

**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 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:**

- **A type of kidney problem (acute interstitial nephritis).** Some people who take proton pump inhibitor (PPI) medicines, including PRILOSEC, may develop a kidney problem called acute interstitial nephritis that can happen at any time during treatment with PRILOSEC. Call your doctor if you have a decrease in the amount that you urinate or if you have blood in your urine.
- **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 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 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.
- **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 proton PPI medicines, including PRILOSEC, 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.

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 for 10 to 14 days to treat an infection caused by bacteria called *H. pylori*. If needed, your doctor may decide to prescribe another 14 to 18 days of PRILOSEC by itself after the antibiotics. 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 treat gastroesophageal reflux disease (GERD) with acid-related damage to the lining of the esophagus [called erosive esophagitis (or EE) due to acid-mediated GERD].
- 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.

For children 1 month to less than 12 months (1 year) of age, PRILOSEC is used:

- for up to 6 weeks to treat gastroesophageal reflux disease (GERD) with acid-related damage to the lining of the esophagus [called erosive esophagitis (or EE) due to acid-mediated GERD]. It is not known if PRILOSEC is safe and

effective for other uses in children 1 month to less than 12 months (1 year) of age, or in children less than 1 month 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.
- are taking a medicine that contains rilpivirine (EDURANT, COMPLERA) used to treat HIV-1 (Human Immunodeficiency Virus).

#### **What should I tell my doctor before taking PRILOSEC?**

##### **Before taking PRILOSEC, tell your doctor about all of your medical conditions, including 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 passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take PRILOSEC.
- **Tell your doctor about all of the medicines you take** including prescription and over-the-counter medicines, 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 an antibiotic that contains clarithromycin or amoxicillin, or if you take clopidogrel (Plavix), methotrexate (Otrixup, Rasuvo, Trexall), St. John's Wort (*Hypericum perforatum*), or rifampin (Rimactane, Rifater, Rifamate).

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.
- PRILOSEC is usually taken 1 time each day. Your doctor will tell you the time of day to take PRILOSEC, based on your medical condition.
- Take PRILOSEC before a meal.
- Antacids may be taken with PRILOSEC.

#### **PRILOSEC Delayed-Release Capsules**

- Swallow PRILOSEC Capsules whole. **Do not chew or crush PRILOSEC Capsules.**
- If you have trouble swallowing a whole capsule, you can open the capsule and take the contents in applesauce. See the "Instructions for Use" at the end of this Medication Guide for instructions on how to take PRILOSEC Capsules with applesauce.

#### **PRILOSEC For Delayed-Release Oral Suspension**

- PRILOSEC Suspension is mixed with water and can be taken by mouth, or given through a nasogastric tube (NG tube) or gastric tube.
- See the "Instructions for Use" at the end of this Medication Guide for instructions on how to take PRILOSEC Suspension, and how to mix and give PRILOSEC Suspension through a nasogastric tube or gastric tube.

If you miss 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 at your regular time. Do not take 2 doses at the same time to make up for the missed dose.

If you take too much PRILOSEC, 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 PRILOSEC?**

##### **PRILOSEC can cause serious side effects, including:**

- See "What is the most important information I should know about PRILOSEC?"
- **Vitamin B-12 deficiency.** PRILOSEC 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 PRILOSEC 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 develop any of these symptoms:**

- |                               |  |                                |
|-------------------------------|--|--------------------------------|
| • seizures                    | • jitteriness                            | • spasms of the hands and feet |
| • dizziness                   | • jerking movements or shaking (tremors) | • cramps or muscle aches       |
| • abnormal or fast heart beat | • muscle weakness                        | • 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.

- **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 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
- throat tightness
- face swelling
- 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 does not go away. These are not all the possible side effects with PRILOSEC. 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 PRILOSEC?**

- Store PRILOSEC Delayed-Release Capsules at room temperature between 59°F to 86°F (15°C to 30°C).
- Store PRILOSEC For 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 the safe and effective use of 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.

**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 xanthan gum.

Manufactured for: Covis Pharma, Zug, 6300 Switzerland

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