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**MEDICATION GUIDE**

**Rabeprazole sodium (ra-BEP-ra-zole SOE-dee-um) delayed-release tablets**

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

**You should take rabeprazole sodium delayed-release tablets exactly as prescribed, at the lowest dose possible and for the shortest time needed.**

**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 tubulointerstitial nephritis).** Some people who take proton pump inhibitor (PPI) medicines, including rabeprazole sodium delayed-release tablets, may develop a kidney problem called acute tubulointerstitial nephritis that can happen at any time during treatment with rabeprazole sodium delayed-release tablets. Call your doctor right away if you have a decrease in the amount that you urinate or if you have blood in your urine.
- **Diarrhea caused by an infection (*Clostridium difficile*) in your intestines.** Call your doctor right away if you have watery stools or stomach pain that does not go away. You may or may not have a fever.
- **Bone fractures (hip, wrist, or spine).** Bone fractures in the hip, wrist, or spine may happen in people who take multiple daily doses of PPI medicines and for a long period of time (a year or longer). Tell your doctor if you have a bone fracture, especially in the hip, wrist, or spine.
- **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.

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 reduces the amount of acid in your stomach.

**In adults,** rabeprazole sodium delayed-release tablets are used for:

- 8 weeks up to 16 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.
- maintaining 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).

- up to 4 weeks to treat daytime and nighttime heartburn and other symptoms that happen with Gastroesophageal Reflux Disease (GERD).
- up to 4 weeks for the healing and relief of symptoms of duodenal ulcers.
- 7 days with certain antibiotic medicines to treat an infection and stomach (duodenal) ulcers caused by bacteria called *H. pylori*.
- the long-term treatment of conditions where your stomach makes too much acid. This includes a rare condition called Zollinger-Ellison syndrome.

**In adolescents 12 years of age and older,** rabeprazole sodium delayed-release tablets are used for up to 8 weeks to treat symptoms of GERD.

It is not known if rabeprazole sodium delayed-release tablets are safe and effective in children less than 12 years of age for other uses.

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

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

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

**Before you take rabeprazole sodium delayed-release tablets, tell your doctor about all of your medical conditions, including if you:**

- have low magnesium levels, low calcium levels and low potassium levels in your blood.
- have liver problems.
- are pregnant or plan to become pregnant. It is not known if rabeprazole sodium delayed-release tablets can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if rabeprazole sodium passes into 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. **Especially tell your doctor** if you take an antibiotic that contains clarithromycin or amoxicillin or if you take warfarin (COUMADIN, JANTOVEN), methotrexate (OTREXUP, RASUVO, TREXALL, XATMEP), digoxin (LANOXIN), or a water pill (diuretic).

**How should I take rabeprazole sodium delayed-release tablets?**

- Take rabeprazole sodium delayed-release tablets exactly as prescribed.
- 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, you should not take the missed dose. You should take your next dose at your regular time. Do not take 2 doses at the same time.
- If you take too much 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 emergency room.
- If your doctor prescribes antibiotic medicines with rabeprazole sodium delayed-release tablets, read the patient information that comes with the antibiotic medicines before you take them.

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

**Rabeprazole sodium delayed-release tablets can 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:
  - o pain, swelling or discomfort
  - o headaches, dizziness, or weakness
  - o unusual bruising (bruises that happen without known cause or that grow in size)
  - o nosebleeds
  - o bleeding gums
  - o bleeding from cuts take a long time to stop
  - o menstrual bleeding that is heavier than normal
  - o pink or brown urine
  - o red or black stools
  - o coughing up blood
  - o vomiting blood or vomit that looks like coffee grounds
- **Low vitamin B-12 levels** in the body can happen in people who have taken rabeprazole sodium delayed-release tablets for a long time (more than 3 years). Tell your doctor if you have symptoms of low vitamin B-12 levels, including shortness of breath, lightheadedness, irregular heartbeat, muscle weakness, pale skin, feeling tired, mood changes, and tingling or numbness in the arms and legs.
- **Low magnesium levels in the body** can happen in people who have taken rabeprazole sodium delayed-release tablets for at least 3 months. Tell your doctor if you have symptoms of low magnesium levels, including seizures, dizziness, irregular heartbeat, jitteriness, muscle aches or weakness, and spasms of hands, feet or voice.
- **Stomach growths (fundic gland polyps).** People who take PPI medicines for a long time have an increased risk of developing a certain type of stomach growths called fundic gland polyps, especially after taking PPI medicines for more than 1 year.
- **Severe skin reactions.** Rabeprazole sodium delayed-release tablets can cause rare but serious skin reactions that may affect any part of your body. These serious skin reactions may need to be treated in a hospital and may be

- life threatening.
  - o Skin rash which may have blistering, peeling or bleeding on any part of your skin (including your lips, eyes, mouth, nose, genitals, hands or feet).
  - o You may also have fever, chills, body aches, shortness of breath, or enlarged lymph nodes.

Stop taking rabeprazole sodium delayed-release tablets and call your doctor right away. These symptoms may be the first sign of a severe skin reaction.

**The most common side effects of rabeprazole sodium delayed-release tablets in adults include:** pain, sore throat, gas, infection, and 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, and stomach-area (abdomen) pain.

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), excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

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

**General Information about the safe and effective use of 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 hydrate, USP

**Inactive ingredients:** diethyl phthalate, ethyl cellulose, hypromellose phthalate, magnesium oxide, magnesium stearate, mannitol, povidone, sodium starch glycolate, talc, and titanium dioxide. Ferric oxide yellow is the coloring agent for the tablet coating.

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

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**Manufactured by:** Torrent Pharmaceuticals LTD., India.

**Manufactured for:** Torrent Pharma INC., Basking Ridge, NJ 07920.

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