

Composition:

Vono™ 10 mg Tablet: Each enteric coated tablet contains Vonoprazan Fumarate INN equivalent to Vonoprazan 10 mg.

Vono™ 20 mg Tablet: Each enteric coated tablet contains Vonoprazan Fumarate INN equivalent to Vonoprazan 20 mg.

Pharmacology:

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.

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

Dose and administration:

- Gastric ulcer, duodenal ulcer: The usual adult dosage for oral use is 20 mg of Vonoprazan administered orally once daily an 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 Vonoprazan 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. However, 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 low-dose aspirin administration: The usual adult dosage is one tablet of 10 mg of Vonoprazan administered orally 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 Vonoprazan administered orally once daily.
- 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 twice daily.

If Helicobacter pylori eradication with a three-drug regimen comprising a proton pump inhibitor, amoxicillin hydrate and clarithromycin has been unsuccessful, as an alternative treatment, adults should be administered the following three drugs orally twice daily for seven days: 20 mg dose of Vonoprazan, 750 mg (potency) dose of amoxicillin hydrate, and 250 mg dose of metronidazole.

Contraindication:

Vono™ is contraindicated in patients with known hypersensitivity to the active substance or to any of the excipients. Vono™ tablets should not be co-administered with Atazanavir & Rilpivirine.

Warning & Precaution:

- Vonoprazan should be administered to patients who continue receiving low-dose aspirin to prevent thrombogenesis/embolization. A medical history of gastric or duodenal ulcer should be checked before starting administration of vonoprazan.
- Vonoprazan should be administered to patients who continue receiving NSAID to control pain associated with rheumatoid arthritis, osteoarthritis, etc. A medical history of gastric or duodenal ulcer should be checked before starting administration of vonoprazan.
- For adjunct therapy to Helicobacter pylori eradication
 - The efficacy of Helicobacter pylori eradication in patients with advanced gastric MALT lymphoma has not been established.
 - For patients with idiopathic thrombocytopenic purpura, the Helicobacter pylori eradication should be performed only in patients who are considered eligible for the eradication therapy in light of the guideline, etc.
 - The efficacy of the Helicobacter pylori eradication for treatment of the stomach after endoscopic resection of early stage gastric cancer has been established, but not for other therapies for prevention of gastric cancer development.
 - Before vonoprazan is administered, the patients should be checked that they are Helicobacter pylori positive and endoscopically that they are affected by Helicobacter pylori gastritis.

Side effects:

The most common adverse reaction was constipation, diarrhoea, skin rash & nausea.

Use in Pregnancy & Lactation:

Available data from pharmacovigilance reports with vonoprazan use in pregnant women are not sufficient to evaluate for a drug-associated risk for major birth defects, miscarriage or other adverse maternal or fetal outcomes. There are no data regarding the presence of vonoprazan in human milk, the effects on the breastfed infant or the effects on milk production.

Use in Children and Adolescents:

Safety and effectiveness of Vonoprazan in pediatric patients have not been established.

Drug Interactions:

Effect of Digoxin, Methyl Digoxin may be enhanced when administered with Vonoprazan. Effect of Itraconazole, Tyrosine kinase inhibitors, Gefitinib, Nilotinib, Erlotinib may be diminished when administered with Vonoprazan.

Overdose:

There have been no reports of overdose with vonoprazan. In clinical studies, a single dose of 120 mg resulted in no serious adverse reactions. If overdose occurs, treatment should be symptomatic and supportive.

Storage:

Do not store above 30°C, protect from light & moisture.
Keep out of reach of children.

Packing:

Vono™ 10 mg Tablet: Each box contains 30 (3x10's) tablets in Alu-Alu blister pack.

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