MEDICATION GUIDE

Omeprazole and Sodium Bicarbonate
(oh mep' ra zole and soe' dee um bye kar' bo nate)
Powder for Oral Suspension

Read this Medication Guide before you start taking Omeprazole and Sodium Bicarbonate powder for oral suspension 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 powder for oral suspension?

Omeprazole and Sodium Bicarbonate powder for oral suspension may help with your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor.

Omeprazole and Sodium Bicarbonate powder for oral suspension can cause serious side effects, including:

- **Omeprazole and Sodium Bicarbonate powder for oral suspension 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 powder for oral suspension 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 and Sodium Bicarbonate powder for oral suspension 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 powder for oral suspension.

Omeprazole and Sodium Bicarbonate powder for oral suspension can have other serious side effects. See **"What are the possible side effects of Omeprazole and Sodium Bicarbonate powder for oral suspension?"**

What is Omeprazole and Sodium Bicarbonate powder for oral suspension?
Omeprazole and Sodium Bicarbonate powder for oral suspension is a prescription medicine called a proton pump inhibitor (PPI). Omeprazole and Sodium Bicarbonate powder for oral suspension reduces the amount of acid in your stomach.

Omeprazole and Sodium Bicarbonate powder for oral suspension 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 Omeprazole and Sodium Bicarbonate powder for oral suspension.
- 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 powder for oral suspension 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 Omeprazole and Sodium Bicarbonate powder for oral suspension is safe and effective in children less than 18 years of age.

Who should not take Omeprazole and Sodium Bicarbonate powder for oral suspension?
Do not take Omeprazole and Sodium Bicarbonate powder for oral suspension if you:
- are allergic to omeprazole or any of the other ingredients in Omeprazole and Sodium Bicarbonate powder for oral suspension. See the end of this Medication Guide for a complete list of ingredients in Omeprazole and Sodium Bicarbonate powder for oral suspension.
- are allergic to any other proton pump inhibitor (PPI) medicine.

What should I tell my doctor before I take Omeprazole and Sodium Bicarbonate powder for oral suspension?

Before you take Omeprazole and Sodium Bicarbonate powder for oral suspension, 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 powder for oral suspension 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 powder for oral suspension 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 powder for oral suspension.

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 powder for oral suspension may affect how other medicines work, and other medicines may affect how Omeprazole and Sodium Bicarbonate powder for oral suspension 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 powder for oral suspension?

- Take Omeprazole and Sodium Bicarbonate powder for oral suspension exactly as prescribed by your doctor.
- Do not change your dose or stop taking Omeprazole and Sodium Bicarbonate powder for oral suspension without talking to your doctor. Take Omeprazole and Sodium Bicarbonate powder for oral suspension on an empty stomach at least one hour before a meal.
- Empty the contents of a packet of Omeprazole and Sodium Bicarbonate 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.
- If you miss a dose of Omeprazole and Sodium Bicarbonate powder for oral suspension, 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 Omeprazole and Sodium Bicarbonate Powder for Oral Suspension 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 powder for oral suspension, 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 powder for oral suspension 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 Omeprazole and Sodium Bicarbonate Powder for Oral Suspension through a nasogastric tube or orogastric tube.

What are the possible side effects of Omeprazole and Sodium Bicarbonate powder for oral suspension?

Omeprazole and Sodium Bicarbonate powder for oral suspension may cause serious side effects, including:

- **See “What is the most important information I should know about Omeprazole and Sodium Bicarbonate powder for oral suspension?”**
- **Chronic (lasting a long time) inflammation of the stomach lining (Atrophic Gastritis).** Taking Omeprazole and Sodium Bicarbonate powder for oral suspension 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.
- **Vitamin B-12 deficiency.** Omeprazole and Sodium Bicarbonate powder for oral suspension 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 powder for oral suspension 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 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:

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  - 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 powder for oral suspension, or during treatment, if you will be taking Omeprazole and Sodium Bicarbonate powder for oral suspension for a long period of time.

The most common side effects with Omeprazole and Sodium Bicarbonate powder for oral suspension 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 powder for oral suspension.
  - rash
  - face swelling
  - throat tightness
  - difficulty breathing

Your doctor may stop Omeprazole and Sodium Bicarbonate powder for oral suspension if these symptoms happen.

Using Omeprazole and Sodium Bicarbonate powder for oral suspension 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 powder for oral suspension.

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 powder for oral suspension. 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 powder for oral suspension?

- Store Omeprazole and Sodium Bicarbonate powder for oral suspension at room temperature between 15 to 30°C (59 to 86°F).
- Keep Omeprazole and Sodium Bicarbonate powder for oral suspension in a dry place and out of the light.

Keep Omeprazole and Sodium Bicarbonate powder for oral suspension and all medicines out of the reach of children.

General information about Omeprazole and Sodium Bicarbonate powder for oral suspension

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Omeprazole and Sodium Bicarbonate powder for oral suspension for any condition for which it was not prescribed by your doctor. Do not give Omeprazole and Sodium Bicarbonate powder for oral suspension 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 powder for oral suspension. 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 powder for oral suspension that is written for healthcare professionals.

For more information, contact Ajanta Pharma USA Inc. at 855-664-7744.

What are the ingredients in Omeprazole and Sodium Bicarbonate powder for oral suspension?

Active ingredients: omeprazole and sodium bicarbonate

Inactive ingredients of Omeprazole and Sodium Bicarbonate Powder for Oral Suspension: xylitol, sucralose, xanthan gum, colloidal silicon dioxide and flavorings.

Instructions for Use

For instructions on taking Omeprazole and Sodium Bicarbonate Powder for Oral Suspension by mouth, see **"How should I take Omeprazole and Sodium Bicarbonate powder for oral suspension?"**

Giving Omeprazole and Sodium Bicarbonate 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 Omeprazole and Sodium Bicarbonate Powder for Oral Suspension through a 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.

Omeprazole and Sodium Bicarbonate powder for oral suspension is

Marketed by:

Ajanta Pharma USA Inc.
Bridgewater, NJ 08807.

Manufactured by:

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