Ometid®

Omeprazole

Description: Omeprazole (**Ometid®**) is a substituted benzimidazole, a compound that inhibits gastric acid secretion. The stability of Omeprazole is a function of pH; it is rapidly degraded in acid media, but has acceptable stability under alkaline conditions. The half life is highly pH dependant.

Mode of action: Omeprazole (**Ometid®**) suppress gastric acid secretion by specific inhibition of the H+/K+ ATPase enzyme system at the secretory surface of the gastric parietal cell. Because this enzyme system is regarded as the acid (proton) pump within the gastric mucosa, Omeprazole has been characterized as a gastric acid-pump inhibitor, in that it blocks the final step of acid production.

Pharmacokinetics: *Absorption & Bioavailability:* Absorption of Omeprazole begins only after the granules leave the stomach. Absorption is rapid, with peak plasma levels occurring within 0.5 to 3.5 hours. Absolute bioavailability (compared with intravenous administration) is about 30-40% at doses of 20-40 mg. In healthy subjects the plasma half-life is 0.5 to 1 hour and the total body clearance is 500-600 mL/min. Based on a relative bioavailability study, the AUC and Cmax of Omeprazole Oral Suspension were 87% and 88% of those for Omeprazole Capsules, respectively. *Distribution:* Protein binding is approximately 95%. *Metabolism and Elimination:* Extensively metabolized by the cytochrome P450 enzyme system. The majority of the dose (about 77%) is eliminated through urine.

Composition:
Ometid® 20 mg Capsule: Each capsule (as enteric coated 23.5% Omeprazole pellets) contains Omeprazole BP 20 mg.
Ometid® 40 mg Capsule: Each capsule (as enteric coated 23.5% Omeprazole pellets) contains Omeprazole BP 40 mg.
Ometid® 40 mg IV Injection: Each vial contains Omeprazole 40 mg as a sterile lyophilized Omeprazole Sodium BP.

Indications with dosage & administration: Omeprazole Capsules or Oral Suspension should be taken before 30 minutes of meal.
Short-Term Treatment of Active Duodenal Ulcer: The recommended adult oral dose is 20 mg once daily. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy.
H. pylori Eradication for the Reduction of the Risk of Duodenal Ulcer Recurrence: ***Triple Therapy*** - The recommended adult oral regimen is Omeprazole 20 mg plus Clarithromycin 500 mg plus Amoxicillin 1000 mg each given twice daily for 10 days. In patients with an ulcer present at the time of initiation of therapy, an additional 18 days of Omeprazole 20 mg once daily is recommended for ulcer healing and symptom relief. ***Dual Therapy*** - The recommended adult oral regimen is Omeprazole 40 mg once daily plus Clarithromycin 500 mg three times daily for 14 days. In patients with an ulcer present at the time of initiation of therapy, an additional 14 days of Omeprazole 20 mg once daily is recommended for ulcer healing and symptom relief.
Gastric Ulcer: The recommended adult oral dose is 40 mg once daily for 4-8 weeks.
Gastroesophageal Reflux Disease (GERD): The recommended adult oral dose for the treatment of patients with symptomatic GERD and no esophageal lesions is 20 mg daily for up to 4 weeks.
Maintenance of Healing of Erosive Esophagitis: The recommended adult oral dose is 20 mg daily.
Pathological Hypersecretory Conditions: The dosage of Omeprazole in patients with pathological hypersecretory conditions varies with the individual patient.
The recommended adult oral starting dose is 60 mg once daily. Doses should be adjusted to individual patient needs and should continue for as long as clinically indicated. Doses up to 120 mg three times daily have been administered. Daily dosages of greater than 80 mg should be administered in divided doses.
Zollinger-Ellison Syndrome: Initially 60 mg once daily, usual range 20 - 120 mg. The dose above 80 mg should be administered in divided doses.

Pediatric Dose

Neonate	700 mcg/kg once daily increased if necessary after 7-14 days to 1.4 mg/kg
Child 1 month-2 years	700 micrograms/kg once daily, increased if necessary to 3 mg/kg once daily
Body weight 10-20 kg	10 mg once daily increased if necessary to 20 mg once daily (in severe ulcerating reflux oesophagitis, max. 12 weeks at higher dose)
Body weight over 20 kg	20mg once daily increased if necessary to 40 mg once daily (in severe ulcerating reflux oesophagitis max. 12 weeks at higher dose)

Contraindications: In patients with known hypersensitivity to any component of the formulation.