

MEDICATION GUIDE

PRILOSEC (pry-lo-sec) (omeprazole) Delayed-Release Capsules

PRILOSEC (pry-lo-sec) (omeprazole magnesium) for Delayed-Release Oral Suspension

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

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

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

PRILOSEC can cause serious side effects, including:

- **Diarrhea.** PRILOSEC 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 proton pump inhibitor 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 PRILOSEC 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 PRILOSEC.

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

What is PRILOSEC?

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

PRILOSEC is used in adults:

- for up to 8 weeks for the healing of duodenal ulcers. The duodenal area is the area where food passes when it leaves the stomach.

- with certain antibiotics 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 up to 8 weeks for healing stomach ulcers
- for up to 4 weeks to treat 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 8 weeks to heal acid-related damage to the lining of the esophagus (called erosive esophagitis or EE). If needed, your doctor may decide to prescribe another 4 weeks of PRILOSEC.
- to maintain healing of the esophagus. It is not known if PRILOSEC is safe and effective when used for longer than 12 months (1 year) for this purpose.
- for the long-term treatment of conditions where your stomach makes too much acid. This includes a rare condition called Zollinger-Ellison Syndrome.

For children 1 to 16 years of age, PRILOSEC is used:

- for up to 4 weeks to treat heartburn and other symptoms that happen with gastroesophageal reflux disease (GERD).
- for up to 8 weeks to heal acid-related damage to the lining of the esophagus (called erosive esophagitis or EE)
- to maintain healing of the esophagus. It is not known if PRILOSEC is safe and effective when used longer than 12 months (1 year) for this purpose.

It is not known if PRILOSEC is safe and effective for the treatment of gastroesophageal reflux disease (GERD) in children under 1 year of age.

Who should not take PRILOSEC?

Do not take PRILOSEC if you:

- are allergic to omeprazole or any of the ingredients in PRILOSEC. See the end of this Medication Guide for a complete list of ingredients in PRILOSEC.
- are allergic to any other Proton Pump Inhibitor (PPI) medicine.

What should I tell my doctor before taking PRILOSEC?

Before you take PRILOSEC, 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 PRILOSEC will harm your unborn baby.
- are breastfeeding or plan to breastfeed. PRILOSEC can pass into your breast milk and may harm your baby. You and your doctor should decide if you will take PRILOSEC or breastfeed. You should not do both. Talk to your doctor about the best way to feed your baby if you breastfeed.

Tell your doctor about all of the medicines you take

including prescription and non-prescription drugs, anti-cancer drugs, vitamins and herbal supplements. PRILOSEC may affect how other medicines work, and other medicines may affect how PRILOSEC works.

Especially tell your doctor if you take:

- atazanavir (Reyataz)
- nelfinavir (Viracept)
- saquinavir (Fortovase)
- cilostazol (Pletal)
- ketoconazole (Nizoral)
- voriconazole (Vfend)
- an antibiotic that contains ampicillin, amoxicillin or clarithromycin
- products that contain iron
- warfarin (Coumadin, Jantoven)
- digoxin (Lanoxin)
- tacrolimus (Prograf)
- diazepam (Valium)
- phenytoin (Dilantin)
- disulfiram (Antabuse)
- clopidogrel (Plavix)
- St. John's Wort (*Hypericum perforatum*)
- rifampin (Rimactane, Rifater, Rifamate),
- erlotinib (Tarceva)
- methotrexate

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 PRILOSEC?

- Take PRILOSEC exactly as prescribed by your doctor.

- Do not change your dose or stop PRILOSEC without talking to your doctor.
- Take PRILOSEC at least 1 hour before a meal.
- Swallow PRILOSEC capsules whole. **Do not chew or crush PRILOSEC Capsules.**
- If you have trouble swallowing PRILOSEC Capsules, you may take as follows:
 - Place 1 tablespoon of applesauce into a clean bowl.
 - Carefully open the capsule and empty the contents (pellets) onto the applesauce. Mix the pellets with the applesauce.
 - Swallow the applesauce and pellet mixture right away with a glass of cool water. Do not chew or crush the pellets. Do not store the applesauce and pellet mixture for later use.
- If you forget to take a dose of PRILOSEC, 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 on time. Do not take a double dose to make up for a missed dose.
- If you take too much PRILOSEC, tell your doctor right away.
- See the “Instructions for Use” at the end of this Medication Guide for instructions on how to take PRILOSEC For Delayed-Release Oral Suspension, and how to mix and give PRILOSEC For Delayed-Release Oral Suspension, through a nasogastric tube or gastric tube.

What are the possible side effects of PRILOSEC?

