

MEDICATION GUIDE
Pantoprazole Sodium
(pan-TOE-pra-zole SOE-dee-um)
for Delayed-Release Oral Suspension

What is the most important information I should know about pantoprazole sodium for delayed-release oral suspension?

You should take pantoprazole sodium for delayed-release oral suspension exactly as prescribed, at the lowest dose possible and for the shortest time needed.

Pantoprazole sodium for delayed-release oral suspension may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor.

Pantoprazole sodium for delayed-release oral suspension 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 for delayed-release oral suspension, may develop a kidney problem called acute tubulointerstitial nephritis that can happen at any time during treatment with pantoprazole sodium for delayed-release oral suspension. 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 for delayed-release oral suspension, 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.

Pantoprazole sodium for delayed-release oral suspension can have other serious side effects. See **“What are the possible side effects of pantoprazole sodium for delayed-release oral suspension?”**

What is pantoprazole sodium for delayed-release oral suspension?

A prescription medicine called a proton pump inhibitor (PPI) used to reduce the amount of acid in your stomach.

In adults, pantoprazole sodium for delayed-release oral suspension is 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 for delayed-release oral suspension 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 for delayed-release oral suspension is 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 for delayed-release oral suspension is used for:

- up to 8 weeks for the healing and symptom relief of EE.

It is not known if pantoprazole sodium for delayed-release oral suspension is safe if used longer than 8 weeks in children.

Pantoprazole sodium for delayed-release oral suspension is not for use in children under 5 years of age. It is not known if pantoprazole sodium for delayed-release oral suspension is safe and effective in children for treatment other than EE.

Do not take pantoprazole sodium for delayed-release oral suspension if you are:

- allergic to pantoprazole sodium, any other PPI medicine, or any of the ingredients in pantoprazole sodium for delayed-release oral suspension. 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 for delayed-release oral suspension, tell your doctor about all of your medical conditions, including if you:

- have low magnesium levels in your blood.
- are pregnant or plan to become pregnant. Pantoprazole sodium for delayed-release oral suspension may harm your unborn baby. Tell your doctor if you become pregnant or think you may be pregnant during treatment with pantoprazole sodium for delayed-release oral suspension.
- are breastfeeding or plan to breastfeed. Pantoprazole sodium for delayed-release oral suspension can pass into your breast milk. Talk with your doctor about the best way to feed your baby if you take pantoprazole sodium for delayed-release oral suspension.

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 for delayed-release oral suspension?

- Take pantoprazole sodium for delayed-release oral suspension exactly as prescribed by your doctor.
 - **Do not split, chew, or crush pantoprazole sodium for delayed-release oral suspension.**
 - Take pantoprazole sodium for delayed-release oral suspension about 30 minutes before a meal.
 - Pantoprazole sodium for delayed-release oral suspension should **only** be given by mouth mixed in apple juice or applesauce **or** through a nasogastric (NG) tube or gastrostomy tube mixed in apple juice. Do not mix pantoprazole sodium for delayed-release oral suspension in liquids other than apple juice or foods other than applesauce.
 - Do not divide a packet of pantoprazole sodium for delayed-release oral suspension to make a smaller dose.
 - See the **“Instructions for Use”** at the end of this Medication Guide for instructions on how to mix and take pantoprazole sodium for delayed-release oral suspension by mouth in applesauce or apple juice or how to mix and give the suspension through an NG tube or gastrostomy tube mixed in apple juice.
- If you miss a dose of pantoprazole sodium for delayed-release oral suspension, 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 for delayed-release oral suspension, 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 for delayed-release oral suspension?

Pantoprazole sodium for delayed-release oral suspension can cause serious side effects, including:

- See **“What is the most important information I should know about pantoprazole sodium for delayed-release oral suspension?”**
- **Low vitamin B-12 levels** in your body can happen in people who have taken pantoprazole sodium for delayed-release oral suspension 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 your body** can happen in people who have taken pantoprazole sodium for delayed-release oral suspension 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.

