

Vonoprazan

10 mg - 20 mg

Film-Coated Tablet

Keep this leaflet. You may need to read it again

For further information, please contact:

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Therapeutic Class:

Gastrointestinal agent

Potassium-competitive acid blocker (P-CAB) acting on gastric parietal cells (Proton Pump inhibitor)

Therapeutic Indication:

Vonoprazan is indicated in adults for:

- Gastric ulcer, duodenal ulcer, and erosive esophagitis due to gastroesophageal reflux
- Prevention of relapse of erosive esophagitis (maintenance therapy)
- Gastroesophageal reflux disease (GERD) (rapid relief of symptoms such as heartburn)
- the relief of heartburn associated with non-erosive gastroesophageal reflux disease
- Adjunctive therapy in eradication of *Helicobacter pylori* infection
- Prevention of gastric and duodenal ulcers associated with NSAIDs and low-dose aspirin
- Zollinger-Ellison syndrome

General Information for the patient:

This medicine has been prescribed specifically for the treatment of your current illness; therefore, Do not pass it on to others.

Talk to your physician or pharmacist if any of the following applies to you:

1. A history of allergy.
2. Pregnancy or breastfeeding.
3. Liver or kidney problems
4. Common side effects such as abdominal pain or changes in bowel habits (constipation or diarrhea) are usually mild. If they become severe or troublesome, consult your doctor.
5. Seek immediate medical attention if you experience:
 - Severe skin rash
 - Swelling of the face
 - Difficulty breathing
 - Vomiting blood

Contraindications:

Do not take vonoprazan under the following conditions, and talk to your physician or pharmacist

- hypersensitivity to vonoprazan or any of its components
- Concomitant use with certain antiviral drugs such as atazanavir or rilpivirine (reduced absorption and loss of efficacy of this drugs).
- Children and adolescents aged under 18 years because it has not been studied yet in this age group.

Pregnancy and Breastfeeding:

Pregnancy : There are no adequate and well-controlled studies of vonoprazan in pregnant women. Adverse events have been observed in animal reproduction studies .use of this medicine in pregnant woman is not recommended. consult your doctor if you are pregnant or planning to pregnancy.

Breast-feeding: Use of this medicine is not recommended because of the potential risk of adverse liver effects shown in animal studies . consult your doctor if you are breast feeding or planning to breastfeed.

Warnings:

Talk to your physician or pharmacist before taking vonoprazan if you have following conditions.

-presence of gastric malignancy: Before starting treatment, especially in elderly patients or those with alarm symptoms (unexplained weight loss, persistent vomiting, dysphagia, gastrointestinal bleeding), malignancy should be ruled out as this medicine may mask symptoms.

-H. pylori infection: this medicine Must be used as part of a complete eradication regimen with appropriate antibiotics.

-Severe skin reactions: Discontinue immediately and seek medical attention if severe rash or systemic symptoms (fever or eyes , mouth problems) occur.

-renal or hepatic impairment: Dose adjustment and monitoring may be required.

-acute tubulointerstitial nephritis: if you have a decrease in the amount of urine or blood in urine. call your doctor right away.

-Interactions with diagnostic tests for neuroendocrine tumors: CgA levels increase and may cause false positive results in diagnostic tests for neuroendocrine tumors. discontinue this medicine at least 14 days before assessing CgA levels.

And hyper response in gastrin secretion in response to secretin stimulation test falsely suggesting gasterinoma, stop this medicine at least 14 days before test .

-Risks of long-term Use of this medicine:

Long-term use of strong acid-suppressing agents may increase the risk of:

- Gastrointestinal infections (e.g., *Clostridioides difficile*)
- Bone fractures (hip, wrist, spine), especially with high doses or prolonged use (>1 year)
- Hypomagnesemia and mineral metabolism: (symptoms of hypomagnesemia, hypocalcemia, and hypokalemia should be reported to doctor. consider monitoring magnesium levels prior to initiation of this medicine and periodically in patients expected to be on prolonged treatment and in patients are taking drugs may have increased toxicity in the presence of hypomagnesemia (e.g., digoxin) or taking drugs that may cause hypomagnesemia (e.g., diuretics).
- consider monitoring magnesium and calcium levels in patients with a preexisting risk of hypocalcemia (e.g., hypoparathyroidism). Supplement with magnesium and/or calcium, as necessary.
- Vitamin B12 deficiency (rare)
- Fundic gland polyps (generally benign)

Precautions:

Do not take this medicine with other medications without a doctor's prescription.

-If you miss a dose, take it as soon as you remember on the same day. Do not double the dose to make up for a missed dose.

Drug Interactions:

Talk to your physician or pharmacist if you are taking any other medicines.

Drugs absorption dependent on gastric pH:

- Vonoprazan Reduced absorption of some of drugs (e.g., atazanavir, rilpivirine, nelfinavir itraconazole, ketoconazole, iron salts, erlotinib, dasatinib, nilotinib, mycophenolate mofetil).
- concomitant use of rilpivirine or atazanavir with vonoprazan is contraindicated.
- avoid concomitant use of nelfinavir with vonoprazan.
- Vonoprazan may increase absorption of some medicines (e.g., digoxin).

