Composition

Ornova® 10 tablet: Each coated tablet contains Vonoprazan Fumarate INN equivalent to Vonoprazan 10 mg.

Ornova® 20 tablet: Each coated tablet contains Vonoprazan Fumarate INN equivalent to Vonoprazan 20 mg.

Pharmacology

Ornova® is the preparation of Vonoprazan which 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. **Ornova®** is a strong base with a high affinity for the acid pump of gastric cells inhibiting gastric acid production.

Indication

Ornova® is indicated for-

- Treatment of gastric ulcer (GU), duodenal ulcer (DU), reflux esophagitis (RE) (erosive esophagitis EE).
- Maintenance treatment of reflux esophagitis (erosive esophagitis).
- Prevention of recurrence of gastric ulcer or duodenal ulcer during NSAIDs administration.
- Adjunct to *Helicobacter pylori* eradication.

Dose and administration

Route of administration: **Ornova®** should be taken in oral route without regard to food or timing of food.

Dosing instructions

Gastric ulcer: The dose is 20 mg of **Ornova®** once daily for 8 weeks.

Duodenal ulcer: The dose is 20 mg of **Ornova®** once daily for 6 weeks.

Reflux esophagitis (erosive esophagitis): The dose is 20 mg of **Ornova®** once daily for 4 to 8 weeks. In addition, for the maintenance of healing of reflux esophagitis in patients with repeat recurrence and relapse of the condition, a dose of 10 mg is administered once daily; however, when the efficacy is inadequate, a dose of 20 mg may be administered once daily.

Prevention of recurrence of gastric ulcer or duodenal ulcer during NSAIDs administration: The dose is 10 mg of **Ornova®** once daily.

Adjunct to Helicobacter pylori eradication: The recommended dose is **Ornova®** 20 mg, Amoxicillin 1,000 mg and Clarithromycin 500 mg, each given twice daily (in the morning and evening, 12 hours apart), for 14 days.

Or,

Ornova® 20 mg twice daily (in the morning and evening) and Amoxicillin 1,000 mg three times daily (in the morning, mid-day and evening) for 14 days.

Contraindication

It is contraindicated in patient with hypersensitivity to vonoprazan or any other components of this product. It is also contraindicated in patients receiving atazanavir sulphate, nelfinavir or rilpivirine hydrochloride.

Warning and precaution

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. Vonoprazan should be administered with care in patients with renal disorders. Administration of vonoprazan is not recommended to be taken with drugs for which absorption is dependent on acidic intragastric pH. Gastric malignancy may present with symptoms associated with acid-related disorders which initially respond to drugs that elevate intragastric pH. A symptomatic response to vonoprazan does not exclude the presence of gastric malignancy. If abdominal pain and frequent diarrhea occur, appropriate measures, such as immediate discontinuation of the treatment, should be taken. Benign gastric polyp has been observed in patient on long-term administration of PPIs. The risk of fracture is especially increased in the patients receiving high dose or long term treatment. Severe hypomagnesaemia has been reported in patients on prolonged treatment with PPIs for at least three months and in most cases for a year.

Side effects

The most common side effects are diarrhea, constipation, drug hypersensitivity (including anaphylactic shock), drug eruption, urticaria, hepatotoxicity, jaundice, rash, nausea, abdominal distension, edema and eosinophilia.

Use in pregnancy and lactation

Pregnancy: No clinical studies have been conducted to date to evaluate vonoprazan in subjects who are pregnant. 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. During treatment with vonoprazan, nursing should be avoided if the administration of this drug is necessary for the mother.

Use in children and adolescents

The safety and efficacy of vonoprazan has not been established in patients under 18 years of age.

Drug interaction

Drug interaction with medication: Administration of vonoprazan results in elevation of intragastric pH, suggesting that it may interfere with the absorption of drugs where gastric pH is an important determinant of oral bioavailability. Use of vonoprazan is therefore not recommended with atazanavir and nelfinavir, due to significant reduction in their bioavailability. With strong CYP3A4 inhibitors, e.g., clarithromycin, blood concentration of vonoprazan may increase. There were no clinically significant effects of NSAIDs on the pharmacokinetics of vonoprazan and no clinically significant effects of vonoprazan on the pharmacokinetics of NSAIDs.

Drug interaction with food and others: Not applicable.

Overdose

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

Storage

Store in a cool (below 30^{O} C) and dry place protected from light. Keep away from the reach of children.

Packing

Ornova® 10 tablet: Carton of 50 tablets in blister pack.

Ornova® 20 tablet: Carton of 50 tablets in blister pack.