

Omeprazol

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Composition

Omeprazol 20 Capsule: Each capsule contains 20 mg of Omeprazole USP as enteric coated pellets.

Omeprazol 40 Capsule: Each capsule contains 40 mg of Omeprazole BP as enteric coated pellets.

Omeprazol 40 IV Injection: Each vial contains 40 mg of Omeprazole as sterile Omeprazole Sodium BP.

Pharmacology

Omeprazole is a specific inhibitor of the gastric proton pump (H^+/K^+ -ATPase) in the parietal cell. It inhibits acid secretion by binding to the H^+/K^+ -ATPase enzyme.

Indications

Omeprazol Capsule: Capsule is used for the relief of Duodenal ulcer, Gastric ulcer, Gastroesophageal Reflux Disease (GERD), GERD with Erosive esophagitis, Zollinger-Ellison Syndrome, Resistant ulcers, eradication of *Helicobacter pylori* in combination with antibiotics, lesions associated with NSAIDs & prevention of acid aspiration syndrome.

Omeprazol IV injection: IV injection is indicated for the treatment of gastric ulcer, duodenal ulcer, reflux esophagitis and also for the treatment of Zollinger-Ellison syndrome.

Dosage and Administration

Capsule:

Indication	Dose	Frequency
Duodenal ulcer	20 mg	Once daily for 4 to 8 weeks
Gastric ulcer	40 mg	Once daily for 4 to 8 weeks
Gastroesophageal reflux disease (GERD)	20 mg	Once daily for 4 weeks
GERD with erosive esophagitis	20 mg	Once daily for 4 to 8 weeks
Zollinger - Ellison syndrome	60 mg	Once daily
Resistant ulcers	40 mg	Once daily for 4 weeks
Eradication of <i>Helicobacter pylori</i> in combination with antibiotics	20 mg	Twice daily
Lesions associated with NSAIDs	20 - 40 mg	Once daily

Children (over 2 years): Severe ulcerating reflux esophagitis : 0.7-1.4 mg/kg daily for 4-12 weeks; maximum 40 mg daily (to be initiated by hospital pediatricians). Elderly: Dosage adjustment is not required in elderly patients.

IV injection:

In patients with Duodenal Ulcer, Gastric Ulcer or Reflux Esophagitis 40 mg once daily dose is recommended. In patients with Zollinger-Ellison Syndrome the recommended initial dose is 60 mg daily. Higher daily doses may be required and the dose should be adjusted individually. When doses exceed 60 mg daily, the dose should be divided and given twice daily. Impaired Renal Function: Dose adjustment is not needed in patients with Impaired Renal Function. Impaired Hepatic Function: As plasma half-life of Omeprazole is increased in patients with Impaired Hepatic Function, a daily dose of 10 - 20 mg may be sufficient. Elderly: Dose adjustment is not needed in the elderly. Children: The safety and effectiveness of Omeprazole injection in children have not yet been established.

Method of Administration

IV Injection: IV injection should be given as a slow intravenous injection. The solution for IV injection is obtained by adding to the vial 10 ml WFI provided. After reconstitution the injection should be given slowly over a period of at least 2.5 minutes at a maximum rate of 4 ml per minute. The solution should be used within 4 hour of reconstitution when stored in original vial in a cool place. The reconstituted solution should not be used if it contains visible particulate matter.

IV Infusion: For IV infusion reconstitute one sterile single dose vial of **Omeprazol** IV injection with 10 ml of water for injection to make 10 ml solution containing 4 mg/ml of Omeprazole approximately. Subsequently add 10 ml of reconstituted solution containing 4 mg/ml of Omeprazole approximately, to 90 ml 0.9% Sodium Chloride solution or 90 ml of 5% Dextrose solution to make 100 ml solution of 0.4 mg/ml of Omeprazole approximately. The resultant infusion should be given intravenously over a period of 20-30 minutes. Chemical and physical instability has been demonstrated for 12 hour after reconstitution with saline or for 6 hour after reconstitution with 5% Dextrose. From a microbiological point of view, the product should be used immediately. Any unused portion should be discarded.

Side Effects

Omeprazol is generally well tolerated. Nausea, diarrhoea, flatulence, abdominal pain, constipation, dizziness and headache have been stated to be generally mild and transient and not requiring a reduction in dosage.

Contraindications

Patients known to have hypersensitivity to any component of the preparation.

Drug Interactions

The absorption of some medicines might be altered due to the decreased intragastric acidity. As Omeprazole is metabolised in the liver it can prolong the elimination of Diazepam, Warfarin and Phenytoin. Plasma concentrations of Omeprazole and Clarithromycin are increased during concomitant administration but there is no interaction with Metronidazole or Amoxicillin. These antimicrobials are used together with Omeprazole for eradication of *Helicobacter pylori*.

Precaution

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

Use in Pregnancy and Lactation

There are no adequate or well-controlled studies in pregnant women. Use during pregnancy only if the potential benefit justifies the risk to the fetus. Omeprazole is excreted in breast milk. So a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to the mother.

Overdosage

Doses up to 400 mg have not resulted in severe symptoms. Symptomatic and supportive therapy should be given as appropriate. Omeprazole IV doses of up to 270 mg on a single day and up to 650 mg over a three-day period have been given in clinical trials without any dose-related adverse reactions.

Storage

Store in a cool & dry place, protect from light.

Packaging

Omeprazol 20 Capsule: Each box contains 7 X 8's capsules in Alu-Alu blister pack.

Omeprazol 40 Capsule: Each box contains 4 X 7's capsules in Alu-Alu blister pack.

Omeprazol 40 IV Injection: Each box contains 1 vial with 1 ampoule of 10 ml Water for Injection BP in blister Pack and a 10 ml sterile disposable syringe.

Manufactured by



Ziska Pharmaceuticals Ltd.

Kaliakoir, Gazipur, Bangladesh