

Medication Guide

ZEGERID (ze ger id)

(omeprazole/sodium bicarbonate)

Powder for Oral Suspension and Capsules

Read this Medication Guide before you start taking ZEGERID 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 ZEGERID?

ZEGERID may help with your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor.

ZEGERID can cause serious side effects, including:

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

ZEGERID can have other serious side effects. See **“What are the possible side effects of ZEGERID?”**

What is ZEGERID?

ZEGERID is a prescription medicine called a proton pump inhibitor (PPI). ZEGERID reduces the amount of acid in your stomach.

ZEGERID is 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 ZEGERID.
- 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 ZEGERID is safe and effective if used longer than 12 months (1 year).
- to lower the risk of stomach bleeding in critically ill people (40 mg Oral Suspension only).

It is not known if ZEGERID is safe and effective in children less than 18 years of age.

Who should not take ZEGERID?

Do not take ZEGERID if you:

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

What should I tell my doctor before I take ZEGERID?

Before you take ZEGERID, 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 ZEGERID can harm your unborn baby.
- are breastfeeding or plan to breastfeed. ZEGERID can pass into your breast milk and may harm your baby. You and your doctor should decide if you will take ZEGERID or breastfeed. You should not do both. Talk with your doctor about the best way to feed your baby if you take ZEGERID.

Tell your doctor about all the medicines you take, including prescription and non-prescription drugs, anti-cancer drugs, vitamins and herbal supplements. ZEGERID may affect how other medicines work, and other medicines may affect how ZEGERID 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 ZEGERID?

- Take ZEGERID exactly as prescribed by your doctor.
- Do not change your dose or stop taking ZEGERID without talking to your doctor. Take ZEGERID on an empty stomach at least one hour before a meal.
- Empty the contents of a packet of ZEGERID Powder for Oral Suspension into a small cup containing 1 to 2 tablespoons of water. **Do not use other liquids or foods.** Stir well and drink immediately. Refill cup with water and drink.
- Swallow ZEGERID 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 ZEGERID, 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 packets for one 40 mg packet of ZEGERID Powder for Oral Suspension because you will receive twice the amount of sodium bicarbonate. Talk to your doctor if you have questions.
- Do not substitute two 20 mg capsules for one 40 mg capsule of ZEGERID because you will receive twice the amount of sodium bicarbonate. Talk to your doctor if you have questions.
- If you take too much ZEGERID, call your doctor or Poison Control Center right away, or go to the nearest hospital emergency room.
- Your doctor may prescribe antibiotic medicines with ZEGERID 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.
- See the “Instructions for Use” at the end of this Medication Guide for instructions on how to mix and give ZEGERID Powder for Oral Suspension through a nasogastric tube or orogastric tube.

What are the possible side effects of ZEGERID?

ZEGERID may cause serious side effects, including:

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

The most common side effects with ZEGERID 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 ZEGERID.
 - rash
 - face swelling
 - throat tightness
 - difficulty breathing

Your doctor may stop ZEGERID if these symptoms happen.

Using ZEGERID 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 ZEGERID.

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 ZEGERID. 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 ZEGERID?

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

Keep ZEGERID and all medicines out of the reach of children.

General information about ZEGERID

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ZEGERID for any condition for which it was not prescribed by your doctor. Do not give ZEGERID 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 ZEGERID. If you would like more information, talk to your doctor. You can also ask your doctor or pharmacist for information about ZEGERID that is written for healthcare professionals.

For more information, go to www.Salix.com or 1-800-321-4576.

What are the ingredients in ZEGERID?

Active ingredients: omeprazole and sodium bicarbonate

Inactive ingredients of ZEGERID Powder for Oral Suspension: xylitol, sucrose, sucralose, xanthan gum, and flavorings.

Inactive ingredients of ZEGERID Capsules: croscarmellose sodium and sodium stearyl fumarate.

Instructions for Use

For instructions on taking ZEGERID Capsules and ZEGERID Powder for Oral Suspension by mouth, see **“How should I take ZEGERID?”**

Giving ZEGERID Powder for Oral Suspension through a nasogastric tube (NG tube) or gastric tube:

- Add 20 mL of water to a catheter tipped syringe and then add the contents of a packet as prescribed by your doctor. Use only a catheter tipped syringe to give ZEGERID through an NG tube or orogastric tube.
- Shake the syringe to dissolve the powder.
- Give the medicine through the NG or orogastric tube into the stomach right away.
- Refill the syringe with an equal amount of water.
- Shake and flush any remaining contents from the NG tube or orogastric tube into the stomach.

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

ZEGERID® Capsules and Powder for Oral Suspension are

Manufactured for:

Salix Pharmaceuticals, a division of
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Bridgewater, NJ 08807 USA

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