

## DESIGN OF INSERT OF VONOFIX TABLET

# Vonofix

Vonoprazan INN

### COMPOSITION

**Vonofix 10 Tablet:** Each film coated tablet contains Vonoprazan Fumarate INN 13.36 mg equivalent to Vonoprazan 10 mg.

**Vonofix 20 Tablet:** Each film coated tablet contains Vonoprazan Fumarate INN 26.72 mg equivalent to Vonoprazan 20 mg.

### PHARMACOLOGY

Vonoprazan fumarate, is a Potassium-Competitive Acid Blocker (P-CAB). It suppresses basal and stimulated gastric acid secretion at the secretory surface of the gastric parietal cell through inhibition of the H<sup>+</sup>/K<sup>+</sup> ATPase enzyme system in a potassium competitive manner. It does not require activation by acid. Vonoprazan may selectively concentrate in the parietal cells in both the resting and stimulated states. It binds to the active proton pumps in a non-covalent and reversible manner.

### INDICATIONS

Vonoprazan is usually used to treat gastric/duodenal ulcer, reflux esophagitis and for suppression of recurrence of gastric ulcer & duodenal ulcer associated with low-dose aspirin or nonsteroidal anti-inflammatory drug, medication in combination with clarithromycin and amoxicillin for the eradication of *Helicobacter pylori*.

### DOSAGE AND ADMINISTRATION

Vonoprazan tablet is administered orally before or after food.

The recommended doses of Vonoprazan for general adults are as follows:

Indication	Recommended Dose	Dose Frequency
Gastric ulcer	20 mg	Once daily for up to 8 weeks
Duodenal ulcer	20 mg	Once daily for up to 6 weeks
Reflux esophagitis	20 mg	Once daily for up to 4 weeks. If the effect is insufficient, the treatment may be continued for up to 8 weeks
Maintenance therapy for repeatedly relapsing reflux esophagitis	10 mg	Once daily. If the effect is insufficient, the dosage may be increased to 20 mg once daily
Suppression of recurrence of gastric/duodenal ulcers associated with low-dose aspirin or non-steroidal anti-inflammatory drug therapy	10 mg	Once daily
In combination with clarithromycin and amoxicillin for the eradication of <i>Helicobacter pylori</i>	20 mg	Twice daily for 7 days

### CONTRAINDICATIONS

Vonoprazan is contraindicated in patients with hypersensitivity to Vonoprazan or to any excipient of the product. Also it is contraindicated in patients receiving atazanavir sulphate, nelfinavir or rilpivirine hydrochloride.

### WARNINGS AND PRECAUTIONS

Vonoprazan should be administered with care in patients with hepatic and renal 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.

### SIDE EFFECTS

Most commonly reported adverse reactions include constipation, diarrhea, enlarged feeling of abdomen, nausea, rash and edema.

### USE IN SPECIAL GROUP

**Use in Pregnancy & Lactation:** There are no adequate and well-controlled studies with Vonoprazan in pregnant women. Vonoprazan should be used during pregnancy only if clearly needed. It is not known whether Vonoprazan is excreted in human milk. During treatment with Vonoprazan, nursing should be avoided if the administration of this drug is necessary for the mother.

**Use in Children:** Vonoprazan has not been studied in patients under 18 years of age.

**Use in Geriatric Patients:** 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 may interfere with the absorption of other drugs where gastric pH is an important determinant of oral bioavailability (e.g. Atazanavir, nelfinavir).

### 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, keep in dry place & protect from light.
- Keep out of reach of children.

### PACKING

**Vonofix 10 Tablet:** Each box contains 60 tablets in alu-alu blister pack.

**Vonofix 20 Tablet:** Each box contains 30 tablets in alu-alu blister pack.

Manufactured by:  
 **ARISTOPHARMA LTD.**  
Shampur-Kadamtali I/A, Dhaka-Bangladesh