

Vonolend Kit

Vonoprazan Fumarate INN, Clarithromycin USP
& Amoxicillin Trihydrate BP



Composition

Vonolend Kit: Each kit contains **2 Vonoprazan 20 mg Tablets** (Each film coated tablet contains Vonoprazan Fumarate INN equivalent to Vonoprazan 20 mg), **2 Clarithromycin 500 mg Tablets** (Each film coated tablet contains Clarithromycin USP 500 mg) & **4 Amoxicillin 500 mg Capsules** (Each capsule contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 500 mg).

Description

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, Vonoprazan has been characterized as a type of gastric proton-pump inhibitor, in that it blocks the final step of acid production. Vonoprazan does not require activation by acid. Vonoprazan may selectively concentrate in the parietal cells in both the resting and stimulated states. Vonoprazan binds to the active proton pumps in a noncovalent and reversible manner. Amoxicillin is a penicillin antimicrobial drug. Clarithromycin is a macrolide antimicrobial drug. Acid suppression enhances the replication of *H. pylori* bacteria and the stability and effectiveness of antimicrobials in the treatment of *H. pylori* infection.

Indication

Vonoprazan Triple therapy should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Dosage & Administration

Vonolend Kit: The recommended dosage regimen is Vonoprazan 20 mg plus Amoxicillin 1,000 mg plus Clarithromycin 500 mg, each given twice daily (morning and evening, 12 hours apart), with or without food, for 14 days.

Contraindications

Known hypersensitivity to Vonoprazan, Amoxicillin or any other betalactams, clarithromycin or any other macrolide antimicrobial or any component of this kit.

- Pimozide.
- Lomitapide, lovastatin, and simvastatin.
- Ergot alkaloids (ergotamine or dihydroergotamine).
- Colchicine in renal or hepatic impairment.
- History of cholestatic jaundice/hepatic dysfunction with use of Clarithromycin.
- Rilpivirine-containing products.

Precautions

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

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

QT Prolongation: Avoid this kit in patients with known QT prolongation or receiving drugs known to prolong the QT interval, ventricular arrhythmia (torsades de pointes), hypokalemia/hypomagnesemia, significant bradycardia, or taking Class IA or III antiarrhythmics.

Hepatotoxicity: Discontinue if signs and symptoms of hepatitis occur with this kit.

Serious adverse reactions due to concomitant use with other drugs: Serious adverse reactions can occur with this kit due to drug interactions of clarithromycin with colchicine, some lipid lowering agents, some calcium channel blockers, and other drugs.

Embryo-Fetal Toxicity: Based on the findings from animal studies and human observational studies in pregnant women treated with clarithromycin, this kit is not recommended for use in pregnant women except in clinical circumstances where no alternative therapy is appropriate.

Exacerbation of myasthenia gravis can occur with this kit since it has been reported in patients receiving clarithromycin tablets if suspected and promptly seek medical advice.

Adverse Reactions

Most common adverse reactions of this kit ($\geq 2\%$) were dysgeusia, diarrhea, vulvovaginal candidiasis, headache, abdominal pain, and hypertension.

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 this kit administration.
- Geriatrics: This kit increased risk of torsades de pointes due to the clarithromycin component.
- Renal Impairment: Avoid use in severe renal impairment.
- Hepatic Impairment: Avoid use in moderate and severe hepatic impairment.

Drug Interaction

Components of this kit has the potential for important drug interactions. See full prescribing information for others drug interactions with this kit.

Storage

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

Packaging

Vonolend Kit: Each box contains 7x8's kit. Each kit contains 2 Vonoprazan tablets, 2 Clarithromycin tablets and 4 Amoxicillin capsules.

Manufactured by



Ziska Pharmaceuticals Ltd.
Kaliakoir, Gazipur, Bangladesh

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