Xevon

Vonoprazan Fumarate INN

Compositions:
Each film-coated tablet contains Vonoprazan Fumarate INN equivalent to 20 mg of Vonoprazan.

Pharmacology:
Vonoprazan is a potassium-competitive acid blocker (P-CAB) and does not require activation by acid. It inhibits H+, and K+-ATPase in a reversible and potassium-competitive manner. Vonoprazan has 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 the formation of mucosal damage in the upper part of the gastrointestinal tract.

Dosage And Administration:
Gastric and Duodenal Ulcer: The usual adult dosage for oral use is Xevon 20 administered orally once daily an 8-week treatment for gastric ulcer and a 6-week treatment for duodenal ulcer. Gastroesophageal Reflux Disease (GERD): The usual adult dosage for oral use is Xevon 20 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 GERD showing recurrence and recrudescence, the maximum dose for oral use is Xevon 20 once daily. Maintenance Therapy for Recurrence and Recrudescence of Reflux Esophagitis: Xevon 10 once daily. However, when the efficacy is inadequate, the dosage may be increased to Xevon 20 once daily. Prevention of Recurrence of Gastric or Duodenal Ulcer During Low-dose Aspirin or Non-steroidal Anti-inflammatory Drug (NSAID) Administration: The usual adult dosage is Xevon 10 once daily. Adjunct to Helicobacter pylori eradication: Dual Therapy: The recommended dosage regimen is Xevon 20 twice daily (morning and evening) plus Amoxicillin 1,000 mg, three times a day (morning, mid-day, and evening), with or without food, for 14 days. Triple Therapy: The recommended dosage regimen is Xevon 20 mg plus Amoxicillin 1,000 mg & Clarithromycin 500 mg, twice daily (morning and evening, 12 hours apart), with or without food, for 14 days.

Contraindications:
Vonoprazan is contraindicated in patients with hypersensitivity to Vonoprazan or any excipient of the product and Patients receiving Atazanavir Sulphate, Nelfinavir, or Rilpivirine Hydrochloride.

Warning And Precaution:
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.

Side Effects:
Following adverse reactions have been reported with the use of Vonoprazan: 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, y - GPT increased, edema and eosinophilia.

Use in Pregnancy and Lactation:
Pregnancy: Vonoprazan should be used in pregnant women or women having a possibility of being pregnant only if the expected therapeutic benefit is thought to outweigh any possible risk. Lactation: It is advisable to avoid the administration of Vonoprazan to nursing mothers. However, when the administration is indispensable, nursing should be discontinued.

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.

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

Storage:
Store at below 30°C in a dry place, protect from light. Keep out of reach of children.

Packing:
Xevon 20 Tablet: Each box contains 5x10 tablets in an Alu-Alu blister pack.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.