



Regerd™

Omeprazole

PRESENTATION:

Regerd™ 20 Capsule: Each capsule contains Omeprazole BP 20 mg as enteric coated pellets.
Regerd™ 40 Capsule: Each capsule contains Omeprazole BP 40 mg as enteric coated pellets.

PHARMACOLOGY:

Omeprazole, a substituted benzimidazole, is an inhibitor of gastric acid secretion. Omeprazole inhibits secretion of gastric acid by blocking the H⁺/K⁺ATPase enzyme system, that called 'Proton Pump' of the gastric parietal cell.

INDICATIONS:

Regerd™ (Omeprazole) is indicated for gastroesophageal reflux disease including reflux esophagitis, acid reflux disease, duodenal and benign gastric ulcers, Helicobacter pylori eradication in peptic ulcer disease, prophylaxis of acid aspiration, Zollinger-Ellison syndrome and for the treatment of NSAID associated gastric ulcers, duodenal ulcers or gastroduodenal erosions.

DOSAGE & ADMINISTRATION:

Omeprazole should be taken before meal. The recommended dosage schedule for Omeprazole capsule is to be as followed as below.

Gastroesophageal reflux disease including reflux esophagitis: The usual dosage is 20 mg Omeprazole once daily. The majority of patients are healed after 4 weeks. For those patients not fully healed after the initial course, healing usually occurs during a further 4-8 weeks treatment. Omeprazole has also been used in a dose of 40 mg once daily in patients with reflux esophagitis refractory to therapy. Healing usually occurred within 8 weeks. Patients can be continued at a dosage of 20 mg once daily.

Acid reflux disease: For long-term management, Omeprazole 10 mg once daily is recommended, increasing to 20 mg if symptoms return.

Duodenal and benign gastric ulcers: The usual dose is 20 mg Omeprazole once daily. The majority of patients with duodenal ulcer are healed after 4 weeks. The majority of patients with benign gastric ulcer are healed after 8 weeks. In severe or recurrent cases the dose may be increased to 40 mg Omeprazole daily. Long-term therapy for patients with a history of recurrent duodenal ulcer is recommended at a dose of 20 mg Omeprazole once daily. For prevention of relapse in patients with duodenal ulcer, the recommended dose is Omeprazole 10 mg once daily, increasing to 20 mg once daily if symptoms return.

Helicobacter pylori eradication in peptic ulcer disease: Omeprazole is recommended at a dose of 40 mg once daily or 20 mg twice daily in association with antimicrobial agents Amoxicillin 1 g and Clarithromycin 500 mg both twice daily for 7 to 14 days.

Prophylaxis of acid aspiration: For patients considered to be at risk of aspiration of the gastric contents during general anaesthesia, the recommended dose is Omeprazole 40 mg on the evening before surgery followed by Omeprazole 40 mg 2 to 6 hours prior to surgery.

Zollinger-Ellison syndrome: The recommended initial dosage is 60 mg Omeprazole once daily. The dosage should be adjusted individually and treatment continued as long as clinically indicated. More than 90% of patients with severe disease and inadequate response to other therapies have been effectively controlled on doses of 20 to 120 mg daily. When doses above 80 mg daily, the dose should be divided and given twice daily.

For the treatment of NSAID-associated gastric ulcers, duodenal ulcers or gastroduodenal erosions: The recommended dosage of Omeprazole is 20 mg once daily. Symptom resolution is rapid and in most patients healing occurs within 4 weeks. For those patients who may not be fully healed after the initial course, healing usually occurs during a further 4 weeks treatment. For the prophylaxis of NSAID-associated gastric ulcers, duodenal ulcers, gastroduodenal erosions and dyspeptic symptoms in patients with a previous history of gastroduodenal lesions who require continued NSAID treatment, the recommended dosages Omeprazole is 20 mg once daily.

CONTRAINDICATIONS:

There are no known contraindications to the use of Omeprazole. When gastric ulcer is suspected, the possibility of malignancy should be excluded before treatment with Omeprazole is instituted as treatment may alleviate symptoms and delay diagnosis.

PRECAUTIONS:

Symptomatic response to therapy with Omeprazole does not preclude the presence of gastric malignancy.

SIDE EFFECTS:

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

DRUG INTERACTIONS:

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

USE IN PREGNANCY & LACTATION:

Pregnancy: There are no adequate and well-controlled studies on the use of Omeprazole in pregnant women. Therapeutic doses during pregnancy are unlikely to pose a substantial teratogenic risk. Omeprazole should be used during pregnancy only if the potential benefit to pregnant women justifies the potential risk to the fetus.

Lactation: Omeprazole is excreted in human milk. Thus, a decision should be taken to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

STORAGE:

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

PACKING:

Regerd™ 20 Capsule: Each box contains 10 X 10 capsules in Alu-Alu blister strip.

Regerd™ 40 Capsule: Each box contains 7 X 4 capsules in Alu-Alu blister strip.

Manufactured by:

Organic Health Care Ltd.
Gazipur, Bangladesh.

