

MEDICATION GUIDE Omeprazole and Sodium Bicarbonate for Oral Suspension oh mep' ra zole and soe' dee um bye kar' bo nate for oral suspension
What is the most important information I should know about Omeprazole and Sodium Bicarbonate? Omeprazole and Sodium Bicarbonate may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor. Omeprazole and Sodium Bicarbonate 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 and sodium bicarbonate, may develop a kidney problem called acute tubulointerstitial nephritis that can happen at any time during treatment with omeprazole and sodium bicarbonate. Call your doctor right away if you have a decrease in the amount that you urinate or if you have blood in your urine. • Omeprazole and Sodium Bicarbonate contains sodium bicarbonate. Long-term use of bicarbonate with calcium or milk can cause a condition called "milk-alkali syndrome". Long-term use of sodium bicarbonate can cause a condition called "systemic alkalosis". Talk to your doctor about any questions you may have. Too much sodium can cause swelling and weight gain. Tell your doctor if you are on a low-sodium diet or if you have Barter'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 caused by an infection (<i>Clostridium difficile</i>) in your intestines. Call your doctor right away if you have watery stools or stomach pain that does not go away. You may or may not have a fever. • Bone fractures (hip, wrist, or spine). Bone fractures in the hip, wrist or spine may happen in people who take multiple daily doses of PPI medicines and for a long period of time (a year or longer). Tell your doctor if you have bone fracture, especially in the hip, wrist, or spine. 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, 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. Talk to your doctor about your risk of these serious side effects. Omeprazole and sodium bicarbonate can have other serious side effects. See "What are the possible side effects of Omeprazole and Sodium Bicarbonate?"
What is Omeprazole and Sodium Bicarbonate? A prescription medicine called a proton pump inhibitor (PPI) used to reduce the amount of acid in your stomach. Omeprazole and sodium bicarbonate for oral suspension is used in adults for: • up to 8 weeks for the healing of duodenal ulcers. • up to 8 weeks for the healing of stomach ulcers. • up to 4 weeks to treat heartburn and other symptoms that happen with gastroesophageal reflux disease (GERD). • up to 8 weeks for the healing and symptom relief of acid-related damage to the lining of the esophagus (called erosive esophagitis or EE). Your doctor may prescribe another 4 weeks of omeprazole and sodium bicarbonate in patients whose EE does not heal. • maintaining healing of EE and to help prevent the return of heartburn symptoms caused by GERD. It is not known if omeprazole and sodium bicarbonate is safe and effective when used for longer than 12 months for this purpose. Omeprazole and Sodium Bicarbonate for oral suspension is used : • in critically ill adults to lower the risk of stomach bleeding (40 mg oral suspension only) It is not known if omeprazole and sodium bicarbonate is safe and effective in children.
Do not take omeprazole and sodium bicarbonate if you are: • allergic to omeprazole, any other PPI medicine, or any of the ingredients in omeprazole and sodium bicarbonate. See the end of this Medication Guide for a complete list of ingredients in omeprazole and sodium bicarbonate. • taking a medicine that contains rilpivirine, used to treat HIV-1 (Human Immunodeficiency Virus).
Before taking Omeprazole and Sodium Bicarbonate tell your doctor about all of your medical conditions, including if you: • have low magnesium, calcium, or potassium levels in your blood. • have problems with the acid-base (pH) balance in your body. • have liver problems. • have heart failure. • are on a low-sodium diet. • have Barter's syndrome (a rare kidney problem). • are of Asian descent and have been told that your body's ability to break down (metabolize) omeprazole is poor or if your genotype called CYP2C19 is not known. • are pregnant or plan to become pregnant. It is not known if omeprazole and sodium bicarbonate will harm your unborn baby. • are breastfeeding or plan to breastfeed. Omeprazole and sodium bicarbonate can pass into your breast milk. Talk with your doctor about the best way to feed your baby if you take omeprazole and sodium bicarbonate. Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Especially tell your doctor if you take: • digoxin (Lanoxin) • clopidogrel (Plavix) • St. John's wort (<i>Hypericum perforatum</i>) • 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? • Take omeprazole and sodium bicarbonate exactly as prescribed by your doctor. • Do not change your dose or stop taking omeprazole and sodium bicarbonate without talking to your doctor. • Omeprazole and sodium bicarbonate can be taken by mouth or given through a nasogastric (NG) or orogastric (OG) tube. • See the "Instructions for Use" that come with omeprazole and sodium bicarbonate for instructions on how to mix omeprazole and sodium bicarbonate for oral suspension with water and give the medicine through a NG tube or OG tube. • If you miss a dose of omeprazole and sodium bicarbonate 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 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, call your doctor or Poison Control Center at 1-800-222-1222 right away or go to the nearest hospital emergency room.
