VOPRAZAN®

Vonoprazan 10 mg

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Dosage Form & Strengths

VOPRAZAN® tablets are supplied in 10 mg and 20 mg strengths.

Mechanism of Action

A potassium-competitive acid blocker suppresses basal and stimulated gastric acid secretion at the secretory surface of the gastric parietal cell through inhibition of the H+, K+-ATPase enzyme system in a potassium competitive manner.

Indications

Gastroesophageal reflux disease, erosive or nonerosive:

- Treatment of erosive esophagitis
- Maintenance of healing of erosive esophagitis
- Symptomatic gastroesophageal reflux disease: Relief of heartburn associated with erosive or nonerosive gastroesophageal reflux disease in adults.

Helicobacter pylori eradication:

- As part of a multidrug regimen for H. pylori eradication in adults.

Dosing

Gastroesophageal reflux disease, erosive or nonerosive

Erosive esophagitis

Treatment: Oral: 20 mg once daily for 8 weeks.

Maintenance of healing: Oral: 10 mg once daily for up to 6 months.

Nonerosive gastroesophageal reflux disease: Oral: 10 mg once daily for 4 weeks.

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Missed dose:

Administer missed dose as soon as possible within 12 hours of scheduled dose. If >12 hours have passed, skip the missed dose and resume dosing at regular scheduled time.

H. pylori eradication:

Oral: 20 mg twice daily (12 hours apart) as part of an appropriate combination regimen with antibiotics for 14 days.

Missed dose:

Administer missed dose as soon as possible within 4 hours of scheduled dose. If >4 hours have passed, skip the missed dose and resume dosing at regular scheduled time.

Kidney Impairment

H. pylori eradication

GFR ≥30 mL/minute: No dosage adjustment is needed.

GFR <30 mL/minute: Use is not recommended.

Maintenance of erosive esophagitis or nonerosive gastroesophageal reflux disease:

No dosage adjustment is needed.

Treatment of erosive esophagitis

GFR ≥30 mL/minute: No dosage adjustment is needed.

GFR <30 mL/minute: 10 mg once daily.

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Hepatic Impairment

H. pylori eradication

Child-Turcotte-Pugh class A: No dosage adjustment is needed.

Child-Turcotte-Pugh class B and C: Use is not recommended.

Maintenance of erosive esophagitis or nonerosive gastroesophageal reflux disease

No dosage adjustment is needed.

Treatment of erosive esophagitis

Child-Turcotte-Pugh class A: No dosage adjustment is needed.

Child-Turcotte-Pugh class B and C: 10 mg once daily.

Administration

Oral: May **administer without regard to food**. Swallow tablets whole; do not chew or crush.

Adverse Reactions

1-10%:

- **Cardiovascular:** Hypertension (3%), peripheral edema (≤1%), syncope (≤1%), tachycardia (≤1%)
- **Dermatologic:** Eczema (≤1%), skin rash (≤1%), urticaria (≤1%)
- **Endocrine & metabolic:** Diabetes mellitus (≤1%)
- **Gastrointestinal:** Abdominal distention (2%), abdominal pain (2% to 4%), constipation (2%), diarrhea (2%), dyspepsia (4%), dysphagia (≤1%), eructation (≤1%), flatulence (≤1%), gastric polyp (≤1%; including fundic gland polyp), gastritis (3% to 6%), intestinal polyps (duodenal: ≤1%), nausea (2%), vomiting (≤1%), xerostomia (≤1%)

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- **Genitourinary:** Urinary tract infection (2% to 3%)
- **Hematologic & oncologic:** Anemia (≤1%), lymphocytosis (≤1%)
- **Hepatic:** Increased liver enzymes (≤1%)
- **Nervous system:** Asthenia (≤1%), depression (≤1%), dizziness (≤1%), headache (≤1%), insomnia (≤1%), vertigo (≤1%)
- **Neuromuscular & skeletal:** Bone fracture (≤1%)
- **Renal:** Interstitial nephritis (≤1%; including acute interstitial nephritis)

Pregnancy consideration

Adverse events have been observed in animal reproduction studies.

Breastfeeding Consideration

It is not known if vonoprazan is present in breast milk.
Breastfeeding is not recommended by the manufacturer.

Contraindication

Hypersensitivity (eg, anaphylactic shock) to vonoprazan or any component of the formulation; concomitant use with rilpivirine-containing products.

Warnings/Precautions

- **Clostridioides difficile-associated infection:** Use of proton pump inhibitors (PPIs), as well as vonoprazan, may increase risk of Clostridioides difficile-associated infection (CDAD), especially in hospitalized patients; consider CDAD diagnosis in patients with persistent diarrhea that does not improve. Use shortest duration of therapy for the condition being treated.
- **Dermatologic reactions:** Severe cutaneous adverse reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported. Discontinue and evaluate patients if severe cutaneous reaction or other signs of hypersensitivity occur.

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- **Fractures:** Increased incidence of osteoporosis-related bone fractures of the hip, spine, or wrist may occur with PPI therapy, as well as vonoprazan. Patients on high-dose (multiple daily doses) or long-term therapy (≥1 year) should be monitored. Use the shortest duration of therapy, use vitamin D and calcium supplementation, and follow appropriate guidelines to reduce risk of fractures in patients at risk.

- **Fundic gland polyps:** Use of vonoprazan increases risk of fundic gland polyps, especially with long-term use (>1 year). May occur without symptoms. Use the shortest duration of therapy appropriate for the condition being treated.

- **Hypomagnesemia:** Hypomagnesemia has been reported in post-marketing studies. Hypomagnesemia may lead to or exacerbate hypocalcemia in patients at risk (eg, hypoparathyroidism). Hypomagnesemia may also lead to hypokalemia. Hypomagnesemia and hypocalcemia may be corrected by magnesium/calcium supplementation, although discontinuation of vonoprazan may be necessary.

- **Tubulointerstitial nephritis:** Acute tubulointerstitial nephritis has been reported. Discontinue and evaluate patients if acute tubulointerstitial nephritis is suspected.

- **Vitamin B12 deficiency:** Prolonged treatment (≥2 years) may lead to vitamin B12 malabsorption and subsequent vitamin B12 deficiency; evaluate patients if symptoms consistent with vitamin B12 deficiency develop.

- **Gastric malignancy:** Relief of symptoms does not preclude the presence of a gastric malignancy.

- **Laboratory test interference:** Serum chromogranin A (CgA) levels increase secondary to drug-induced decreases in gastric acid; may cause false-positive results in diagnostic investigations for neuroendocrine tumors. Temporarily interrupt vonoprazan treatment at least 14 days before CgA test; if CgA level is high, repeat test to confirm. Use same commercial laboratory for testing to prevent variable results.

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Monitoring Parameters

Magnesium (baseline and periodically thereafter; especially if taking concomitant digoxin, diuretics, or other drugs known to cause hypomagnesemia or with prolonged therapy)

calcium (baseline and periodically in patients at risk [eg, hypoparathyroidism]).

Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date.

Store VOPRAZAN® at room temperature below 30°C.

Reference:

Vonoprazan Drug Information- UpToDate [May 2025]

Orchid Pharmed

Sky's the Limit

Arvand Pharmed