

MEDICATION GUIDE

PROTONIX (pro-TAH-nix) (pantoprazole sodium)

Delayed-Release Tablets and For Delayed-Release Oral Suspension

Read this Medication Guide before you start taking PROTONIX and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about PROTONIX?

PROTONIX may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor.

PROTONIX can cause serious side effects, including:

- **A type of kidney problem (acute interstitial nephritis).** Some people who take proton pump inhibitor (PPI) medicines, including PROTONIX, may develop a kidney problem called acute interstitial nephritis that can happen at any time during treatment with PROTONIX. Call your doctor if you have a decrease in the amount that you urinate or if you have blood in your urine.
- **Diarrhea.** PROTONIX 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 (a year or longer) may have an increased risk of fractures of the hip, wrist or spine. You should take PROTONIX exactly as prescribed, at the lowest dose possible for your treatment and for the shortest time needed. Talk to your doctor about your risk of bone fracture if you take PROTONIX.
- **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 PROTONIX, 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.

PROTONIX can have other serious side effects. See **“What are the possible side effects of PROTONIX?”**

What is PROTONIX?

PROTONIX is a prescription medicine called a proton pump inhibitor (PPI). PROTONIX reduces the amount of acid in your stomach.

PROTONIX is used in adults:

- for up to 8 weeks to heal acid-related damage to the lining of the esophagus (erosive esophagitis or EE) and to relieve symptoms caused by gastroesophageal reflux disease (GERD). If needed, your doctor may decide to prescribe another 8 weeks of PROTONIX.
- to maintain the healing of acid-related damage to the lining of the esophagus and help prevent return of heartburn symptoms caused by GERD. It is not known if PROTONIX is safe and effective if used longer than 12 months (1 year).
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 the long-term treatment of conditions where your stomach makes too much acid. This includes a rare condition called Zollinger-Ellison syndrome.

PROTONIX is used in children 5 years of age and older for up to 8 weeks to heal acid-related damage to the lining of the esophagus (erosive esophagitis or EE) caused by GERD.

It is not known if PROTONIX is safe if used longer than 8 weeks in children. PROTONIX is not for use in children under 5 years of age.

Who should not take PROTONIX?

Do not take PROTONIX if you are:

- allergic to pantoprazole sodium or any of the other ingredients in PROTONIX. See the end of this Medication Guide for a complete list of ingredients in PROTONIX.
- allergic to any proton pump inhibitor (PPI) medicine.

What should I tell my doctor before taking PROTONIX?

Before taking PROTONIX, tell your doctor if you:

- have been told that you have low magnesium levels in your blood
- have liver problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if PROTONIX will harm your unborn baby.
- are breastfeeding or plan to breastfeed. PROTONIX may pass into your milk. You and your doctor should decide if you will take PROTONIX or breastfeed. You should not do

both. Talk with your doctor about the best way to feed your baby if you take PROTONIX.

Tell your doctor about all of the medicines you take, including prescription and non-prescription drugs, vitamins and herbal supplements. PROTONIX may affect how other medicines work, and other medicines may affect how PROTONIX works.

Especially tell your doctor if you take:

- atazanavir (Reyataz)
- nelfinavir (Viracept)
- warfarin (Coumadin, Jantoven)
- ketoconazole (Nizoral)
- a product that contains iron
- an antibiotic that contains ampicillin
- methotrexate
- mycophenolate mofetil (Cellcept)

Ask your doctor or pharmacist for a list of these medicines, if you are not sure.

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 PROTONIX?

- Take PROTONIX exactly as prescribed by your doctor.
- Do not change your dose or stop PROTONIX without talking to your doctor.
- If you forget to take a dose of PROTONIX, take it as soon as you remember. 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 two doses to try to make up for a missed dose.
- If you take too much PROTONIX, call your doctor right away or go to the nearest hospital emergency room.
- See the Instructions for Use at the end of this Medication Guide for detailed instructions about:
 - how to take PROTONIX Tablets
 - how to take PROTONIX Delayed-Release Oral Suspension
 - how to mix and give PROTONIX For Delayed-Release Oral Suspension through a nasogastric tube or gastric tube.

What are the possible side effects of PROTONIX?

PROTONIX may cause serious side effects, including:

See “What is the most important information I should know about PROTONIX?”

- **Vitamin B-12 deficiency.** PROTONIX reduces 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 PROTONIX 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 if you have any of these symptoms:

- seizures
- dizziness
- abnormal or fast heartbeat
- 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 PROTONIX or during treatment, if you will be taking PROTONIX for a long period of time.

