Voniza™

Vonoprazan

COMPOSITION

Voniza™ 10: Each film coated tablet contains Vonoprazan Fumarate INN equivalent to 10 mg of Vonoprazan.

Voniza™ 20: Each film coated tablet contains Vonoprazan Fumarate INN equivalent to 20 mg of Vonoprazan.

PHARMACOLOGY

Vonoprazan is a potassium competitive acid blocker (PCAB) and inhibits H+, K+-ATPase in a reversible and potassium-competitive manner. It does not require activation by acid. Vonoprazan is a strong base with a high affinity for the acid pump of gastric cells inhibiting gastric acid production. Vonaprazon blocks gastric H+, K+-ATPase by reversible and K+-competitive ionic binding and thus relieves symptoms of hyperacidity.

PHARMACOKINETICS

Pharmacokinetics at single administration: Following 7 day repeat once daily doses of vonoprazan at doses of 10-40 mg, in healthy adult male subjects, $AUC_{\tau,ss}$ and $C_{max,ss}$ increase in a slightly greater than dose proportional manner. Steady state has been reached by day 3 of administration, since the trough level of the blood concentration of vonoprazan is constant between day 3 and day 7 of administration.

INDICATIONS/USES

- Gastric ulcer (GU)
- Duodenal ulcer (DU)
- Reflux esophagitis (RE) and (erosive esophagitis EE)
- Maintenance treatment of reflux esophagitis (erosive esophagitis) in patients with repeat recurrence and relapse of the condition
- Prevention of recurrence of gastric ulcer or duodenal ulcer during NSAIDs administration

  Adjunct to *Helicobacter pylori* eradication associated with: Gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, the stomach after endoscopic resection of early stage cancer, or *Helicobacter pylori* gastritis

DOSAGE

Indication	Dose	Frequency
Gastric ulcer	20 mg	Once daily for 8 weeks
Duodenal ulcer	20 mg	Once daily for 6 weeks
Reflux esophagitis (erosive esophagitis):	20 mg	Once daily for 4 weeks
Prevention of recurrence of gastric ulcer or duodenal ulcer during NSAIDs administration	10 mg	Once a day

METHOD OF ADMINISTRATION

Vonoprazan can be taken without regard to food or timing of food.

SIDE EFFECTS

Diarrhoea, Nausea and Vomiting, Constipation, Abdominal Pain, Skin Rash.

OVERDOSAGE

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.

CONTRAINDICATIONS

Hypersensitivity to the active ingredients or to any of the excipients.

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.

USE IN PREGNANCY & LACTATION

Pregnancy: No clinical studies have been conducted to date to evaluate vonoprazan in subjects who are pregnant. In a rat toxicology study, embryo-fetal toxicity was observed following exposure of more than approximately 28 times of the exposure (AUC) at the maximum clinical dose (40 mg/day) of vonoprazan. As a precaution, vonoprazan should not be administered to women who are or may be pregnant, unless the expected therapeutic benefit is thought to outweigh any possible risk.

Lactation: No clinical studies have been conducted to date to evaluate vonoprazan in subjects who are lactating. It is unknown whether vonoprazan is excreted in human milk. In animal studies it has been shown that vonoprazan was excreted in milk. During treatment with vonoprazan, nursing should be avoided if the administration of this drug is necessary for the mother.

STORAGE

Store below 30° C., protect from light & moisture. Keep all medicine out of the reach of children.

HOW SUPPLIED

Voniza™ 10: Each box contains 30 tablets in a blister pack.

Voniza™ 20: Each box contains 30 tablets in a blister pack.

Manufactured by

SQUARE

PHARMACEUTICALS LTD.

BANGLADESH