PATIENT INFORMATION
VOQUEZNA® (voe kwez nah)
(vonoprazan)
tablets, for oral use

What is VOQUEZNA?
VOQUEZNA is a prescription medicine called a potassium-competitive acid blocker. VOQUEZNA reduces the amount of acid in your stomach.

VOQUEZNA is used in adults:

- for 8 weeks to heal acid-related damage to the lining of the esophagus (called erosive esophagitis) and for relief of heartburn related to erosive esophagitis.
- for up to 6 months to maintain healing of erosive esophagitis and for relief of heartburn related to erosive esophagitis.
- for 4 weeks for relief of heartburn related to gastroesophageal reflux disease.
- for 14 days with the antibiotics amoxicillin and clarithromycin to treat an infection caused by bacteria called *Helicobacter pylori (H. pylori)*.
- for 14 days with the antibiotic amoxicillin to treat an infection caused by bacteria called *H. pylori*.

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

Do not take VOQUEZNA if you are:

- allergic to vonoprazan or any of the ingredients in VOQUEZNA. See the end of this Patient Information leaflet for a complete list of ingredients in VOQUEZNA. Allergic reaction symptoms may include trouble breathing, rash, itching, and swelling of your face, lips, tongue, or throat.
- taking a medicine that contains rilpivirine (EDURANT, JULUCA, ODEFSEY, COMPLERA) used to treat HIV-1 (Human Immunodeficiency Virus).

Before taking VOQUEZNA, tell your healthcare provider about all of your medical conditions, including if you:

- have low magnesium, calcium, or potassium in your blood or you are taking a medicine to increase urine (diuretic).
- have kidney problems.
- have liver problems.
- are pregnant, think you may be pregnant, or plan to become pregnant. It is not known if VOQUEZNA will harm your unborn baby.
    - **Pregnancy Exposure Registry:** There is a pregnancy registry for women who take VOQUEZNA during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. If you are pregnant or become pregnant during treatment with VOQUEZNA, talk to your healthcare provider about how you can join this pregnancy registry or you can enroll in the registry by calling 1-866-609-1612 or visiting https://voqueznapregnancyregistry.com/.
- are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you will take VOQUEZNA while breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine. VOQUEZNA may affect how other medicines work, and other medicines may affect how VOQUEZNA works.

How should I take VOQUEZNA?

- Take VOQUEZNA exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop taking VOQUEZNA without talking to your healthcare provider first.
- Take VOQUEZNA with or without food.
- Swallow VOQUEZNA tablets whole. Do not chew or crush the tablet.
- For the treatment of erosive esophagitis or the relief of heartburn related to gastroesophageal reflux disease:
    - If you miss a dose of VOQUEZNA, take it as soon as possible within 12 hours after the missed dose. If more than 12 hours have passed, skip the missed dose and take the next dose at the regularly scheduled time.
- For the treatment of *H. pylori* infection:

- If you miss a dose of VOQUEZNA, take it as soon as possible within 4 hours after the missed dose. If more than 4 hours have passed, skip the missed dose and take the next dose at the regularly scheduled time. Continue your regular dosing schedule until the treatment is completed.

What are the possible side effects of VOQUEZNA?

VOQUEZNA may cause serious side effects, including:

- **A type of kidney problem (acute tubulointerstitial nephritis).** Some people who take VOQUEZNA may develop a kidney problem called acute tubulointerstitial nephritis. Call your healthcare provider right away if you have a decrease in the amount that you urinate or if you have blood in your urine.
- **Diarrhea caused by an infection (*Clostridioides difficile*) in your intestines.** Call your healthcare provider right away if you have watery stools, stomach pain, or fever that does not go away.
- **Bone fractures (hip, wrist, or spine).** Bone fractures in the hip, wrist, or spine may happen in people who take multiple daily doses of another type of medicine that reduces acid in your stomach known as proton pump inhibitors (PPI medicines) for a long period of time (a year or longer). Tell your healthcare provider if you have a bone fracture, especially in the hip, wrist, or spine.
- **Severe skin reactions.** VOQUEZNA 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, genital, hands, or feet).
  - You may also have fever, chills, body aches, shortness of breath, or enlarged lymph nodes.

  If you have any of these symptoms, stop taking VOQUEZNA and call your healthcare provider right away. These symptoms may be the first sign of a severe skin reaction.
- **Low Vitamin B-12 levels.** VOQUEZNA lowers the amount of acid in your stomach. Stomach acid is needed to absorb Vitamin B12 properly. Tell your healthcare provider if you have symptoms of low vitamin B12 levels, including irregular heartbeat, shortness of breath, lightheadedness, tingling or numbness in the arms and legs, muscle weakness, pale skin, feeling tired, or mood changes. Talk with your healthcare provider about the risk of low Vitamin B12 levels if you have been on VOQUEZNA for a long time.
- **Low magnesium levels in the body** can happen in people who take VOQUEZNA. Tell your healthcare provider right away if you have symptoms of low magnesium levels, including seizures, dizziness, irregular heartbeat, jitteriness, muscle aches or weakness, or spasms of the hands, feet, or voice.
- **Stomach growths (fundic gland polyps).** A certain type of stomach growth called fundic gland polyps may happen in people who take VOQUEZNA for a long time (more than a year). Talk with your healthcare provider about the risk of fundic gland polyps if you have been on VOQUEZNA for a long time.

The most common side effects of VOQUEZNA for treatment of erosive esophagitis or relief of heartburn related to gastroesophageal reflux disease include:

- stomach inflammation
- diarrhea
- stomach bloating
- stomach pain
- nausea
- indigestion
- constipation
- high blood pressure
- urinary tract infection

The most common side effects of VOQUEZNA when used with antibiotics for treatment of *H. pylori* infection include:

- diarrhea
- temporary changes in sense of taste
- vaginal yeast infection
- stomach pain
- headache
- high blood pressure
- cold-like symptoms

These are not all the possible side effects of VOQUEZNA.

For more information, ask your healthcare provider 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 VOQUEZNA?

- Store VOQUEZNA at room temperature between 68°F to 77°F (20°C to 25°C).

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

General information about the safe and effective use of VOQUEZNA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use VOQUEZNA for a condition for which it was not prescribed. Do not give VOQUEZNA to other people, even if they have the same symptoms you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about VOQUEZNA that is written for health professionals.

What are the ingredients of VOQUEZNA?
Active ingredient: vonoprazan
Inactive ingredients: ascorbic acid, croscarmellose sodium, ferric oxide red (only in 20 mg tablets), ferric oxide yellow (only in 10 mg tablets), fumaric acid, hydroxypropyl cellulose, hypromellose, magnesium stearate, mannitol, microcrystalline cellulose, polyethylene glycol 8000, and titanium dioxide.

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