What are the possible side effects of Omeprazole and Sodium Bicarbonate? Omeprazole and Sodium Bicarbonate can cause serious side effects, including:

• See "What is the most important information I should know about Omeprazole and Sodium Bicarbonate?" • Low vitamin B-12 levels in your body can happen in people who have taken omeprazole and sodium bicarbonate for a long time (more than 3 years). Tell your doctor if you have symptoms of low vitamin B-12 levels, including shortness of breath, lightheadedness, irregular heartbeat, muscle weakness, pale skin, feeling tired, mood changes, and tingling or numbness in the arms and legs. • Low magnesium levels in your body can happen in people who have taken Omeprazole and sodium bicarbonate for at least 3 months. Tell your doctor right away if you have symptoms of low magnesium levels, including seizures, dizziness, irregular heartbeat, jitteriness, muscle aches or weakness, and spasms of hands, feet or voice. • Stomach growths (fundic gland polyps). People who take PPI medicines for a long time have an increased risk of developing a certain type of stomach growths called fundic gland polyps, especially after taking PPI medicines for more than 1 year. • Severe skin reactions. Omeprazole and Sodium Bicarbonate can cause rare but severe skin reactions that may affect any part of your body. These serious skin reactions may need to be treated in a hospital and may be life threatening: ○ Skin rash which may have blistering, peeling or bleeding on any part of your skin (including your lips, eyes, mouth, nose, genitals, hands or feet). ○ You may also have fever, chills, body aches, shortness of breath, or enlarged lymph nodes. Stop taking Omeprazole and Sodium Bicarbonate and call your doctor right away. These symptoms may be the first sign of a severe skin reaction. • The most common side effects of omeprazole and sodium bicarbonate include: ○ headache ○ abdominal pain ○ nausea ○ diarrhea ○ vomiting ○ gas These are not all the possible side effects of omeprazole and sodium bicarbonate. 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? • Store omeprazole and sodium bicarbonate at room temperature between 68°F to 77°F (20°C to 25°C). • Keep omeprazole and sodium bicarbonate in a tightly closed container. • Keep omeprazole and sodium bicarbonate in a dry place and out of light. Keep Omeprazole and Sodium Bicarbonate and all medicines out of the reach of children.
General information about the safe and effective use of Omeprazole and Sodium Bicarbonate Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use omeprazole and sodium bicarbonate for any condition for which it was not prescribed. Do not give omeprazole and sodium bicarbonate to other people, even if they have the same symptoms that you have. It may harm them. You can also ask your doctor or pharmacist for information about omeprazole and sodium bicarbonate that is written for health professionals.
What are the ingredients in Omeprazole and Sodium Bicarbonate? Active ingredients: omeprazole and sodium bicarbonate Inactive ingredients in omeprazole and sodium bicarbonate for oral suspension: xylitol, xanthan gum, sucralose powder, peach powder, sucrose and peppermint flavor. The brands listed are trademarks of their respective owners. For more information, go to www.strides.com or 1-877-244-9825. This Medication Guide has been approved by the U.S. Food and Drug Administration.
INSTRUCTIONS FOR USE Omeprazole and Sodium Bicarbonate oh mep' ra zole and soe' dee um bye kar' bo nate for oral suspension Taking Omeprazole and Sodium Bicarbonate for oral suspension: Important: Omeprazole and Sodium Bicarbonate should be taken on an empty stomach at least 1 hour before a meal. 1. Omeprazole and sodium bicarbonate comes in packets containing 20 mg or 40 mg of omeprazole. 2. Use an oral syringe to draw up the amount of water needed to mix your dose. Ask your pharmacist for an oral syringe. 3. Using the oral syringe, draw up 5 mL to 10 mL of water and add the water to a small cup. Do not mix Omeprazole and sodium bicarbonate with foods or liquids other than water. 4. Empty the contents of the packet into the small cup. 5. Stir well to dissolve the powder and drink the mixture right away. 6. If any medicine remains after drinking, add more water, stir, and drink right away. Giving omeprazole and sodium bicarbonate for oral suspension with water through a nasogastric (NG) tube or orogastric (OG) tube: Important: For patients receiving omeprazole and sodium bicarbonate through a NG tube or OG tube, enteral feeding should be stopped approximately 3 hours before giving omeprazole and sodium bicarbonate. You should wait at least 1 hour after giving omeprazole and sodium bicarbonate before you start enteral feeding again. 1. Omeprazole and sodium bicarbonate comes in packets containing 20 mg or 40 mg of omeprazole. 2. You will mix omeprazole and sodium bicarbonate with 20 mL of water in a catheter tipped syringe. 3. Use only a catheter tipped syringe to give omeprazole and sodium bicarbonate through the NG or OG tube. Talk to your doctor about the size catheter tipped syringe you should use. 4. Add 20 mL of water to the catheter tipped syringe. Do not use any food or liquids other than water to mix omeprazole and sodium bicarbonate 5. Add the contents of 1 packet of omeprazole and sodium bicarbonate to the syringe. 6. Shake the syringe well to dissolve the powder. 7. Inject the medicine through the NG or OG tube into the stomach right away. 8. Refill the syringe with the same amount of water (20 mL) you used to prepare your dose of omeprazole and sodium bicarbonate. 9. Shake the syringe and flush any remaining medicine from the NG tube or OG tube into the stomach. Distributed by: Strides Pharma Inc. East Brunswick, NJ 08816
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