

About VOQUEZNA® (vonoprazan) tablets for Erosive GERD*



VOQUEZNA® for the healing and maintenance of healing of all grades of Erosive GERD, and associated heartburn symptom relief

VOQUEZNA (vonoprazan) is indicated for use in adults with Erosive Esophagitis, also referred to as Erosive GERD or Erosive Acid Reflux, a form of gastroesophageal reflux disease (GERD) characterized by erosions in the mucosa caused by acidic reflux of stomach contents into the esophagus. VOQUEZNA has been shown to:

- ▶ help heal Erosive GERD erosions and relieve associated heartburn and
- ▶ maintain healing of Erosive GERD and relieve associated heartburn

It is also the first and only potassium-competitive acid blocker (PCAB) approved in the United States by the FDA.

*GERD (gastroesophageal reflux disease)

VOQUEZNA is a novel first-in-class potassium-competitive acid blocker (PCAB)

VOQUEZNA (vonoprazan) is a PCAB – a first-in-class acid suppressant that works quickly to suppress gastric acid secretion by competitively inhibiting the binding of potassium ions to the proton pump. PCABs work differently from other medications that block gastric acid secretion.

VOQUEZNA has demonstrated **rapid**, **potent**, and **durable** acid suppression in a phase 1, open-label, crossover study with 44 healthy volunteers¹



RAPID

Increased pH within 2-3 hours, reaching pH >4 within 4 hours



POTENT

Achieved strong acid suppression on Day 1, with a mean pH of 4.6



DURABLE

Maintained continuous acid suppression over 24 hours after dosing

Notable attributes of VOQUEZNA:

- ▶ Has a long half-life (7.9 hours)
- ▶ Can be taken with or without food (acid not required for activation)
- ▶ Binds to the pumps in a reversible manner (noncovalent and reversible interaction with active proton pumps)

¹Laine L, Sharma P, Mulford DJ, Hunt B, Leifke E, Smith N, Howden CW. Pharmacodynamics and Pharmacokinetics of the Potassium-Competitive Acid Blocker Vonoprazan and the Proton Pump Inhibitor Lansoprazole in US Subjects. Am J Gastroenterol. 2022 Jul 1;117(7):1158-1161. doi: 10.14309/ajg.0000000000001735. Epub 2022 Mar 16. PMID: 35294415.

Important Information about VOQUEZNA

What is the most important information you need to know about VOQUEZNA?

Do not take VOQUEZNA if you:

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

▶ Please [click here](#) for Prescribing Information.

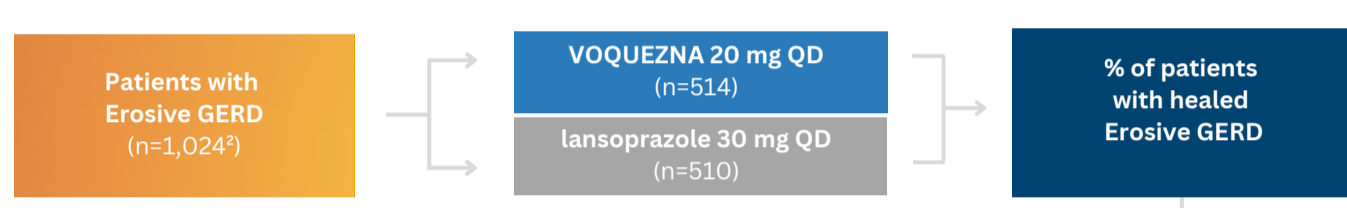
▶ Please see additional Important Safety Information below.

Approval of VOQUEZNA was based on a large, multi-national Phase 3 trial

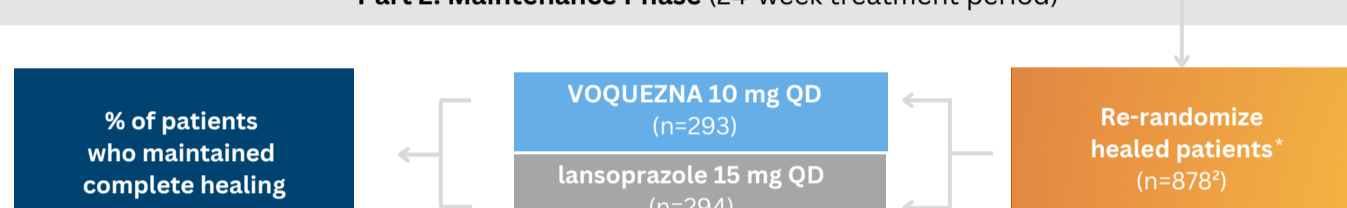
VOQUEZNA was studied in 1,024 patients with Erosive GERD in the U.S. and Europe.

The effectiveness and safety of VOQUEZNA was evaluated in a randomized, active-controlled, double-blind study conducted in the United States and Europe in patients with endoscopically confirmed Erosive GERD.

