

Vonolend

Vonoprazan Fumarate INN



Composition

Vonolend 10 Tablet: Each film coated tablet contains Vonoprazan Fumarate INN equivalent to Vonoprazan 10 mg.

Vonolend 20 Tablet: Each film coated tablet contains Vonoprazan Fumarate INN equivalent to Vonoprazan 20 mg.

Description

Vonolend (Vonoprazan) 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. Because this enzyme is regarded as the acid (proton) pump within the parietal cell, Vonolend (Vonoprazan) has been characterized as a type of gastric proton-pump inhibitor, in that it blocks the final step of acid production. Vonolend (Vonoprazan) does not require activation by acid. Vonolend (Vonoprazan) may selectively concentrate in the parietal cells in both the resting and stimulated states. Vonolend (Vonoprazan) binds to the active proton pumps in a noncovalent and reversible manner.

Indication

Gastric ulcer, duodenal ulcer, reflux esophagitis, prevention of recurrence of gastric or duodenal ulcer during low-dose aspirin administration, prevention of recurrence of gastric or duodenal ulcer during non-steroidal anti-inflammatory drug (NSAID) administration.

Adjunct to *Helicobacter pylori* eradication in the following settings: Gastric ulcer, duodenal ulcer, gastric mucosa-associated lymphatic tissue (MALT) lymphoma, idiopathic thrombocytopenic purpura, the stomach after endoscopic resection of early-stage gastric cancer, or *Helicobacter pylori* gastritis.

Dosage & Administration

Gastric ulcer, duodenal ulcer: The usual adult dosage is 20 mg of Vonolend orally once daily a 8-week treatment for gastric ulcer and a 6-week treatment for duodenal ulcer.

Reflux esophagitis: The usual adult dose for oral use is 20 mg of Vonolend administered once daily for a total of 4 weeks of treatment. If that dosing proves insufficient, the administration should be extended, but for no longer than 8 weeks of treatment. For the maintenance therapy of reflux esophagitis showing recurrence and recrudescence, the dose for oral use is 10 mg once daily. When the efficacy is inadequate, the dosage may be increase up to 20 mg once daily. Prevention of recurrence of gastric or duodenal ulcer during non-steroidal anti-inflammatory drug (NSAID) administration, the usual adult dosage is one tablet of 10 mg of Vonolend administered orally once daily.

Helicobacter pylori: Adjunct to *Helicobacter pylori* eradication for adults, the following three-drug regimen should be administered orally at the same time twice daily for seven days: 20 mg dose of Vonoprazan, 750 mg (potency) dose of amoxicillin hydrate, and 200 mg (potency) dose of clarithromycin. The dose of clarithromycin may be increased as clinically warranted. However, dosage should not exceed 400 mg (potency)/dose of clarithromycin twice daily.

Contraindications

Known hypersensitivity to Vonoprazan, or any component of Vonoprazan.

Precautions

Hypersensitivity Reactions: Serious and occasionally fatal reactions (e.g., anaphylaxis) have been reported with components of Vonoprazan. If hypersensitivity reactions occur, discontinue Vonoprazan and institute immediate therapy (e.g., anaphylaxis management).

Severe Cutaneous Adverse Reactions (SCAR): Discontinue Vonoprazan at the first signs or symptoms of SCAR or other signs of hypersensitivity and consider further evaluation.

Adverse Reactions

Vonoprazan: Most common adverse reactions (≥ 2%) were diarrhea, abdominal pain, vulvovaginal candidiasis and nasopharyngitis.

Use in Specific Population

- Lactation: Breastfeeding not recommended during treatment, but a lactating woman can pump and discard breast milk during treatment and for 2 days after Vonolend administration.
- Renal Impairment: Avoid use in severe renal impairment.
- Hepatic Impairment: Avoid use in moderate and severe hepatic impairment.

Drug Interaction

Components of Vonolend has the potential for clinically important drug interactions. Clarithromycin, Digoxin, Methylidigoxin, Itraconazole, Tyrosine kinase inhibitors, Gefitinib, Nilotinib & Erlotinib.

Storage

Do not store above 25°C. Protect from light. Keep out of the reach of children.

Packaging

Vonolend 10 Tablet: Each box contains 3x10's tablets in blister pack.

Vonolend 20 Tablet: Each box contains 3x10's tablets in blister pack.

Manufactured by



Ziska Pharmaceuticals Ltd.
Kaliakoir, Gazipur, Bangladesh

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