MEDICATION GUIDE

Omeprazole Delayed-Release Capsules, USP
(oh mep' ra zole)

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:

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

Omeprazole can have other serious side effects. See **"What are the possible side effects of omeprazole delayed-release capsules?"**

What are 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 are 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 omeprazole 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 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 1 to 16 years of age, omeprazole delayed-release capsules are 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 omeprazole delayed-release capsules are 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, omeprazole 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 omeprazole delayed-release capsules are 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 omeprazole delayed-release capsules?
Do not take omeprazole delayed-release capsules if you:

- are allergic to omeprazole delayed-release capsules 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.
- 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 omeprazole delayed-release capsules?
Before taking omeprazole delayed-release capsules, 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 omeprazole will harm your unborn baby.
- are breastfeeding or plan to breastfeed. Omeprazole passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take omeprazole delayed-release capsules.
- **Tell your doctor about all of the medicines you take** including prescription and over-the-counter medicines, vitamins and herbal supplements. Omeprazole delayed-release capsules

may affect how other medicines work, and other medicines may affect how omeprazole delayed-release capsules works. Especially tell your doctor if you take an antibiotic that contains clarithromycin or amoxicillin, or if you take clopidogrel (Plavix), methotrexate (Otrxup, Rasuvo, Trexall), St. John's Wort (*Hypericum perforatum),* or *rifampin (Rimac*tane, 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 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.
- Omeprazole is usually taken 1 time each day. Your doctor will tell you the time of day to take omeprazole, based on your medical condition.
- Take omeprazole delayed-release capsules before a meal.
- Antacids may be taken with omeprazole.

Omeprazole Delayed-Release Capsules

- Swallow omeprazole delayed-release capsules whole. **Do not chew or crush omeprazole delayed-release 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 omeprazole Capsules with applesauce.

If you miss 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 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 omeprazole delayed release capsules, 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 omeprazole delayed-release capsules?
Omeprazole can cause serious side effects, including:

- **See "What is the most important information I should know about omeprazole?"**

- **Vitamin B-12 deficiency.** Omeprazole delayed-release capsules 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 omeprazole delayed-release capsules 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
  - 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 omeprazole delayed-release capsules or during treatment if you will be taking omeprazole delayed-release capsules for a long period of time.

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 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 omeprazole:
- rash
- throat tightness
- face swelling
- difficulty breathing

Your doctor may stop omeprazole 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 omeprazole delayed-release capsules. 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 omeprazole delayed-release capsules?
- Store omeprazole delayed-release capsules at room temperature between 68°F to 77°F (20°C to 25°C).

- 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 the safe and effective use of 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 contact Apotex Corp., Drug Safety at 1-800-706-5575.

What are the ingredients in omeprazole delayed-release capsules?
Active ingredient in omeprazole delayed-release capsules: omeprazole
Inactive ingredients in omeprazole delayed-release capsules: magnesium hydroxide, mannitol, methacrylic acid copolymer dispersion, povidone and triethyl citrate. The capsule shells have the following inactive ingredients: D&C Red No. 28*, D&C Red No.33*, D&C Yellow No. 10*, FD&C Blue No. 1*, FD&C Red No. 40*, gelatin, iron oxide red* and titanium dioxide (*contains one or more of these ingredients). The capsule shells have the following inactive ingredients: gelatin, red iron oxide and titanium dioxide. The capsule imprinting ink contains ammonium hydroxide, black iron oxide, ethyl alcohol, isopropyl alcohol, n-butyl alcohol, potassium hydroxide, propylene glycol and shellac.

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

INSTRUCTIONS FOR USE

Omeprazole delayed-release capsules
(oh mep’ ra zole)

Taking Omeprazole Delayed-Release Capsules with applesauce:

1. Place 1 tablespoon of applesauce into a clean container.

2. Carefully open the capsule and sprinkle the pellets onto the applesauce. Mix the pellets with the applesauce.

3. Swallow the applesauce and pellet mixture right away. Do not chew or crush the pellets. Do not store the applesauce and pellet mixture for later use.

APOTEX INC.
OMEPRAZOLE DELAYED-RELEASE CAPSULES, USP
10 mg, 20 mg and 40 mg

Manufactured by
Apotex Inc.
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Manufactured for
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