

COMPOSITION

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

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

PHARMACOLOGY

Vonoprazan is a potassium-competitive acid blocker (PCAB). It inhibits H⁺, K⁺ -ATPase in a reversible and potassium-competitive manner. It does not require activation by acid. Due to the high affinity of Vonoprazan for the acid pump of gastric cells, it inhibits gastric acid production.

INDICATION

It is indicated for the treatment of gastric ulcer, duodenal ulcer, or reflux esophagitis; prevention of recurrent gastric or duodenal ulcer associated with low-dose aspirin administration; and prevention of recurrent gastric or duodenal ulcer associated with non-steroidal anti-inflammatory drug administration.

It is also indicated as an adjunct therapy to *Helicobacter pylori* eradication in the following: gastric or 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 AND ADMINISTRATION

Vonoprazan can be taken without regard to food or the timing of food.

Treatment of gastric ulcer and duodenal ulcer: The usual adult dosage is 20 mg, once daily. The usual treatment period should be up to 8 weeks for gastric ulcer and up to 6 weeks for duodenal ulcer.

Treatment of reflux esophagitis: The usual adult dosage is 20 mg, once daily. The usual treatment period should be up to 4 weeks, but it may be extended up to 8 weeks if a response to the initial course of the treatment is inadequate.

For the maintenance therapy to prevent recurrence or relapse of reflux esophagitis, the dosage is 10 mg, once daily. However, when response to the initial dose is inadequate, the dose may be increased to 20 mg once daily.

Prevention of recurrent gastric or duodenal ulcer associated with low-dose aspirin administration: The usual adult dosage is 10 mg, once daily.

Prevention of recurrent gastric or duodenal ulcer associated with non-steroidal anti-inflammatory drug administration: The usual adult dosage is 10 mg, once daily.

Adjunct therapy to *Helicobacter pylori* eradication: For adults, the following drug regimen of 20 mg Vonoprazan, 750 mg Amoxicillin, and 200 mg Clarithromycin should be administered orally at the same time twice daily for 7 days. The dose of clarithromycin may be increased as clinically warranted, but it should not exceed 400 mg twice daily.

In adult patients in whom *Helicobacter pylori* eradication with a 3-drug regimen comprising a proton pump inhibitor, Amoxicillin and Clarithromycin was unsuccessful, an alternative 3-drug regimen (20 mg Vonoprazan, 750 mg of Amoxicillin and 250 mg of Metronidazole) should be administered twice daily for 7 days.

If you miss a dose, take the missed dose as soon as possible. In such instances, let more than 8 hours pass before the next dose. You should never take two doses at one time.

CONTRAINDICATION

It is contraindicated in patients with hypersensitivity to Vonoprazan or to any excipient of it.

WARNING & PRECAUTION

- In the long-term treatment with Vonoprazan, close observation generally be made. In the maintenance of healing of reflux esophagitis, Vonoprazan should be administered only to the patients who repeat recurrence and recrudescence of the condition. When the healing is maintained over a long period and when there is no risk of recurrence, the dose reduction to a dose of 10mg from a dose 20mg should be considered.

- Discontinuation of Vonoprazan is recommended in patients who have evidence of liver function abnormalities or if they develop signs or symptoms suggestive of liver dysfunction.

- Gastric malignancy may present with symptoms associated with acid-related disorders which initially respond to drugs that elevate intragastric pH. A symptomatic response to Vonoprazan does not exclude the presence of gastric malignancy.

- If *Clostridium difficile*-associated diarrhea, including *Pseudomembranous colitis*, occurs appropriate measures, including discontinuation of the treatment, should be taken.

- An increased risk for osteoporosis-related fractures of the hip, wrist, or spine, predominantly in the elderly or in presence of other recognized risk factors, has been reported with use of high doses of PPI over a long-term period (>1 year).

- Vonoprazan should be administered with care in patients with renal or hepatic disorders due to an increase in the concentration of Vonoprazan in the blood.

SIDE EFFECT

Side effects with the use of Vonoprazan are diarrhea, constipation, hypersensitivity (including anaphylactic shock), urticaria, hepatotoxicity, jaundice, rash, nausea, abdominal distension, edema and eosinophilia.

USE IN PREGNANCY & LACTATION

Vonoprazan should not be used in pregnant women or women having the possibilities of being pregnant only if the expected therapeutic benefit is thought to outweigh any possible risk. It is advisable to avoid the administration of Vonoprazan to nursing mothers.

USE IN CHILDREN

Vonoprazan has not been studied in patients under 18 years of age.

DRUG INTERACTION

Administration of Vonoprazan results in the elevation of intragastric pH. Use of Vonoprazan is therefore not recommended with some of these drugs for which absorption is dependent on acidic intragastric pH such as atazanavir and nelfinavir, due to significant reduction in their bioavailability. Co-administration of midazolam (a sensitive CYP3A4 substrate) with multiple doses of Vonoprazan increased the concentration of midazolam. Caution is advised when Vonoprazan is co-administered with other sensitive CYP3A4 substrates, notably those having a narrow therapeutic index.

OVERDOSAGE

There is no experience of overdose with Vonoprazan. Vonoprazan is not removed from the blood circulation by hemodialysis. If overdose occurs, treatment should be symptomatic and supportive.

STORAGE

Do not store above 30°C. Keep away from light and out of the reach of children.

HOW SUPPLIED

Unigerd 10 Tablet: Each box contains 30 tablets in Alu-Alu blister pack.

Unigerd 20 Tablet: Each box contains 30 tablets in Alu-Alu blister pack.