



Vonoprazan Fumarate INN Film Coated Tablet

DESCRIPTION

Vini™ is a preparation of Vonoprazan. Vonoprazan is a potassium competitive acid blocker (P-CAB) and does not require activation by acid. It inhibits H⁺, K⁺-ATPase in a reversible and potassium competitive manner. Vonoprazan has a strong basicity and 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. Vonoprazan does not exhibit anti-*Helicobacter pylori* activity nor inhibitory activity against *Helicobacter pylori* urease.

INDICATIONS

- 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 AND ADMINISTRATION

Gastric ulcer and duodenal ulcer: The usual adult dosage for oral use is 20mg of Vonoprazan administered orally once daily an 8 weeks treatment for gastric ulcer and a 6 weeks treatment for duodenal ulcer.

Reflux esophagitis: The usual adult dose for oral use is 20mg 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 10mg of Vonoprazan once daily. However, when the efficacy is inadequate, the dosage may be increase up to 20mg of Vonoprazan once daily.

Prevention of recurrence of gastric or duodenal ulcer during low-dose aspirin administration: The usual adult dosage is one tablet of 10mg 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 10mg 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: 20mg of Vonoprazan, 750mg of amoxicillin hydrate and 200mg of clarithromycin. The dose of clarithromycin may be increased as clinically warranted. However, dosage should not exceed 400mg 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: 20mg of Vonoprazan, 750mg of amoxicillin hydrate and 250mg of metronidazole.

CONTRAINDICATIONS

- Patients with hypersensitivity to Vonoprazan or to any excipient of the product.
- Patients receiving Atazanavir sulphate, Nelfinavir or Rilpivirine hydrochloride.

SIDE EFFECTS

Diarrhea, constipation, drug hypersensitivity (including anaphylactic shock), drug eruption, urticaria, hepatotoxicity, jaundice, rash, nausea, abdominal distension, gamma-glutamyl transferase increased, AST increased, Liver function test abnormal, ALT increased, ALP increased, LDH increased, γ - GPT increased, edema and eosinophilia.

DRUG INTERACTION

Drugs	Signs	Mechanism & Risk Factors
CYP3A4 inhibitors Clarithromycin etc.	Blood conc. of Vonoprazan may increase.	It has been reported that blood conc. of Vonoprazan increased in concomitant use with clarithromycin.
Digoxin Methylidigoxin	Effect of these dugs may be enhanced	Gastric antisecretory effect of Vonoprazan may inhibit hydrolysis of digoxin, resulting in increase in the blood concentration of digoxin.

PRECAUTION AND WARNING

At the treatment, the course of the disease should closely be observed and the minimum therapeutic necessity should be used according to the disease condition. In the long-term, treatment with Vonoprazan, close observation by such means as endoscopy should 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. Administration to the patients who do not necessitate maintenance of healing should be avoided. 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, or suspension of administration should be considered.

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.

PHARMACEUTICAL PRECAUTION

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

PACKAGING

Vini™ 10 Tablet: Box containing 3 strips of 10 tablets each. Each film coated tablet contains Vonoprazan Fumarate INN equivalent to Vonoprazan 10mg.

Vini™ 20 Tablet: Box containing 3 strips of 10 tablets each. Each film coated tablet contains Vonoprazan Fumarate INN equivalent to Vonoprazan 20mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

TM TRADEMARK

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