

Medication Guide

Omeprazole and Sodium Bicarbonate Capsules (oh mep' ra zole and soe' dee um bye kar' bo nate)

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

What is the most important information I should know about omeprazole and sodium bicarbonate capsules?

Omeprazole and sodium bicarbonate capsules may help with your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor.

Omeprazole and sodium bicarbonate 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 and sodium bicarbonate capsules, may develop a kidney problem called acute interstitial nephritis that can happen at any time during treatment with omeprazole and sodium bicarbonate capsules. Call your doctor if you have a decrease in the amount that you urinate or if you have blood in your urine.
- **Omeprazole and sodium bicarbonate capsules contains sodium bicarbonate.** Tell your doctor if you are on a sodium restricted diet or if you have Bartter's Syndrome (a rare kidney disorder). Tell your doctor right away if you have confusion, shaking hands, dizziness, muscle twitching, nausea, vomiting, and numbness or tingling in the face, arms, or legs.
- **Diarrhea.** Omeprazole and sodium bicarbonate 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 and sodium bicarbonate 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 and sodium bicarbonate 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 PPI medicines, including omeprazole and sodium bicarbonate capsules, 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 and sodium bicarbonate capsules can have other serious side effects. See “**What are the possible side effects of omeprazole and sodium bicarbonate capsules?**”

What are omeprazole and sodium bicarbonate capsules?

Omeprazole and sodium bicarbonate capsules are a prescription medicine called a proton pump inhibitor (PPI). Omeprazole and sodium bicarbonate capsules reduce the amount of acid in your stomach.

Omeprazole and sodium bicarbonate capsules are used in adults:

- for 4 weeks to heal ulcers in the first part of the small bowel (duodenal ulcers). Your doctor may prescribe another 4 weeks of omeprazole and sodium bicarbonate capsules.
- 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 from the 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).
- to maintain healing of the esophagus. It is not known if omeprazole and sodium bicarbonate capsules are safe and effective if used longer than 12 months (1 year).

It is not known if omeprazole and sodium bicarbonate capsules are safe and effective in children less than 18 years of age.

Who should not take omeprazole and sodium bicarbonate capsules?

Do not take omeprazole and sodium bicarbonate capsules if you:

- are allergic to omeprazole or any of the other ingredients in omeprazole and sodium bicarbonate capsules. See the end of this Medication Guide for a complete list of ingredients in omeprazole and sodium bicarbonate capsules.
- are allergic to any other proton pump inhibitor (PPI) medicine.

What should I tell my doctor before I take omeprazole and sodium bicarbonate capsules?

Before you take omeprazole and sodium bicarbonate capsules, tell your doctor if you:

- have been told that you have low magnesium, calcium, or potassium levels in your blood
- have liver problems
- have heart failure
- have Bartter's syndrome (a rare kidney disorder)
- have any allergies
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if omeprazole and sodium bicarbonate capsules can harm your unborn baby.
- are breastfeeding or plan to breastfeed. Omeprazole and sodium bicarbonate can pass into your breast milk and may harm your baby. You and your doctor should decide if you will take omeprazole and sodium bicarbonate capsules or breastfeed. You should not do both. Talk with your doctor about the best way to feed your baby if you take omeprazole and sodium bicarbonate capsules.

Tell your doctor about all the medicines you take, including prescription and non-prescription drugs, anti-cancer drugs, vitamins and herbal supplements. Omeprazole and sodium bicarbonate capsules may affect how other medicines work, and other medicines may affect how omeprazole and sodium bicarbonate capsules works.

Especially tell your doctor if you take:

- Mycophenolate mofetil (Cellcept)
- diazepam (Valium)
- warfarin (Coumadin, Jantoven)
- phenytoin (Dilantin)
- cyclosporine (Gengraf, Neoral, Sandimmune)
- disulfiram (Antabuse)
- a benzodiazepine medicine
- ketoconazole (Nizoral)
- an antibiotic that contains ampicillin

- products that contain iron
- digoxin (Lanoxin)
- voriconazole (Vfend)
- atazanavir (Reyataz)
- nelfinavir (Viracept)
- tacrolimus (Prograf)
- saquinavir (Fortovase)
- clarithromycin (Biaxin, Biaxin XL)
- clopidogrel (Plavix)
- St. John's Wort (*Hypericum perforatum*)
- rifampin (Rifater, Rifamate, Rimactane, Rifadin)
- 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 and sodium bicarbonate capsules?