Part 1: Healing Phase (2- to 8-week treatment period)



Part 2: Maintenance Phase (24-week treatment period)



* A higher dose VOQUEZNA treatment group not shown although this group is included in the total number of randomized patients.
² Represents modified intent to treat (mITT) population

Erosive GERD Healing, Maintenance of Healing, and Heartburn Relief with VOQUEZNA

VOQUEZNA demonstrated healing rates that are strong and sustained. In a recent clinical study, most adults who took VOQUEZNA were able to achieve Erosive GERD healing by 2 months and maintain healing for 6 months:

Healing Phase

93%

9 out of 10 achieved Erosive GERD healing by 2 months (Primary Endpoint)³

93% of adults taking VOQUEZNA 20 mg for Erosive Acid Reflux experienced healing by 2 months compared to 85% taking another treatment.³

74%

Most adults experienced healing in as early as 2 weeks

74% of patients taking VOQUEZNA 20 mg achieved healing by 2 weeks as compared to 68% of patients taking another treatment.⁴

⁴ This endpoint was not statistically significant and should not be interpreted as providing evidence of superiority.

³ Noninferiority

Maintenance Phase

Some adults were healed by VOQUEZNA or another treatment⁴ during the healing phase then took VOQUEZNA 10 mg once daily for up to 6 months during the maintenance phase.

~8 out of 10 patients taking VOQUEZNA maintained Erosive GERD healing for 6 months (Primary Endpoint)³

79% of those stayed healed for 6 months on VOQUEZNA 10 mg maintenance treatment compared to 72% taking another treatment.⁴

24h

24-hour heartburn-free relief on most days (Secondary Endpoint)³

Over 6 months, 81% of days spent on VOQUEZNA 10 mg were heartburn free for 24 hours compared to 79% of days on another treatment.⁴

³ Noninferiority
⁴ Lansoprazole

Safety Profile of VOQUEZNA

VOQUEZNA was evaluated in clinical trials of adults with confirmed Erosive GERD and demonstrated a safety profile comparable to lansoprazole (PREVACID®).

Healing Phase (up to 2 months)

Most common side effects: (reported in at least 2% of patients in the VOQUEZNA arm)	VOQUEZNA 20 mg once daily 514 adults	Lansoprazole (Prevacid) 30 mg once daily 510 adults
Gastritis ^b	3%	2%
Diarrhea ^b	2%	3%
Abdominal distention	2%	1%
Abdominal pain ^b	2%	1%
Nausea	2%	1%

6-Month Maintenance Phase

Most common side effects: (reported in at least 3% of patients in the VOQUEZNA arm)	VOQUEZNA 10 mg once daily 296 adults	Lansoprazole (Prevacid) 15 mg once daily 297 adults
Gastritis ^b	6%	3%
Abdominal pain ^b	4%	2%
Dyspepsia	4%	3%
Hypertension ^b	3%	2%
Urinary tract infection	3%	2%

^b Represents grouped term and includes related terms

The trial was not designed to support comparative claims for VOQUEZNA for the adverse reactions reported in this table.

INDICATION AND IMPORTANT SAFETY INFORMATION

What is VOQUEZNA?

- VOQUEZNA® (vonoprazan) is a prescription medicine used in adults:
 - for 8 weeks to heal acid-related damage to the lining of the esophagus (called Erosive Esophagitis or Erosive Acid Reflux) and for relief of heartburn related to Erosive Acid Reflux.
 - for up to 6 months to maintain healing of Erosive Acid Reflux and for relief of heartburn related to Erosive Acid Reflux.

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 other ingredients in VOQUEZNA. Allergic reaction symptoms may include trouble breathing, rash, itching and swelling of your face, lips, tongue or throat.
- are taking a medicine that contains rilpivirine (EDURANT, COMPLERA, JULUCA, ODEFSEY, CABENUVA) used to treat HIV-1 (Human Immunodeficiency Virus).

Before taking VOQUEZNA, tell your healthcare provider about all 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 or 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.
- are breastfeeding or plan to breastfeed. It is not known if VOQUEZNA passes into your breast milk. You and your healthcare provider should decide if you will take VOQUEZNA or breastfeed. You should not do both.

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. Especially tell your healthcare provider if you take medicine that contains rilpivirine (EDURANT, COMPLERA, JULUCA, ODEFSEY, CABENUVA).

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 notice 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, and 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 inhibitors (PPI) 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.
 - You may also have fever, chills, body aches, shortness of breath, or enlarged lymph nodes.If you experience 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 or 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 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 another type of medicine that reduces acid in your stomach known as proton pump inhibitors (PPI medicines) for a long time. Talk with your healthcare provider about the possibility 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 Acid Reflux include:

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

These are not all the possible side effects of VOQUEZNA. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects.

You are encouraged to report suspected adverse reactions by contacting Phathom Pharmaceuticals at 1-888-775-PHAT (7428) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please [click here](#) to see Patient Information and [click here](#) for full Prescribing Information for VOQUEZNA.