

## MEDICATION GUIDE

### Omeprazole Delayed-Release Capsules, USP

Read this Medication Guide before you start taking Omeprazole Delayed-Release Capsules 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 Omeprazole Delayed-Release Capsules?**

**Omeprazole Delayed-Release Capsules may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor.**

**Omeprazole Delayed-Release Capsules can cause serious side effects, including:**

- **Diarrhea.** Omeprazole Delayed-Release Capsules 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 Omeprazole Delayed-Release Capsules 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 Omeprazole Delayed-Release Capsules.

Omeprazole Delayed-Release Capsules can have other serious side effects. See "[What are the possible side effects of Omeprazole Delayed-Release Capsules?](#)"

#### **What is Omeprazole Delayed-Release Capsules?**

Omeprazole Delayed-Release Capsules is a prescription medicine called a proton pump inhibitor (PPI). Omeprazole Delayed-Release Capsules reduces the amount of acid in your stomach.

Omeprazole Delayed-Release Capsules is used in adults:

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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 Omeprazole Delayed-Release Capsules.
- to maintain healing of the esophagus. It is not known if Omeprazole Delayed-Release Capsules 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 2 to 16 years of age, Omeprazole Delayed-Release Capsules 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 Omeprazole Delayed-Release Capsules is safe and effective when used longer than 12 months (1 year) for this purpose.

It is not known if Omeprazole Delayed-Release Capsules is safe and effective for the treatment of gastroesophageal reflux disease (GERD) in children under 2 years of age.

### **Who should not take Omeprazole Delayed-Release Capsules?**

#### **Do not take Omeprazole Delayed-Release Capsules if you:**

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

## **What should I tell my doctor before taking Omeprazole Delayed-Release Capsules?**

### **Before you take Omeprazole Delayed-Release Capsules, 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 Omeprazole Delayed-Release Capsules will harm your unborn baby.
- are breastfeeding or plan to breastfeed. Omeprazole Delayed-Release Capsules can pass into your breast milk and may harm your baby. You and your doctor should decide if you will take Omeprazole Delayed-Release Capsules 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, anticancer drugs, vitamins and herbal supplements. Omeprazole Delayed-Release Capsules may affect how other medicines work, and other medicines may affect how Omeprazole Delayed-Release Capsules work.

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 Omeprazole Delayed-Release Capsules?**

Take Omeprazole Delayed-Release Capsules exactly as prescribed by your doctor.

- Do not change your dose or stop Omeprazole Delayed-Release Capsules without talking to your doctor.
- Take Omeprazole Delayed-Release Capsules at least 1 hour before a meal.
- Swallow Omeprazole Delayed-Release Capsules whole. **Do not chew or crush Omeprazole Delayed-Release Capsules.**
- If you have trouble swallowing Omeprazole Delayed-Release Capsules, you may take as follows:
  - Place 1 tablespoon of applesauce into a clean bowl.
  - Carefully open the capsule and empty the contents (microtablets) onto the applesauce. Mix the microtablets with the applesauce.
  - Swallow the applesauce and microtablet mixture right away with a glass of cool water. Do not chew or crush the microtablets. Do not store the applesauce and microtablet mixture for later use.
- If you forget to take a dose of Omeprazole Delayed-Release Capsules, 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 Omeprazole Delayed-Release Capsules, tell your doctor right away.

### **What are the possible side effects of Omeprazole Delayed-Release Capsules?**

**Omeprazole Delayed-Release Capsules can cause serious side effects, including:**

- See "[What is the most important information I should know about Omeprazole Delayed-Release Capsules?](#)"
- **Chronic (lasting a long time) inflammation of the stomach lining (Atrophic Gastritis).** Using Omeprazole Delayed-Release Capsules 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:

Your doctor may check the level of magnesium in your body before you start taking Omeprazole Delayed-Release Capsules or during treatment if you will be taking Omeprazole Delayed-Release Capsules for a long period of time.

- 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

The most common side effects with Omeprazole Delayed-Release Capsules 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 2 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 Omeprazole Delayed-Release Capsules:

- rash
- face swelling
- throat tightness
- difficulty breathing

Your doctor may stop Omeprazole Delayed-Release Capsules 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 Omeprazole Delayed-Release Capsules.

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 Omeprazole Delayed-Release Capsules?**

- Store Omeprazole Delayed-Release Capsules at controlled room temperature 68°F to 77°F (20°C to 25°C) (See USP Controlled Room Temperature).
- Keep the container of Omeprazole Delayed-Release Capsules closed tightly.
- Keep the container of Omeprazole Delayed-Release Capsules dry and away from light.

**Keep Omeprazole Delayed-Release Capsules and all medicines out of the reach of children.**

### **General information about Omeprazole Delayed-Release Capsules**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Omeprazole Delayed-Release Capsules for a condition for which it was not prescribed. Do not give Omeprazole Delayed-Release Capsules 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 Omeprazole Delayed-Release Capsules. 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.kremersurban.com](http://www.kremersurban.com) or call 1-866-822-0068.

### **Instructions for Use**

For instructions on taking Delayed-Release Capsules, please see "**[How should I take Omeprazole Delayed-Release Capsules?](#)**"

## **What are the ingredients in Omeprazole Delayed-Release Capsules?**

**Active ingredient in Omeprazole Delayed-Release Capsules:** omeprazole

**Inactive ingredients in Omeprazole Delayed-Release Capsules:** (including the capsule shells): crospovidone, glyceryl behenate, hypromellose, lactose monohydrate, methacrylic acid copolymer dispersion, silicon dioxide, talc, titanium dioxide and triethyl citrate. The capsule shells also contain gelatin and may contain sodium lauryl sulfate. In addition, the 20 mg and 40 mg capsule shells also contain yellow iron oxide. The imprinting ink also contains ammonium hydroxide, butyl alcohol, black iron oxide, isopropyl alcohol, propylene glycol and shellac glaze. The ink may also contain dehydrated alcohol.

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

Manufactured by:  
Schwarz/Kremers/

1101 C Ave. West  
Seymour, IN 47274

Distributed by:  
McKesson Packaging Services  
a business unit of McKesson Corporation  
7101 Weddington Rd., Concord, NC 28027

IS-4005666-R6  
July 2011