IMPORTANT SAFETY INFORMATION

KONVOMEP® (omeprazole and sodium bicarbonate for oral suspension)

KONVOMEP is a combination of omeprazole, a proton pump inhibitor (PPI), and sodium bicarbonate, indicated in adults for:

- treatment of active benign gastric ulcer
- reduction of risk of upper gastrointestinal (GI) bleeding in critically ill patients

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

Shake the KONVOMEP solution well before each use. A calibrated measuring device is recommended to measure and deliver the prescribed dose accurately. A household teaspoon or tablespoon is not an adequate measuring device. Ask your pharmacist or doctor for assistance in the selection of a dosing device.

Additional Important Safety Information

Do not take KONVOMEP if you are:

- allergic to omeprazole, any other PPI medicine, or any of the ingredients in KONVOMEP.
- taking a medicine that contains rilpivirine, used to treat HIV-1 (Human Immunodeficiency Virus).

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

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

What are the possible side effects of KONVOMEP?

KONVOMEP can cause serious side effects, including:

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

KONVOMEP 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”. Tell your doctor if you are on a low-sodium diet or if you have Bartter's Syndrome (a rare kidney disorder). Talk to your doctor about any questions you may have. Too much sodium can cause swelling and weight gain. 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.

The total sodium content per 40 mg dose (volume of 20 mL) of KONVOMEP is 526 mg (22.8 mEq). Each mL of the KONVOMEP liquid suspension contains 84 mg of sodium bicarbonate (equivalent to 1 mEq/mL of sodium). The total content of sodium, from active and inactive ingredients per mL of KONVOMEP suspension is 26.3 mg (1.14 mEq).

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 KONVOMEP, 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.

Low vitamin B-12 levels in your body can happen in people who have taken KONVOMEP 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 KONVOMEP 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. KONVOMEP 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 KONVOMEP and call your doctor right away. These symptoms may be the first sign of a severe skin reaction.

Before taking KONVOMEP, tell your doctor about all 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 KONVOMEP will harm your unborn baby.
- Are breastfeeding or plan to breastfeed. KONVOMEP can pass into your breast milk. Talk with your doctor about the best way to feed your baby if you take KONVOMEP.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medications, vitamins, and herbal supplements. KONVOMEP and other medications may affect each other, causing side effects. Especially tell your doctor if you take:

- Digoxin
- Clopidogrel
- St. John's wort (Hypericum perforatum)
- Rifampin
- Methotrexate

How should I take KONVOMEP?

- Take KONVOMEP exactly as prescribed by your doctor.
- KONVOMEP is mixed (reconstituted) by a healthcare provider and you will receive KONVOMEP as an oral suspension that can be taken by mouth or given through a nasogastric or orogastric tube.
- Shake the KONVOMEP oral suspension well before each use.
- Measure the KONVOMEP 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.
- **Do not** change your dose or stop taking KONVOMEP without talking to your doctor.
- If you miss a dose of KONVOMEP, 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 KONVOMEP, call your doctor or Poison Control Center at 1-800-222-1222 right away, or go to the nearest hospital emergency room.

Store KONVOMEP oral solution in the refrigerator, protect from light, and discard unused portions after 30 days.

The most common side effects of KONVOMEP include:

- Headache
- Abdominal Pain

- Nausea
- Diarrhea
- Vomiting
- Gas

These are not all the possible side effects of KONVOMEP. Call your doctor for medical advice about side effects.

The Important Safety Information does not include all the information needed to use KONVOMEP safely and effectively. Please see accompanying full Prescribing Information for KONVOMEP.

To report SUSPECTED ADVERSE REACTIONS, contact Azurity Pharmaceuticals, Inc. at 1-800-461-7449, or FDA at 1-800-FDA-1088 or www.fda.gov/MedWatch.

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