mep® Omeprazole **40mg** *Powder for* I.V. Injection/Infusion

For intravenous use only

صرف وریدی استعمال کے لئے

میپ ۴۰ ملی گرام

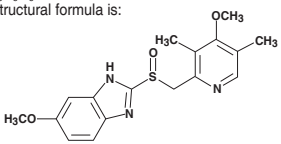
(اومیپرازول) آئی۔وی۔انجکشن/انفیوژن

DESCRIPTION:

mep® 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:



QUALITATIVE AND QUANTITATIVE COMPOSITION

mep® 40mg Powder for I.V. Injection/Infusion

Each Vial Contains:

Omeprazole Sodium eq.to Omeprazole.....40mg

Genix Specification

THERAPEUTIC INDICATIONS:

mep® (Omeprazole) I.V. should be administered intravenously only either as an infusion or injection and should not be given by another route. mep® (Omeprazole) I.V. is indicated for patients who are unable to take oral therapy for the short-term (Upto 5 days) treatment of:

1. Gastro-oesophageal reflux disease
2. Peptic ulcer disease.
3. Treatment and prophylaxis of NSAID-associated ulceration.
4. Duodenal Ulcer.
5. Zollinger-Ellision Syndrome.
6. Prophylaxis of acid aspiration.

CLINICAL PHARMACOLOGY:

Mechanism of Action: Omeprazole suppresses 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: Absorption of omeprazole begins only after the granules leave the stomach. Absorption is rapid, with peak plasma levels of omeprazole occurring within 0.5 to 3.5 hours. Peak plasma concentrations of omeprazole and AUC are approximately proportional to doses up to 40mg, but because of a saturable first-pass effect, a greater than linear response in peak plasma concentration and AUC occurs with doses greater than 40mg. Absolute bioavailability is about 30-40% at doses of 20-40mg, due in large part to presystemic metabolism. In healthy subjects the plasma half-life is 0.5 to 1 hour and the total body clearance is 500-600 ml/min.

Distribution: Protein binding is approximately 95%.

Metabolism: Omeprazole is extensively metabolized by the cytochrome p450 (cyp) enzyme system.

Excretion: The majority of the dose (about 77%) is eliminated in urine as at least six metabolites. The remainder of the dose is recoverable in feces. This implies a significant biliary excretion of the metabolites of omeprazole.

Hepatic impairment: In patients with chronic hepatic disease, the bioavailability increased to approximately 100% compared with an I.V. dose, reflecting decreased first-pass effect, and the plasma half-life of the drug increased to nearly 3 hours compared with the half-life in normals of 0.5-1 hour. Plasma clearance averaged 70 ml/min, compared with a value of 500-600 ml/min in normal subjects. Dose reduction, particularly where maintenance of healing of erosive esophagitis is indicated, for the hepatically impaired should be considered.

Renal impairment: Because urinary excretion is a primary route of excretion of omeprazole metabolites, their elimination slowed in proportion to the decreased creatinine clearance. No dose reduction is necessary in patients with renal impairments.

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:

Indications	Dose & Duration
1-Gastro-oesophageal reflux disease. 2-Peptic ulcer disease. 3-Treatment and prophylaxis of NSAID-associated ulceration. 4-Duodenal ulcer.	Mep (Omeprazole) I.V. 40mg once daily upto 5 days.
Zollinger-Ellison syndrome.	Initial dose of mep (Omeprazole) I.V. given intravenously is 60mg daily. Higher daily doses may be required and the dose should be adjusted individually. Dose greater than 60mg should be given twice daily.
Prophylaxis of acid aspiration during general anesthesia.	Recommended dose of mep (Omeprazole) I.V. is 40mg to be given slowly (over a period of 5 minutes) as an intravenous injection, one hour before surgery.

Hepatic Impaired Patients
For patients with impaired hepatic function a daily dose of 10-20mg may be sufficient.

INSTRUCTIONS FOR USE:
Injection: For I.V. injection, reconstitute mep (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, mep® (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 is stable for approximately 8 hours When stored in the original vial in a cool place.

Infusion: For I.V. infusion, reconstitute mep® (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 infusion solution should not be refrigerated. The diluted infusion solution is approximately stable for upto 18 hours when stored in a cool place and Protected from sunlight. 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.

INSTRUCTIONS:
Dosage as directed by the physician. Store below 25°C. Protect from sunlight & moisture. Keep all medicines out of the reach of children. To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:
mep® (Omeprazole) 40mg powder for I.V. Injection/Infusion is available as one vial with 10mL of ampoule water for injection B.P. with leaflet.

ہدایات:
خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
۲۵ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں، سورج کی روشنی اور نمی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔ صرف رجسٹرڈ ڈاکٹر کے نسخہ پر فروخت کریں۔
انجکشن: تیارشدہ انجکشن ٹھنڈی جگہ پر ۲۸ گھنٹے تک اپنی تاثیر برقرار رکھے گا۔
انفیوژن: تیارشدہ انفیوژن ٹھنڈی جگہ پر ۱۸ گھنٹے تک اپنی تاثیر برقرار رکھے گا۔
ریفریجریٹر میں نہ رکھیں۔

For detailed information
please contact:
GENIX Genix Pharma (Pvt.) Ltd.
44,45-B, Korangi Creek Road, Karachi-75190, Pakistan.
UAN: +92-21-111-10-10-11, **Email:** info@genixpharma.com
ISO 9001:2015 ISO 14001:2015 ISO 45001:2018
www.genixpharma.com