Vonix

Tablet

Vonoprazan

COMPOSITION

Vonix 10: Each film-coated tablet contains Vonoprazan Fumarate INN equivalent to Vonoprazan 10 mg.
Vonix 20: Each film-coated tablet contains Vonoprazan Fumarate INN equivalent to Vonoprazan 20 mg.

PHARMACOLOGY

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.
Adjunctive effect on eradication of *Helicobacter pylori*:
The role of Vonoprazan in the *Helicobacter pylori* eradication is considered to increase intragastric pH leading to the enhancement of antibacterial activity of Amoxicillin Hydrate, Clarithromycin and Metronidazole which are concomitantly administered.

INDICATION

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

Route of Administration: Oral.

• ***Gastric ulcer and 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.
• ***For the maintenance therapy of reflux esophagitis showing recurrence and recrudescence:*** The dose for oral use is 10 mg of Vonoprazan once daily. However, when the efficacy is inadequate, the dosage may be increase up to 20 mg of 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 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.

Or as directed by the registerd physician.

CONTRAINDICATION

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 & PRECAUTION

General: 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 10 mg from a dose 20 mg, or suspension of administration should be considered.

Impaired Renal Function: Vonoprazan should be administered with care in patients with renal disorders as a delay in the excretion of Vonoprazan may occur, which may result in an increase in the concentration of Vonoprazan in the blood.
Impaired Hepatic Function: Vonoprazan should be administered with care in patients with hepatic disorders as a delay in the metabolism and excretion of Vonoprazan may occur, which may result in an increase in the concentration of Vonoprazan in the blood. Hepatic function abnormalities including liver injury have been reported. 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.
Elevation of intragastric pH: Administration of Vonoprazan results in elevation of intragastric pH and is therefore not recommended to be taken with drugs for which absorption is dependent on acidic intragastric pH. Symptomatic response to Vonoprazan does not preclude the presence of gastric malignancy. It is therefore, necessary to ascertain the ulcer is not of a malignant nature before initiating the administration of this drug.
***Clostridium difficile*, serious colitis, including pseudomembranous colitis:** There is an increased risk of gastrointestinal infection caused by *Clostridium difficile*. Serious colitis accompanied with bloody stools, such as pseudomembranous colitis, may occur due to Amoxicillin hydrate or Clarithromycin being used for *Helicobacter pylori* eradication, in combination with Vonoprazan. If abdominal pain and frequent diarrhea occur, appropriate measures, such as immediate discontinuation of the treatment, should be taken.
Benign gastric polyps: Benign gastric polyp has been observed in patient on long-term administration of PPIs.
Fractures: An increased risk for osteoporosis-related fractures of the hip, wrist or spine have been reported in patients under treatment with proton pump inhibitors. The risk of fracture was especially increased in the patients receiving high dose or long term (a year or longer) treatment.
Hypomagnesemia: Severe hypomagnesemia has been reported in patients on prolonged treatment with PPIs for at least three months and in most cases for a year.

SIDE EFFECTS

Common Side Effects: Constipation, diarrhea, nausea, rash.
Rare Side Effects: Hypersensitivity (including anaphylactic shock), hepatic function abnormalities, feeling of abdominal discomfort, feeling of enlarged abdomen, taste abnormality, stomatitis, increased AST (GOT), ALT (GPT), AL-P, LDH, or γ-GPT, edema or eosinophilia.

Note: If hypersensitivity occurs, Vonoprazan should be discontinued. In case of increased AST (GOT), ALT (GPT), AL-P, LDH, or γ-GPT; close observation should be made and if any abnormality is observed, such appropriate measures as discontinuation of Vonoprazan should be taken.

USE IN PREGNANCY & LACTATION

No clinical studies have been conducted to date to evaluate Vonoprazan in subjects who are pregnant or lactating. 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. 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.

GERIATRIC USE

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: Atazanavir sulfate, Rilpivirine hydrochloride, CYP3A4 inhibitors, Clarithromycin, Digoxin, Methyldigoxin, Itraconazole, Tyrosine kinase inhibitors, Gefitinib, Nilotinib, Erlotinib, Nelfinavir mesylate.

OVERDOSE

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 below 30° C temperature & in a dry place, protected from light.
Keep all medicines out of reach of children.

PACKING

Vonix 10: Each box contains 3x10 tablets in Alu-Alu blister strips.
Vonix 20: Each box contains 3x10 tablets in Alu-Alu blister strips.

***Further information is available on request**

Manufactured by:
The ACME Laboratories Ltd.
Dhulivita, Dhamrai, Dhaka, Bangladesh
For Health, Vigour and Happiness