Vonoprazan is a CYP3A4 substrate and is a weak CYP3A4 inhibitor caution is recommended for following medicines:

-CYP3A4 substrates: The effects of some substrates such as midazolam may increase because vonoprazan is a weak CYP3A4 inhibitor. dosage reduction of substrate drugs (e.g., midazolam) may be needed.

-CYP3A4 inhibitors (e.g., clarithromycin, antivirals): These may increase vonoprazan levels.

-CYP3A4 Strong or moderate inducers (e.g., rifampin, efavirenz, anti seizures, St. John's wort): These may reduce vonoprazan effectiveness because it is a CYP3A4 substrate. Avoid concomitant use.

CYP2C19 substrates (e.g., clopidogrel, citalopram, cimetidine):

vonoprazan is a CYP2C19 inhibitor. it may reduce plasma concentration of the active metabolite of clopidogrel and may cause reduction in platelet inhibition. carefully monitor the efficacy of clopidogrel and consider alternative anti-platelet therapy. although No clinically significant interaction has been reported.

Vonoprazan may increase exposure of citalopram and cimetidine.

Methotrexate: Vonoprazan (especially at high doses) Possible increased plasma levels of this medicine.

Dosage and Administration:

Swallow tablets whole with a glass of water.

Do not crush or chew.

Can be taken with or without food.

Adults:

-Gastric ulcer: 20 mg once daily for up to 8 weeks

-Duodenal ulcer: 20 mg once daily for up to 6 weeks

-Healing of erosive esophagitis and relief of heartburn in gastroesophageal reflux disease (GERD): 20 mg once daily for 4 weeks (up to 8 weeks if needed)

-Maintenance therapy healed erosive esophagitis and relief of heartburn : 10 mg once daily for up to 6 months.

-Relief of heartburn associated with non-erosive esophagitis in GERD: 10 mg once daily for 4 weeks.

-NSAID or low dose aspirin -induced ulcer prevention: 10 mg once daily

-Zollinger-Ellison syndrome: individualized dosing

-H. pylori Eradication:

1-Triple therapy (14 days): Vonoprazan 20 mg and amoxicillin 1000 mg plus clarithromycin 500 mg, each given every 12 hours for 14 days

2-Dual therapy (14 days): Vonoprazan 20 mg twice daily plus amoxicillin 1000 mg three times daily for 14 days.

3-Alternative regimen (7 days): Vonoprazan 20 mg plus amoxicillin 1000 mg plus metronidazole 250 mg, each given every 12 hours for 7 days.

Special Populations:

Elderly: Dose adjustment is generally not required, but caution is advised.

Renal or hepatic impairment: Mild to moderate impairment usually requires no adjustment; severe impairment may require dose reduction.

Side Effects:

Like all medicines, this medicine can cause side effects, although not everybody gets them. if any of the side effects listed below become severe, tell your physician or pharmacist.

• Serious side effects:

-A type of kidney problem (acute tubulointerstitial nephritis) : call your doctor right away if you have a decrease in the amount of urine or if you have blood in your urine.

-Diarrhea caused by an infection (Clostridioides difficile) in the intestines : call your doctor 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 patients who take multiple daily doses medicine that reduces acid in stomach known as proton pump inhibitors (e.g., omeprazole, pantoprazole, vonoprazan ...) for a long period of time (a year or longer).

-Severe skin reactions (rare) :

-skin rash which may have blistering, peeling or bleeding on any part of skin (including lips, eyes, mouth, nose, genital, hands or feet) and fever, chills, body aches, shortness of breath, or enlarged lymph nodes. these symptoms may be the first sign of a severe skin reaction. if you have any of these symptoms, stop taking this medicine and call your doctor right away.

-Low vitamin B12 levels (rare): vonoprazan (for a long time use) lowers the amount of acid in stomach and decreases absorption of vitamin B12. tell your doctor 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.

-Low magnesium levels in the body: symptoms of low magnesium levels, including seizures, dizziness, irregular heartbeat, jitteriness, muscle aches or weakness, or spasms of hands, feet, or voice.

-Fundic gland polyps : Fundic gland polyps may happen (generally benign) in people who take this medicine for a long time (more than a year).

• **Common (>=1/100):** Constipation, diarrhea, nausea, abdominal pain or discomfort, indigestion, flatulence

• **Uncommon (>=1/1000 to <1/100):** Skin rash, headache, dizziness, taste disturbances, dry mouth, elevated liver enzymes, high blood pressure, urinary tract infection.

• **Rare/Serious:** Severe allergic reactions, blood disorders, severe skin reactions, hepatitis.

Overdose:

In case of accidental overdose, immediately seek medical attention or contact a healthcare provider.

Storage Instructions:

- Store the medicine at temperatures below 30°C, away from light and moisture.
- Keep the container tightly closed after use and store in original container.
- Keep this medicine out of the sight and reach of children.

Packaging and Available Strengths:

> **10 film-coated tablets:**

Each film-coated tablet contains 10mg vonoprazan. 30 tablets per bottle in a cardboard box with a leaflet.

> **20 mg film-coated tablets:**

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References:

1. Medscape

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