

MEDICATION GUIDE

Pantoprazole Sodium Delayed-Release Tablets USP

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What is the most important information I should know about pantoprazole sodium delayed-release tablets? You should take pantoprazole sodium delayed-release tablets exactly as prescribed, at the lowest dose possible and for the shortest time needed.

Pantoprazole sodium delayed-release tablets may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor. **Pantoprazole 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 pantoprazole sodium delayed-release tablets, may develop a kidney problem called acute tubulointerstitial nephritis that can happen at any time during treatment with pantoprazole 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 pantoprazole sodium delayed-release tablet, 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.
- **Low magnesium and other mineral levels in your body** can happen in people who have taken pantoprazole 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.

Talk to your doctor about your risk of these serious side effects.

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

What are pantoprazole sodium delayed-release tablets?

A prescription medicine called a proton pump inhibitor

(PPI) used to reduce the amount of acid in your stomach.

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

- up to 8 weeks for the healing and symptom relief of acid-related damage to the lining of the esophagus (called erosive esophagitis or EE). Your doctor may prescribe another 8 weeks of pantoprazole sodium delayed-release tablets in patients whose EE does not heal.
- maintaining healing of EE and to help prevent the return of heartburn symptoms caused by GERD. It is not known if pantoprazole sodium delayed-release tablets are safe and effective when used for longer than 12 months for this purpose.
- the long-term treatment of conditions where your stomach makes too much acid. This includes a rare condition called Zollinger-Ellison Syndrome.

In children 5 years of age and older, pantoprazole sodium delayed-release tablets are used for:

- up to 8 weeks for the healing and symptom relief of EE.
It is not known if pantoprazole sodium delayed-release tablets are safe if used longer than 8 weeks in children.

Pantoprazole sodium delayed-release tablets are not for use in children under 5 years of age.

It is not known if pantoprazole sodium delayed-release tablets are safe and effective in children for treatment other than EE.

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

- allergic to pantoprazole sodium, any other PPI medicine, or any of the ingredients in pantoprazole 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, JULUCA) used to treat HIV-1 (Human Immunodeficiency Virus).

Before taking pantoprazole 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.
- are pregnant or plan to become pregnant. Pantoprazole sodium delayed-release tablets may harm your unborn baby. Tell your doctor if you become pregnant or think you may be pregnant during treatment with pantoprazole sodium delayed-release tablets.
- are breastfeeding or plan to breastfeed. pantoprazole sodium delayed-release tablets can pass into your breast milk. Talk with your doctor about the best way to feed your baby if you take pantoprazole 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 methotrexate (Otrexup, Rasuvo,**

Trexall, XATMEP), digoxin (LANOXIN), or a water pill (diuretic).

How should I take pantoprazole sodium delayed-release tablets?

- Take pantoprazole sodium delayed-release tablets exactly as prescribed by your doctor.

Pantoprazole sodium delayed-release tablets:

- **Do not split, chew, or crush pantoprazole sodium delayed-release tablets.**
- Swallow pantoprazole sodium delayed-release tablets whole, with or without food.
- Tell your doctor if you are not able to swallow your pantoprazole sodium delayed-release tablet.
- You may use antacids while taking pantoprazole sodium delayed-release tablets.
- If you miss a dose of pantoprazole sodium delayed-release tablets, take it as soon as possible. If it is almost time for your next dose, do not take the missed dose. Take the next dose at your regular time. Do not take 2 doses at the same time.
- If you take too much pantoprazole 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.

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

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

- **See “What is the most important information I should know about pantoprazole sodium delayed-release tablets?”**
- **Low vitamin B-12 levels** in your body can happen in people who have taken pantoprazole 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.
- **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.** Pantoprazole sodium for delayed-release tablets can cause rare but severe 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:
- 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).
- You may also have fever, chills, body aches, shortness of breath, or enlarged lymph nodes. Stop taking pantoprazole 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 pantoprazole sodium delayed-release tablets in adults include: headache, diarrhea, nausea, stomach-area (abdominal) pain,

vomiting, gas, dizziness, and joint pain.

The most common side effects of pantoprazole sodium delayed-release tablets in children include: upper respiratory infection, headache, fever, diarrhea, vomiting, rash, and stomach-area (abdominal) pain.

These are not all the possible side effects of pantoprazole 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 pantoprazole sodium delayed-release tablets?

Store pantoprazole sodium delayed-release tablets at room temperature between 68°F to 77°F (20°C to 25°C).

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

General information about the safe and effective use of pantoprazole sodium delayed-release tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use pantoprazole sodium delayed-release tablets for a condition for which it was not prescribed. Do not give pantoprazole 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 pantoprazole sodium delayed-release tablets that is written for health professionals.

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

Active ingredient: pantoprazole sodium sesquihydrate USP

Inactive ingredients: calcium stearate, carnauba wax, ferric oxide yellow, hydroxy propyl cellulose, hypromellose, lactose monohydrate, methacrylic acid copolymer, polysorbate 80, propylene glycol, sodium carbonate anhydrous, sodium lauryl sulfate, titanium dioxide, and triethyl citrate. The tablets are imprinted with opacode black containing ammonium hydroxide, iron oxide black, propylene glycol and shellac.

For more information, call Hetero Labs Limited at 1-866-495-1995.

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

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