



COMPOSITION

Nuprazol™ capsule: Each capsule contains Omeprazole USP 20 mg as enteric-coated granules.

DESCRIPTION

Nuprazol™ capsule contains enteric-coated pellets of Omeprazole. It is a substituted benzimidazole that suppress gastric acid secretion by specific inhibition of the gastric acid proton pump (H^+/K^+ ATPase enzyme system) at the secretory surface of the gastric parietal cell. After oral administration, the onset of the antisecretory effect of **Nuprazol™** 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.

INDICATIONS

Nuprazol™ capsule is indicated in the treatment of

- ◆ Benign gastric and duodenal ulcers including those complicating NSAID therapy
- ◆ Heartburn
- ◆ Symptoms associated with GERD
- ◆ Erosive oesophagitis
- ◆ Pathological hypersecretory conditions such as the Zollinger-Ellison syndrome and to eradicate *H. pylori* in combination with Clarithromycin & Amoxicillin

DOSAGE AND ADMINISTRATION

Benign gastric and duodenal ulcers including those complicating NSAID therapy: 20 mg once daily for 4 weeks in duodenal ulceration or 40 mg once a day for 4-8 weeks in gastric ulceration. Sometimes an additional 4 weeks of therapy is required.

Heartburn and other symptoms associated with GERD: 20 mg daily for up to 4 weeks. Erosive oesophagitis: 20 mg daily for 4-8 weeks. If there is recurrence of Erosive oesophagitis or GERD symptoms (e.g., Heartburn), an additional 4-8 weeks therapy may be considered. Maintenance of Healing of Erosive Oesophagitis: 20 mg daily.

Pathological hypersecretory conditions such as the Zollinger-Ellison syndrome: Adult oral starting dose is 60 mg once a day. Doses should be adjusted to individual patient needs and should continue for as long as clinically indicated. Doses up to 120 mg t.i.d. may be administered. Daily doses of greater than 80 mg should be administered in divided doses. Patients with Zollinger-Ellison syndrome may be treated with Omeprazole delayed release preparations continuously for more than 5 years.

Eradication of *H. pylori* in combination with Clarithromycin & Amoxicillin: 20 mg with Clarithromycin 500 mg & Amoxicillin 1000 mg twice daily for 7-14 days.

Pediatric Patients

For the treatment of GERD or other acid-related disorders, the recommended dose for pediatric patients 2 years of age and older is as follows:

Patient Weight	Omeprazole Dose
<20 Kg	10 mg
>20 Kg	20 mg

CONTRAINDICATION

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

USE IN PREGNANCY AND LACTATION

Omeprazole should be used during pregnancy only if the potential benefit to the pregnant woman justifies the potential risk to the fetus. Because Omeprazole is excreted in human milk, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

SIDE EFFECT

Omeprazole is well tolerated and adverse reactions have generally been mild and reversible. Side effects may include nausea, diarrhoea, abdominal colic, paresthesia, dizziness and headache and flatulence. Skin rashes have occurred in few patients. These events have usually been mild and transient and there has been no consistent relationship with treatment.

DRUG INTERACTION

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

Storage Condition

Store in a cool & dry place, away from light. Keep the medicine out of the reach of children.

Commercial Pack

Nuprazol™ Capsule : Each box contains 5x10 capsules in Alu-Alu blister strip.



Manufactured by:
Nuvista Pharma Limited
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A subsidiary of Beximco Pharmaceuticals Ltd.

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