PRILOSEC can cause serious side effects, including:

- **See “What is the most important information I should know about PRILOSEC?”**
- **Chronic (lasting a long time) inflammation of the stomach lining (Atrophic Gastritis).** Using PRILOSEC for a long period of time may increase the risk of inflammation to your stomach lining. You may or may not have symptoms. Tell your doctor if you have stomach pain, nausea, vomiting, or weight loss.
- **Low magnesium levels in your body.** This problem can be serious. Low magnesium can happen in some people who take a proton pump inhibitor 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 develop 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 PRILOSEC or during treatment if you will be taking PRILOSEC for a long period of time.

The most common side effects with PRILOSEC in adults and children include:

- headache
- stomach pain
- nausea
- diarrhea
- vomiting
- gas

In addition to the side effects listed above, the most common side effects in children 1 to 16 years of age include:

- respiratory system events
- fever

Other side effects:

Serious allergic reactions. Tell your doctor if you get any of the following symptoms with PRILOSEC:

- rash
- face swelling
- throat tightness
- difficulty breathing

Your doctor may stop PRILOSEC if these symptoms happen.

Tell your doctor if you have any side effect that bothers you or that do not go away. These are not all the possible side effects with PRILOSEC.

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 PRILOSEC?

- Store PRILOSEC Delayed-Release Capsules at room temperature between 59°F to 86°F (15°C to 30°C).
- Store PRILOSEC Delayed-Release Oral Suspension at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep the container of PRILOSEC Delayed-Release Capsules closed tightly.
- Keep the container of PRILOSEC Delayed-Release Capsules dry and away from light.

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

General information about PRILOSEC

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use PRILOSEC for a condition for which it was not prescribed. Do not give PRILOSEC 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 PRILOSEC. 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.astrazeneca-us.com or call 1-800-236-9933.

Instructions for Use

For instructions on taking Delayed-Release Capsules, please see **“How should I take PRILOSEC?”**

Take PRILOSEC For Delayed-Release Oral Suspension as follows:

- PRILOSEC For Delayed-Release Oral Suspension comes in packets containing 2.5 mg and 10 mg strengths.
- You should use an oral syringe to measure the amount of water needed to mix your dose. Ask your pharmacist for an oral syringe.
- If your prescribed dose is 2.5 mg, add 5 mL of water to a container, then add the contents of the packet containing your prescribed dose.
- If your prescribed dose is 10 mg, add 15 mL of water to a container, then add the contents of the packet containing your prescribed dose.
- If you or your child are instructed to use more than one packet for your prescribed dose, follow the

mixing instructions provided by your pharmacist or doctor.

- Stir.
- Leave 2 to 3 minutes to thicken.
- Stir and drink within 30 minutes. If not used within 30 minutes, throw away this dose and mix a new dose.
- If any medicine remains after drinking, add more water, stir, and drink right away.

PRILOSEC For Delayed-Release Oral Suspension may be given through a nasogastric tube (NG tube) or gastric tube, as prescribed by your doctor. Follow the instructions below:

PRILOSEC For Delayed-Release Oral Suspension:

- PRILOSEC Delayed-Release Oral Suspension comes in packets containing 2.5 mg and 10 mg strengths.
- Use only a catheter tipped syringe to give PRILOSEC through a NG tube or gastric tube (French size 6 or larger).
- If your prescribed dose is 2.5 mg, add 5 mL of water to a catheter tipped syringe, then add the contents of the packet containing your prescribed dose.
- If your prescribed dose is 10 mg, add 15 mL of water to a catheter tipped syringe, then add the contents of the packet containing your prescribed dose.
- Shake the syringe right away and then leave it for 2 to 3 minutes to thicken.
- Shake the syringe and give the medicine through the NG or gastric tube within 30 minutes.
- Refill the syringe with the same amount of water (either 5 mL or 15 mL of water depending on your dose).
- Shake the syringe and flush any remaining medicine from the NG tube or gastric tube into the stomach.

What are the ingredients in PRILOSEC?

Active ingredient in PRILOSEC Delayed-Release

Capsules: omeprazole

Inactive ingredients in PRILOSEC Delayed-Release

Capsules: cellulose, disodium hydrogen phosphate, hydroxypropyl cellulose, hypromellose, lactose, mannitol, sodium lauryl sulfate. Capsule shells: gelatin-NF, FD&C Blue #1, FD&C Red #40, D&C Red #28, titanium dioxide, synthetic black iron oxide, isopropanol, butyl alcohol, FD&C Blue #2, D&C Red #7 Calcium Lake, and, in addition, the 10 mg and 40 mg capsule shells also contain D&C Yellow #10.

Active ingredient in PRILOSEC For Delayed-Release

Oral Suspension: omeprazole magnesium

Inactive ingredients in PRILOSEC For Delayed-Release

Oral Suspension: glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer C, polysorbate, sugar spheres, talc, and triethyl citrate.

Inactive granules in PRILOSEC For Delayed-Release

Oral Suspension: citric acid, crospovidone, dextrose, hydroxypropyl cellulose, iron oxide and xantham gum.

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

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