Omecron

Omeprazole 20 mg &
40 mg Capsule

Omecron (Omeprazole), a substituted benzimidazole, is an inhibitor of gastric acid secretion. It inhibits gastric acid secretion by blocking hydrogen-potassium-adenosine triphosphatase (H^+/K^+ ATPase) enzyme system in the gastric parietal cell. After oral administration, the onset of the antisecretory effect occurs within one hour, with the maximum effect occurring within two hours and inhibition of secretion lasts up to 72 hours. When the drug is discontinued, secretory activity returns gradually, over 3 to 5 days.

COMPOSITION

***Omecron* 20 :** Each capsule contains Omeprazole USP 20 mg as enteric coated pellets.
***Omecron* 40 :** Each capsule contains Omeprazole USP 40 mg as enteric coated pellets.

INDICATION

Omecron (Omeprazole) is indicated for the treatment of gastric and duodenal ulcer, NSAID-associated duodenal and gastric ulcer or as prophylaxis in patients with a history of NSAID-associated duodenal and gastric ulcer, gastro-esophageal reflux disease, long-term management of acid reflux disease, acid-related dyspepsia, severe ulcerating reflux esophagitis, prophylaxis of acid aspiration during general anesthesia, Zollinger-Ellison syndrome and *Helicobacter pylori*-induced peptic ulcer.

DOSAGE AND ADMINISTRATION

Benign gastric and *duodenal ulcer :* 20 mg once daily for 4 weeks in duodenal ulceration, 8 weeks in gastric ulceration; in severe or recurrent cases, dose to be increased to 40 mg daily; maintenance dose for recurrent duodenal ulcer, 20 mg once daily; in prevention of relapse in duodenal ulcer, 10-20 mg daily.
NSAID-associated duodenal or gastric ulcer : 20 mg once daily for 4 weeks, continued for further 4 weeks, if not fully healed. 20 mg once daily is used as prophylaxis in patients with a history of NSAID-associated duodenal or gastric ulcers.
Gastro-esophageal reflux disease : 20 mg once daily for 4 weeks, continued for further 4-8 weeks, if not fully healed; 40 mg once daily has been given for 8 weeks in gastro-esophageal reflux disease, refractory to other treatment; maintenance dose is 20 mg once daily.
Long-term management of acid reflux disease : 10-20 mg daily.
Acid-related dyspepsia : 10-20 mg once daily for 2-4 weeks.
Prophylaxis of acid aspiration : 40 mg on the preceding evening, then 40 mg 2-6 hours before surgery.
Zollinger-Ellison syndrome : Initially 60 mg once daily; usual range 20-120 mg daily (If daily dose is more than 80 mg, 2 divided dose should be used).
Helicobacter pylori eradication regimen in peptic ulcer disease : Omeprazole is recommended at a dose of 20 mg twice daily in association with antimicrobial agents as detailed below :
Amoxicillin 500 mg and Metronidazole 400 mg both three times a day for one week, or Clarithromycin 250 mg and Metronidazole 400 mg both twice a day for one week, or Amoxicillin 1 g and Clarithromycin 500 mg both twice a day for one week.
Paeditaric use in severe ulcerating reflux esophagitis (Child>1 year) : If body-weight 10-20 kg, 10-20 -mg once daily for 4-12 weeks; if body-weight over 20 kg, 20-40 mg once daily for 4-12 weeks.

SIDE EFFECT

Omeprazole is generally well tolerated. Nausea, abdominal colic, paresthesia, dizziness and headache have been stated to be generally mild and transient and not requiring a reduction in dosage.

PRECAUTION

When gastric ulcer is suspected, the possibility of gastric malignancy should be excluded before treatment with Omeprazole is instituted, as treatment may alleviate the symptoms and delay diagnosis.

CONTRAINDICATION

Omeprazole is contraindicated in patients with known hypersensitivity to any of the components of the formulation.

DRUG INTERACTION

Omeprazole can prolong the elimination of diazepam, warfarin and phenytoin. So, reduction of warfarin or phenytoin dose may be necessary when Omeprazole is added to the treatment. There is no evidence of an interaction of Omeprazole with theophylline, propranolol or antacids.

USE IN PREGNANCY AND LACTATION

US FDA pregnancy category of Omeprazole is C. However, results from three prospective epidemiological studies indicate no adverse effects of Omeprazole on pregnancy or on the health of the fetus/newborn child. There is no information available on the passage of Omeprazole into breast milk or its effects on the neonate. Breast-feeding should, therefore, be discontinued, if the use of Omeprazole is considered essential.

STORAGE CONDITION

Keep in a dry place away from light and heat. Keep out of the reach of children.

HOW SUPPLIED

***Omecron* 20 :** Each box contains 50 capsules in Alu-Alu blister pack.
***Omecron* 40 :** Each box contains 40 capsules in Alu-Alu blister pack.

NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Comilla, Bangladesh.