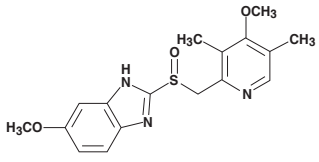
Omeprazole Injection 40mg

Aumi

40mg
Powder for
I.V. Injection/Infusion

INTRODUCTION
Aumi contains omeprazole which is commonly used to treat the acid peptic diseases.

Structural Formula:
Its empirical formula is $C_{17}H_{19}N_3O_3S$, with a molecular weight of 345.42. The structural formula is:



COMPOSITION:
Aumi 40mg I.V. Injection/Infusion
Each Vial Contains:
Omeprazole sodium eq.to
Omeprazole BP 40mg

THERAPEUTIC INDICATIONS:
Aumi for intravenous use is indicated as an alternative to oral therapy for the following indications:
Adults: Treatment of duodenal ulcers, Prevention of relapse of duodenal ulcers,Treatment of gastric ulcers,Prevention of relapse of gastric ulcers,In combination with appropriate antibiotics, Helicobacter pylori (H. pylori) eradication in peptic ulcer disease,Treatment of NSAID-associated gastric and duodenal ulcers,Prevention of NSAID-associated gastric and duodenal ulcers in patients at risk,Treatment of reflux oesophagitis,Long-term management of patients with healed reflux oesophagitis,Treatment of symptomatic gastro-oesophageal reflux disease,Treatment of Zollinger-Ellison syndrome.

CLINICAL PHARMACOLOGY:
Mechanism of Action:
Omeprazole, a racemic mixture of two enantiomers reduces gastric acid secretion through a highly targeted mechanism of action. It is a specific inhibitor of the acid pump in the parietal cell. It is rapidly acting and provides control through reversible inhibition of gastric acid secretion with once daily dosing.
Omeprazole is a weak base and is concentrated and converted to the active form in the highly acidic environment of the intracellular canaliculi within the parietal cell, where it inhibits the enzyme H+,K+-ATPase - the acid pump. This effect on the final step of the gastric acid formation process is dose-dependent and provides for highly effective inhibition of both basal acid secretion and stimulated acid secretion, irrespective of stimulus.

Distribution:
The apparent volume of distribution in healthy subjects is approximately 0.3 l/kg body weight. Omeprazole is 97% plasma protein bound.
Metabolism:
Omeprazole is completely metabolised by the cytochrome P450 system (CYP). The major part of its metabolism is dependent on the polymorphically expressed CYP2C19, responsible for the formation of hydroxyomeprazole, the major metabolite in plasma.
Excretion:
Total plasma clearance is about 30–40 l/h after a single dose. Almost 80% of a dose of omeprazole is excreted as metabolites in the urine, the remainder in the faeces, primarily originating from bile secretion.
Hepatic impairment:
The metabolism of omeprazole in patients with liver dysfunction is impaired, resulting in an increased AUC. Omeprazole has not shown any tendency to accumulate with once-daily dosing.
Renal impairment:
The pharmacokinetics of omeprazole, including systemic bioavailability and elimination rate, are unchanged in patients with reduced renal function.

SIDE EFFECTS:
The most common adverse reactions reported ≥ 2% from omeprazole treated patients enrolled in these studies included headache (2.9%), abdominal pain (5.2%), nausea (4.0%), diarrhea (3.7%), vomiting (3.2%), and flatulence (2.7%). Additional adverse reactions reported ≥ 1% included acid regurgitation (1.9%), URTI (1.9%), constipation (1.5%), dizziness (1.5%), rash (1.5%), asthenia (1.3%), back pain (1.1%), and cough (1.1%).

DRUG INTERACTIONS:
Omeprazole was found to be interfering with atazanavir, saquinavir, ketoconazole, voriconazole, ampicillin esters, iron salts, diazepam, warfarin, phenytoin, theophylline, cyclosporine, disulfiram, benzodiazepines and tacrolimus.

OVER DOSAGE:
Symptoms were transient and no serious clinical outcome has been reported with omeprazole overdose. No specific antidote for omeprazole overdose is known. Omeprazole is extensively bound to plasma proteins and is therefor, not readily dialyzable. In the event of overdose, treatment should be symptomatic and supportive.

DOSAGE & ADMINISTRATION:
By intravenous injection over 5 minutes or by intravenous infusion over 20–30 minutes, treatment and prevention of benign gastric ulcers, duodenal ulcers, or NSAID-associated ulcers, gastro-oesophageal reflux disease, 40mg once daily until oral administration possible Zollinger-Ellison syndrome, initially 60mg once daily, adjusted according to response; daily doses above 60mg given in 2 divided doses. Major peptic ulcer bleeding (following endoscopic treatment) [unlicensed indication], initial intravenous infusion of 80mg over 40–60 minutes, then by continuous intravenous infusion, 8 mg/hour for 72 hours (then change to oral therapy)

INSTRUCTIONS FOR USE:
Injection: For I.V. injection, reconstitute Aumi (Omeprazole) I.V. with 10ml sterile water for injection to make a 10ml solution containing 4mg/ml omeprazole approximately. No other solvents for I.V. injection should be used. After reconstitution,Aumi (Omeprazole) I.V. Should be given as intravenous injection, slowly over a period of atleast 2.5 minutes at a maximum rate of 4ml/min. The reconstituted solution must be stored below 25°C & used within four hours. Do not refrigerate.

Infusion: For I.V. infusion, reconstitute Aumi (Omeprazole) I.V. with 10ml sterile water for injection to make a 10 ml solution containing 4mg/ml omeprazole approximately. Next add the 10 ml reconstituted solution to 90ml of 0.9% w/v of sodium chloride solution for injection, 5%w/v of dextrose solution for injection or 5 % w/v of mannitol to make 100ml solution containing 0.4mg/mL of omeprazole approximately. No other solution should be used for infusion. The reconstituted infusion should be given intravenously over a period of 20-30 minutes.
The prepared infusion solution should be used within 3 hours of preparation and any unused portion should be discarded. The reconstituted solution must be stored below 25°C & used within four hours. Do not refrigerate. The reconstituted and diluted solutions should not be used if it contains visible particulate matter.

CONTRAINDICATION:
Omeprazole is contraindicated in patients with known hypersensitivity to substituted benzimidazoles or to any component of the formulation.

PRECAUTIONS:
Concomitant Gastric Malignancy:
Symptomatic response to therapy with omeprazole does not preclude the presence of gastric malignancy.

Atrophic Gastritis:
Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with omeprazole.

Bone Fracture:
The risk of fracture was increased in patients who received high-dose, defined as multiple daily doses, and long-term PPI therapy (a year or longer).

Pregnancy:
Pregnancy Category C:
There are no adequate and well-controlled studies on the use of omeprazole in pregnant women.

Nursing Mothers:
Omeprazole is excreted in human milk, 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.

Pediatric Use:
Use of OMEPRAZOLE in pediatric and adolescent patients 1 to 16 years of age for the treatment of GERD is supported by (a) extrapolation of results, already included in the currently approved labeling, from adequate and well-controlled studies that supported the approval of Omeprazole for adults, and (b) safety and pharmacokinetic studies performed in pediatric and adolescent patients.

STORAGE:
Store below 30°C
Protect from heat, light & moisture.
Keep all medicines out of the reach of children.

PRESENTATION:
Aumi 40mg Powder for Injection/Infusion: Each bleach board carton contains 1 vial having 40mg powder for injection / Infusion + 10ml water for injection in a Plastic tray & leaf insert

Manufactured by:
GENIX

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ISO 9001
ISO 14001
OHSAS 18001