

Vonotem[®]

Vonoprazan

COMPOSITION :

Vonotem[®] 20 Tablet: Each film coated tablet contains Vonoprazan Fumarate equivalent to Vonoprazan INN 20 mg.

PHARMACOLOGY :

Vonoprazan is a potassium competitive acid blocker (PCAB) and does not require activation by acid. It inhibits H⁺/ K⁺-ATPase in a reversible and potassium-competitive manner. Vonoprazan resides on the acid production site of gastric parietal cells for a long time, thereby inhibiting gastric acid production. Vonoprazan exerts a strong inhibitory effect on formation of mucosal damage in upper part of the gastrointestinal tract.

INDICATIONS :

Vonotem[®] (Vonoprazan) is indicated for :

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 and duodenal ulcer :

The usual adult dose for oral use is 20 mg of Vonoprazan once daily for 8-weeks to treat gastric ulcer and a 6-weeks to treat duodenal ulcer.

Reflux esophagitis :

The usual adult dose for oral use is 20 mg of Vonoprazan daily for a total of 4 weeks of treatment. If that dosing proves insufficient, the treatment should be continued up to 8 weeks.

For the maintenance therapy of reflux esophagitis showing recurrence and recrudescence, the dose for oral use is 10 mg of Vonotem[®](Vonoprazan) once daily. However, when the efficacy is inadequate, the dose may be increased up to 20 mg of Vonoprazan once daily.

Prevention of recurrence of gastric or duodenal ulcer during low-dose aspirin administration :

The usual adult dose for oral use is one tablet of 10 mg of Vonoprazan once daily.

Prevention of recurrence of gastric or duodenal ulcer during non-steroidal anti-inflammatory drug (NSAID) administration :

The usual adult dose for oral use is one tablet of 10 mg of Vonoprazan 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 of Vonoprazan, 750 mg of amoxicillin hydrate and 200 mg of clarithromycin. The dose of clarithromycin may be increased as clinically warranted. However, dosage should not exceed 400 mg 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 of Vonoprazan, 750 mg of amoxicillin hydrate and 250 mg of metronidazole.

CONTRA-INDICATION:

Vonoprazan is contraindicated in:

- Patients with hypersensitivity to Vonoprazan or to any excipient of the product.
- Patients receiving atazanavir sulphate, nelfinavir or rilpivirine hydrochloride.

WARNING & PRECAUTIONS :

For prevention of recurrent gastric or duodenal ulcer associated with low-dose aspirin administration:

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.

For prevention of recurrent gastric or duodenal ulcer associated with non-steroidal anti-inflammatory drug administration:

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.

SIDE EFFECTS :

Following side-effects have been reported with the use of Vonoprazan:

Diarrhea, Constipation, Drug Hypersensitivity (including anaphylactic shock), Urticaria, Hepatotoxicity, Jaundice, Rash, Nausea, Abdominal Distension, Edema and Eosinophilia.

USE IN PREGNANCY AND LACTATION :

Vonoprazan should be used in pregnant women or women having 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. However, when the administration is indispensable, nursing should be discontinued.

USE IN CHILDREN AND ADOLESCENTS :

Vonoprazan has not been studied in patients under 18 years of age. Since the physiological functions such as hepatic or renal function are decreased in elderly patients in general. Vonoprazan should be carefully administered.

DRUG INTERACTION :

Vonoprazan should be administered with care when co-administered with the following drugs : CYP3A4 Inhibitors, Clarithromycin, Digoxin, Methyldigoxin, Itraconazole, Tyrosine kinase inhibitors Gefitinib, Nilotinib and Erlotinib.

OVER DOSE :

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

STORAGE :

Store in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING :

Vonotem[®] 20 Tablet: Each box contains 3 X 10's tablets in Alu-Alu blister pack.



Manufactured by

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