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.

By intravenous injection over 5 minutes or by intravenous infusion: Child 1 month-12 years: Initially 500 micrograms/kg (max. 20 mg) once daily, increased to 2 mg/kg (max. 40 mg) once daily if necessary. Child 12-18 years: 40 mg once daily.
Helicobacter pylori eradication (in combination with antibacterials): Child 1-12 years: 1-2 mg/kg (max. 40 mg) once daily. Child 12-18 years: 40 mg once daily.

Ometid® IV injection

Indication	Dose
Prophylaxis of acid aspiration	40 mg once daily 1 hour before surgery
In patients with duodenal ulcer, gastric ulcer, reflux esophagitis where oral medication is inappropriate.	40 mg once daily up to 5 days
Zollinger-Ellison syndrome	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
Method of administration: The solution for **Ometid®** IV injection is obtained by adding to the vial 10 ml of the solvent provided. After reconstitution the injection should be given slowly over a period of 5 minutes. Reconstituted solution should be used preferably within 4 hours.	

Side effects: Nausea, vomiting, headache, dry mouth, abdominal pain, diarrhea etc. may reports rarely.

Use in pregnancy & lactation: Different expert review of published data on experiences with Omeprazole use during pregnancy concluded that therapeutic doses during pregnancy are unlikely to pose a substantial teratogenic risk.
Omeprazole is excreted in human milk, because of the potential for serious adverse reactions in nursing infants from Omeprazole, 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.
Use in children: Use of Omeprazole in pediatric & adolescent patients 1 month to 16 years of age is supported in different extrapolated results.

Geriatric use: Omeprazole was administered to over 2000 elderly individuals (≥65 years of age) in clinical trials in the U.S. and Europe. There were no differences in safety and effectiveness between the elderly and younger subjects.

Precautions: Omeprazole should be used with caution in patients with liver disease, pregnancy & lactation. Symptomatic response to therapy with Omeprazole does not preclude the presence of gastric malignancy.

Drug interactions: Omeprazole may reduce the rate of metabolism of Diazepam, Phenytoin, Carbamazepine etc. but this is not clinically important.

Over dosage: Reports have been received of over dosage with Omeprazole in humans. Doses ranged up to 2400 mg (120 times the usual recommended clinical dose). Manifestations were variable, but included confusion, drowsiness, blurred vision, tachycardia, nausea, vomiting, headache, dry mouth, and other adverse reactions similar to those seen in normal clinical experience.

Storage: Store in a cool & dry place, protected from light.

Packaging
Ometid® 20 mg Capsule: Each carton contains 10X9 capsules in alu-alu blister pack.
Ometid® 40 mg Capsule: Each carton contains 10X3 capsules in alu-alu blister pack.
Ometid® 40 mg IV injection: Each carton contains one vial of 40 mg powder with one ampoule of 10 ml water and a 10 ml disposable syringe.

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Ideas for healthcare

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