The most common side effects of pantoprazole sodium for delayed-release oral suspension in adults include: headache, diarrhea, nausea, stomach-area (abdominal) pain, vomiting, gas, dizziness, and joint pain.

The most common side effects of pantoprazole sodium for delayed-release oral suspension 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 for delayed-release oral suspension. 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 for delayed-release oral suspension?

Pantoprazole sodium for delayed-release oral suspension comes in a child-resistant package.

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

Keep pantoprazole sodium for delayed-release oral suspension and all medicines out of the reach of children.

General information about the safe and effective use of pantoprazole sodium for delayed-release oral suspension.

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

What are the ingredients in pantoprazole sodium for delayed-release oral suspension?

Active ingredient: pantoprazole sodium sesquihydrate

Inactive ingredients: calcium stearate, crospovidone, ferric oxide yellow, hydroxypropyl cellulose, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, povidone, sodium carbonate, sodium lauryl sulfate, talc, titanium dioxide, and triethyl citrate.

**Instructions for Use
Pantoprazole Sodium
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for Delayed-Release Oral Suspension**

Important information:

- **Do not split, chew, or crush pantoprazole sodium for delayed-release oral suspension.**
- Take pantoprazole sodium for delayed-release oral suspension about 30 minutes before a meal.
- **Pantoprazole sodium for delayed-release oral suspension:**
 - should **only be taken with applesauce or apple juice.**
 - should **not be mixed in water or other liquids, or other foods.**

- packet should **not** be divided to make a smaller dose.

Taking pantoprazole sodium for delayed-release oral suspension with applesauce:

1. Open the packet of pantoprazole sodium for delayed-release oral suspension.
2. Sprinkle all of the granules in the packet on 1 teaspoon of applesauce.
3. Swallow the granules and applesauce **within 10 minutes** of putting the granules on the teaspoon of applesauce.
4. Take sips of water to make sure the granules are washed down into the stomach. Take more sips of water as needed.

Taking pantoprazole sodium for delayed-release oral suspension with apple juice:

1. Open the packet of pantoprazole sodium for delayed-release oral suspension.
2. Empty all of the granules in the packet into a small cup that contains 1 teaspoon of apple juice.
3. Stir the granules-apple juice mixture for 5 seconds. The granules will not break up.
4. Swallow the mixture right away.
5. To make sure that the entire dose is taken, add more apple juice to the cup, stir and swallow the apple juice right away.
6. Repeat step 5 if there are granules left in the cup.

Giving pantoprazole sodium for delayed-release oral suspension through a nasogastric (NG) tube or gastrostomy tube:

• Pantoprazole sodium for delayed-release oral suspension may be given through an NG tube or gastrostomy tube that is **size 16 French or larger**. Do not give pantoprazole sodium for delayed-release oral suspension through an NG tube or gastrostomy tube smaller than size 16 French.

• Mix pantoprazole sodium for delayed-release oral suspension **only in apple juice** when giving through an NG tube or gastrostomy tube.

1. Remove the plunger from a 60 mL (2 ounce) catheter-tip syringe. Throw away the plunger.
2. Connect the tip of the catheter-tip syringe to the NG tube or gastrostomy tube.
3. Hold the syringe attached to the NG tube or gastrostomy tube as high as possible while giving pantoprazole sodium for delayed-release oral suspension to prevent the tubing from bending.
4. Open the packet of pantoprazole sodium for delayed-release oral suspension.
5. Empty all the granules in the packet into the catheter-tip syringe.
6. Add 10 mL (2 teaspoons) of apple juice into the catheter-tip syringe and gently tap or shake the syringe to help empty the syringe.
7. Repeat step 6 at least 2 more times until there are no granules left in the catheter-tip syringe.

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

Keep pantoprazole sodium for delayed-release oral suspension and all medicines out of the reach of children.

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

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