Difficile) getting severe diarrhea. This diarrhea may be caused by an infection

• delayed-release capsules, may develop a kidney problem called acute

Omeprazole delayed-release capsules can cause serious side effects, including:

• a type of kidney problem (acute tubulointerstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including omeprazole delayed-release capsules, may develop certain types of nephritis that can happen at any time during treatment with omeprazole delayed-release capsules. Your doctor should watch you carefully, and you should have a decrease in the amount of urine you urinate or you have blood in your urine.

• 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 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 for longer than 3 months.

• Certain types of lupus erythematosus. Lupus erythematosus is an autoimmune disease (the body’s immune cells attack other cells or organs in the body). Some people who take PPI medicines, including omeprazole delayed-release capsules, may develop certain types of lupus erythematosus or have a worsening of lupus that 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 delayed-release capsules can have other serious side effects. See “What are the possible side effects of omeprazole delayed-release capsules?”

“What are the possible side effects of omeprazole delayed-release capsules?”

Omeprazole delayed-release capsules are prescription medicine called a proton pump inhibitor (PPI). Omeprazole delayed-release capsules reduce 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 of the upper stomach where the food passes when it leaves the stomach.

• with antibiotics for 10 to 14 days to treat an infection caused by bacteria called Helicobacter pylori. Your doctor may prescribe another medicine called a proton PPI medicine for 12 months (1 year) for this purpose.

• to maintain healing of the esophagus (GERD). How long you take omeprazole delayed-release capsules depends on how long you need to keep the infection from returning to the ulcers from coming back.

• for up to 8 weeks for healing stomach ulcers.

• for up to 8 weeks for treatment of other symptoms that happen with gastroesophageal reflux disease (GERD).

• for up to 12 weeks for 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 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 a radiation treatment called radiosurgery that uses a linear accelerator to line up small beams of radiation to the esophagus (or EE) due to acid-mediated GERD.

• to treat other medical conditions. It is not known if omeprazole delayed-release capsules are safe and effective when used for longer than 12 months (1 year) for this purpose.

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.

• you are taking any other proton pump inhibitor (PPI).

• you are taking a medicine that contains rifampine (DURANT, COMPLERA) used to treat tuberculosis.

What should I tell my doctor before taking omeprazole delayed-release capsules?

Before you take omeprazole delayed-release capsules, tell your doctor about all of your medical conditions, including:

• have low magnesium levels in your blood

• 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.

• have low magnesium levels in your blood. This problem can be serious. Low magnesium levels 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 not have symptoms of low magnesium.

Tell your doctor right away if you develop any of these symptoms:

• seizures

• diaphoresis (sweating)

• tinnitus (ringing in the ears)

• abnormal or fast heart beat

• muscle weakness

• spasms of the hands and feet

• muscle pain or muscle cramps

• rash (especially if it gets worse)

• severe or worsening joint pain

• joint swelling (swollen ankles, wrists, hands, hips) or weak muscles

• numbness or tingling in the hands or feet

• 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 does not go away. These are not all the possible side effects of omeprazole delayed-release capsules. For more information, ask your doctor or pharmacist.

Call your doctor for new medicine 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 20° to 25°C (68° to 77°F).

Keep the container of omeprazole delayed-release capsules closed tightly.

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 or pharmacist. This Medication Guide has not been approved by the U.S. Food and Drug Administration.

In this Medication Guide

Rx Only

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