Ometid®

Omeprazole 40 mg IV injection

Description: Omeprazole (**Ometid**®) is a specific inhibitor of the gastric proton pump in the parietal cell. It is rapidly acting and produces reversible control of gastric acid secretion with once daily dosing.

Mode of action: Omeprazole is a weak base and is concentrated and converted to the active form in the acid environment of the intracellular canaliculi within the parietal cell, where it inhibits the enzyme H^+/K^+-ATPase-the proton pump.

Pharmacokinetics: The apparent volume of distribution in healthy subjects is approximately 0.3 L/Kg and a similar volume is also seen in patients with renal insufficiency. The plasma protein binding of Omeprazole is about 95%. The average half-life of the terminal phase of the plasma concentration-time curve following IV administration of Omeprazole is approximately 40 minutes; the total plasma clearance is 0.3 to 0.6 L/min. There is no change in half-life during treatment. Omeprazole is completely metabolised by the cytochrome P450 system, mainly in the liver. The major part of its metabolism is dependent on the polymorphically expressed, specific isoform CYP2C19 (S-mephenytoin hydroxylase), responsible for the formation of hydroxyomeprazole, the major metabolite in plasma. No metabolite has been found to have any effect on gastric acid secretion. Almost 80% of an intravenously given dose is excreted as metabolites in the urine, and the remainder is found in the faeces, primarily originating from biliary secretion.

Composition: Ometid 40 mg IV injection: Each vial contains Omeprazole Sodium 42.6 mg, equivalent to Omeprazole 40 mg. After reconstitution, 1 ml contains Omeprazole Sodium 4.26 mg, equivalent to Omeprazole 4.00 mg. Each ampoule contains 10 ml of solvent for injection.

Indication with dosage and administration:

Indication	Dose
Prophylaxis of acid aspiration	40 mg once daily 1 hour before surgery
Treatment in patients where oral therapy is inappropriate e.g. in severely ill patients with either reflux esophagitis, duodenal ulcer, gastric ulcer	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	

Contraindications: Known hypersensitivity to any of the constituents of the formulation.

Side effects: Omeprazole is well tolerated and adverse reactions have generally been mild and reversible. *Common:* Gastrointestinal: Diarrhea, constipation, abdominal pain, nausea/vomiting and flatulence. Central and peripheral nervous system: Headache. *Uncommon:* Central and peripheral nervous system: Dizziness, paraesthesia, and vertigo. Hepatic: Increased liver enzymes. Skin: Rash and/or pruritus, urticaria. Others include hypersensitivity reactions e.g. angioedema, fever, broncho-spasm, interstitial nephritis and anaphylactic shock. Increased sweating, peripheral edema, blurred vision, taste disturbance and hyponatraemia.

Use in pregnancy and lactation: No evidence of adverse events of Omeprazole on pregnancy or on the health of the foetus/newborn child. Omeprazole can be used during pregnancy. Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used.

Precaution: *Impaired renal function:* Dose adjustment is not needed in patients with impaired renal function. *Impaired hepatic function:* As plasma half-life 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 injection in children have not yet been established.

Drug interactions: Due to the decreased intragastric acidity, the absorption of ketoconazole or itraconazole may be reduced during therapy as it is during treatment with other acid secretion inhibitors. As Omeprazole is metabolised in the liver through cytochrome P450 it can prolong the elimination of diazepam, phenytoin and warfarin. Plasma concentrations of Omeprazole and clarithromycin are increased during concomitant oral administration. Simultaneous treatment with Omeprazole and digoxin in healthy subjects leads to a 10% increase in the bioavailability of digoxin as a consequence of the increased intragastric pH. Omeprazole like other PPIs should not be administered with atazanavir. Concomitant administration of Omeprazole and tacrolimus may increase the serum levels of tacrolimus.

Overdose: Intravenous doses of Omeprazole 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 effects.

Storage: Store in a cool dry place protected from light. Keep out of reach of children.

Packaging: Ometid 40 mg IV injection: One vial of 40 mg powder for solution with one ampoule of 10 ml water for injection and a 10 ml disposable syringe.

Opsonin Pharma
Ideas for healthcare

Manufactured by
Opsonin Pharma Limited
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