- Take omeprazole and sodium bicarbonate capsules exactly as prescribed by your doctor.
- Do not change your dose or stop taking omeprazole and sodium bicarbonate capsules without talking to your doctor. Take omeprazole and sodium bicarbonate capsules on an empty stomach at least one hour before a meal.
- Swallow omeprazole and sodium bicarbonate capsules whole with water. **Do not use other liquids.** Do not crush or chew the capsule. Do not open the capsule and sprinkle contents into food.
- If you miss a dose of omeprazole and sodium bicarbonate 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 two doses to make up for a missed dose.
- Do not substitute two 20 mg capsules for one 40 mg capsule of omeprazole and sodium bicarbonate because you will receive twice the amount of sodium bicarbonate. Talk to your doctor if you have questions.
- If you take too much omeprazole and sodium bicarbonate capsules, call your doctor or Poison Control Center right away, or go to the nearest hospital emergency room.
- Your doctor may prescribe antibiotic medicines with omeprazole and sodium bicarbonate capsules to help treat a stomach infection and heal stomach-area (duodenal) ulcers that are caused by bacteria called *H. pylori*. Make sure you read the patient information that comes with an antibiotic before you start taking it.

What are the possible side effects of omeprazole and sodium bicarbonate capsules?

Omeprazole and sodium bicarbonate capsules may cause serious side effects, including:

- See “**What is the most important information I should know about omeprazole and sodium bicarbonate capsules?**”
- **Vitamin B-12 deficiency.** An omeprazole and sodium bicarbonate capsule 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 and sodium bicarbonate 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 heartbeat
- 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 and sodium bicarbonate capsules, or during treatment, if you will be taking omeprazole and sodium bicarbonate capsules for a long period of time.

The most common side effects with omeprazole and sodium bicarbonate capsules include:

- headache
- abdominal pain
- nausea
- diarrhea
- vomiting
- gas

Other side effects:

- **Serious allergic reactions.** Tell your doctor if you get any of the following symptoms with omeprazole and sodium bicarbonate capsules.
 - rash
 - face swelling
 - throat tightness
 - difficulty breathing

Your doctor may stop omeprazole and sodium bicarbonate capsules if these symptoms happen.

Using omeprazole and sodium bicarbonate capsules for a long time may cause problems such as swelling and weight gain. Tell your doctor if this happens.

If you are on a low-sodium diet or at risk of developing congestive heart failure (CHF), you and your doctor should decide if you will take omeprazole and sodium bicarbonate capsules.

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 and sodium bicarbonate 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 and sodium bicarbonate capsules?

- Store omeprazole and sodium bicarbonate capsules at room temperature between 15° to 30°C (59° to 86°F).
- Keep omeprazole and sodium bicarbonate capsules in a tightly closed container.
- Keep omeprazole and sodium bicarbonate capsules in a dry place and out of the light.

Keep omeprazole and sodium bicarbonate capsules and all medicines out of the reach of children.

General information about omeprazole and sodium bicarbonate capsules

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use omeprazole and sodium bicarbonate capsules for any condition for which it was not prescribed by your doctor. Do not give omeprazole and sodium bicarbonate capsules to other people, even if they have the same symptoms as you. It may harm them.

This Medication Guide summarizes the most important information about omeprazole and sodium bicarbonate capsules. If you would like more information, talk to your doctor. You can also ask your doctor or pharmacist for information about omeprazole and sodium bicarbonate capsules that is written for healthcare professionals.

For more information, contact **FDA at 1-800-FDA-1088**.

What are the ingredients in omeprazole and sodium bicarbonate capsules?

Active ingredients: omeprazole and sodium bicarbonate

Inactive ingredients of omeprazole and sodium bicarbonate capsules: croscarmellose sodium and sodium stearyl fumarate. The black imprinting ink contains black iron oxide, propylene glycol, shellac and potassium hydroxide.

Instructions for Use

For instructions on taking omeprazole and sodium bicarbonate capsules, see **“How should I take omeprazole and sodium bicarbonate capsules?”**

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

Medication guide available at www.northstarrxllc.com/products or call 1-800-206-7821.

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