

MEDICATION GUIDE
KONVOMETM (Kan-vo-mep)
(omeprazole and sodium bicarbonate for oral suspension)

What is the most important information I should know about KONVOMETM?

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

KONVOMETM can cause serious side effects, including:

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

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

What is KONVOMETM?

KONVOMETM is a combination of omeprazole, a proton pump inhibitor (PPI) and sodium bicarbonate.

KONVOMETM is used:

- in adults for up to 8 weeks for the healing of stomach ulcers.
- in critically ill adults to lower the risk of stomach bleeding.

It is not known if KONVOMETM is safe and effective in children.

Do not take KONVOMETM if you are:

- allergic to omeprazole, any other PPI medicine, or any of the ingredients in KONVOMETM. See the end of this Medication Guide for a complete list of ingredients in KONVOMETM.
- taking a medicine that contains rilpivirine, used to treat HIV-1 (Human Immunodeficiency Virus).

Before taking KONVOMETM, 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 heart failure.
- are on a low-sodium diet.
- have Bartter’s syndrome (a rare kidney problem).
- are pregnant or plan to become pregnant. It is not known if KONVOMETM will harm your unborn baby.
- are breastfeeding or plan to breastfeed. KONVOMETM can pass into your breast milk. Talk with your doctor about the best way to feed your baby if you take KONVOMETM.

Tell your doctor about all the medicines you take, including prescription and over-the counter medications, vitamins and herbal supplements.

Especially tell your doctor if you take:

- digoxin
- clopidogrel
- St. John’s wort (*Hypericum perforatum*)
- rifampin
- 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 KONVOME[®]P?

- Take KONVOME[®]P exactly as prescribed by your doctor.
- KONVOME[®]P is mixed (reconstituted) by a healthcare provider, and you will receive KONVOME[®]P as an oral suspension that can be taken by mouth or given through a nasogastric or orogastric tube.
- Shake the KONVOME[®]P oral suspension well before each use.
- Measure the KONVOME[®]P oral suspension with an accurate measuring device. Ask your pharmacist to recommend a measuring device and for instructions on how to measure the correct dose.
- If KONVOME[®]P is given through a nasogastric or orogastric tube, it is important to stop enteral feeding at least **3 hours before** giving KONVOME[®]P. You can start enteral feeding again at least **1 hour after** giving KONVOME[®]P.
- Do not change your dose or stop taking KONVOME[®]P without talking to your doctor.
- If you miss a dose of KONVOME[®]P, 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.
- If you take too much KONVOME[®]P, 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 KONVOME[®]P?

KONVOME[®]P may cause serious side effects, including:

- See “**What is the most important information I should know about KONVOME[®]P?**”
- **Low vitamin B-12 levels** in your body can happen in people who have taken KONVOME[®]P 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 KONVOME[®]P** 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.** KONVOME[®]P 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 KONVOME[®]P and call your doctor right away. These symptoms may be the first sign of a severe skin reaction.

The most common side effects of KONVOME[®]P include:

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

These are not all the possible side effects of KONVOME[®]P. Call your doctor for medical advice about side effects. You may report side effect to FDA at 1-800-FDA-1088.

You may also report side effects to Azurity Pharmaceuticals, Inc. at 1-800-461-7449.

How should I store KONVOME[®]P?

- Store KONVOME[®]P oral suspension in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep the KONVOME[®]P container tightly closed. Protect the container from light.
- Do not freeze KONVOME[®]P.
- Throw away (discard) any unused KONVOME[®]P oral suspension after 30 days.

Keep KONVOME[®]P and all medicines out of the reach of children.

General information about the safe and effective use of KONVOME[®]P.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use KONVOME[®]P for any condition for which it was not prescribed. Do not give KONVOME[®]P 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 KONVOME[®]P that is written for health professionals.

What are the ingredients in KONVOME[®]P?

Active ingredients: omeprazole and sodium bicarbonate

Inactive ingredients in KONVOME[®]P: benzyl alcohol, carboxymethylcellulose sodium, FD&C Red No. 40, poloxamer 188, purified water, simethicone emulsion, sodium citrate (dihydrate), sorbitol solution, strawberry flavor (natural and artificial flavors, propylene glycol and glycerin) and sucralose.

Manufactured for:

Azurity Pharmaceuticals, Inc.

Woburn, MA 01801 USA

For more information, go to www.azurity.com or call 1-800-461-7449.