The most common side effects with PROTONIX in adults include:

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| • Headache | • Vomiting |
| • Diarrhea | • Gas |
| • Nausea | • Dizziness |
| • Stomach pain | • Pain in your joints |
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The most common side effects with PROTONIX in children include:

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| • Upper respiratory infection | • Vomiting |
| • Headache | • Rash |
| • Fever | • Stomach pain |
| • Diarrhea | |
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Other side effects:

- **Serious allergic reactions.** Tell your doctor if you get any of the following symptoms with PROTONIX:
 - rash
 - face swelling

- throat tightness
- difficult breathing

Your doctor may stop PROTONIX if these symptoms happen.

Tell your doctor about any side effects that bother you or that do not go away.

These are not all the possible side effects with PROTONIX. For more information, ask your doctor or pharmacist.

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 PROTONIX?

- Store PROTONIX at room temperature between 68° to 77°F (20° to 25°C).

Keep PROTONIX and all medicines out of the reach of children.

General information about PROTONIX

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

This Medication Guide summarizes the most important information about PROTONIX. For more information, ask your doctor. You can ask your doctor or pharmacist for information that is written for healthcare professionals.

For more information, go to www.pfizer.com or call toll-free 1-800-438-1985.

What are the ingredients in PROTONIX?

Active ingredient: pantoprazole sodium sesquihydrate

Inactive ingredients in PROTONIX Delayed-Release Tablets: calcium stearate, crospovidone, hypromellose, iron oxide, mannitol, methacrylic acid copolymer, polysorbate 80, povidone, propylene glycol, sodium carbonate, sodium lauryl sulfate, titanium dioxide, and triethyl citrate.

Inactive ingredients in PROTONIX For Delayed-Release Oral Suspension: crospovidone, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, povidone, sodium carbonate, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate, and yellow ferric oxide.

Instructions for Use

PROTONIX Delayed-Release Tablets:

- You can take PROTONIX tablets with food or on an empty stomach.
- Swallow PROTONIX tablets whole.
- If you have trouble swallowing a PROTONIX 40 mg tablet, you can take two 20 mg tablets instead.
- Do not split, chew, or crush PROTONIX tablets.

PROTONIX Delayed-Release For Oral Suspension:

- PROTONIX Oral Suspension should be taken 30 minutes before a meal
- PROTONIX Oral Suspension should only be taken with applesauce or apple juice 30 minutes before a meal.
- PROTONIX Oral Suspension should not be taken in or with water or other liquids, or with other foods. See “Directions for use” below.
- PROTONIX Oral Suspension should not be chewed or crushed.
- PROTONIX Oral Suspension packet should not be divided to make a smaller dose.

Directions for use with applesauce:

- Open packet.
- Sprinkle granules on one teaspoonful of applesauce. Do not use any other foods. Do not crush or chew the granules.
- Take within 10 minutes of putting the granules into the teaspoon of applesauce.
- Take sips of water to make sure the granules are washed down into the stomach. Repeat water sips as necessary.

Directions for use with apple juice:

- Open packet.
- Empty granules into a small cup or teaspoon with one teaspoonful of apple juice.
- Stir the mix for 5 seconds (granules will not break up) and swallow it right away.
- To make sure that the entire dose is taken, rinse the container once or twice with apple juice to get out any leftover granules. Swallow the apple juice right away.

Giving PROTONIX Oral Suspension through a Nasogastric Tube or Gastrostomy Tube:

For people who have a nasogastric (NG) tube or gastrostomy tube in place, PROTONIX Oral Suspension can be given as follows:

- Remove the plunger from the barrel of a 2 ounce (60 mL) catheter-tip syringe. Throw away the plunger.
- Connect the catheter tip of the syringe to a 16 French (or larger) tube.
- Hold the syringe attached to the tubing as high as possible while giving PROTONIX Oral Suspension to prevent any bending of the tubing.
- Empty the contents of the packet into the barrel of the syringe.

- Add 10 mL (2 teaspoonfuls) of apple juice and gently tap or shake the barrel of the syringe to help empty the syringe.
- Do this again at least two more times using the same amount of apple juice (10 mL or 2 teaspoonfuls) each time. No granules should be left in the syringe.

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

This product's label may have been updated. For current full prescribing information, please visit www.pfizer.com.



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D78467 Konstanz, Germany

LAB-0574-8.0

Revised 10/2016