, hydroxypropyl cellulose, hypromellose, magnesium oxide, magnesium stearate, mannitol, medium chain triglycerides, methacrylic acid copolymer, oleic acid, polydextrose, polyethylene glycol, polysorbate 80, propylene glycol, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triacetin and triethyl citrate.

The imprinting ink contains the following: black iron oxide, hypromellose and propylene glycol.

Manufactured by: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A.

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For more information, call Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX).

This Medication Guide has been approved by the U.S. Food and Drug Administration.



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