PROMEP IV

(Omeprazole) 40mg

Lyophilized powder for IV Injection & Infusion

پرومیپ ۴۰ ایم جی آئی وی

DESCRIPTION:
PROMEP IV (Omeprazole) a substituted benzimidazole, is a proton pump inhibitor that inhibits gastric acid secretion.

QUALITATIVE & QUANTITATIVE COMPOSITION:
PROMEP IV (Omeprazole) is available as:
PROMEP IV 40mg
Each vial contains:
Omeprazole Sodium Equivalent to Omeprazole..... 40mg

CLINICAL PHARMACOLOGY:
MECHANISM OF ACTION:
Omeprazole belongs to a new class of anti-secretory compounds, the substituted benzimidazoles that do not exhibit anti-cholinergic or histamine antagonistic properties. It inhibits secretion of gastric acid by irreversibly blocking the enzyme system of hydrogen/potassium adenosine triphosphatase (H^+K^- ATPase), the proton pump of the gastric parietal cell. This effect is dose-related and leads to inhibition of both basal and stimulated acid secretion irrespective of the stimulus.

PHARMACOKINETICS:
Distribution:
The apparent volume of distribution in healthy subjects is approximately 0.3L/kg. Plasma protein binding is approximately 95%.
Metabolism:
Omeprazole is completely metabolized in the liver, primarily by the cytochrome P450 isoenzyme CYP2C19 to form hydroxy-omeprazole and to a small extent by CYP3A4 to omeprazole sulfone which are inactive metabolites.
Excretion:
The majority of the dose (about 80%) is eliminated in the urine and the remainder, recoverable in the feces.
The elimination half-life from plasma following IV administration of omeprazole is approximately 40 minutes.
The total plasma clearance is 0.3 to 0.6L/min. There is no change in half-life during treatment.

Special Population:
Pediatric:
There is limited experience with omeprazole administered intravenously in children.
Hepatic Insufficiency:
In patients with impaired liver function the volume of distribution is slightly decreased, while the plasma half-life of omeprazole is increased.

THERAPEUTIC INDICATIONS:
PROMEP IV (Omeprazole) should be administered intravenously only either as an injection or infusion and should not be given by any other route.
PROMEP IV (Omeprazole) is indicated for patients who are unable to take oral therapy for the short-term (upto 5 days) treatment of:
1-Gastro-Esophageal Reflux Disease (GERD).
2-Peptic ulcer disease.
3-Treatment and prophylaxis of NSAID – associated ulceration.
4-Duodenal ulcer.
5-Zollinger-Ellison syndrome.
6-Prophylaxis of acid aspiration.

DOSAGE & ADMINISTRATION:
ADULTS DOSAGE:

INDICATION	DOSAGE
-Gastro-Esophageal Reflux Disease (GERD). -Peptic ulcer disease. -Treatment and prophylaxis of NSAID – associated ulceration. -Duodenal ulcer.	**PROMEP IV** 40mg once daily for 5 days.
Zollinger-Ellison Syndrome	Initial dose **PROMEP IV** given intravenously is 60mg daily. Higher daily doses may be required and the dose should be adjusted individually. Dose greater than 60 mg should be given twice daily.
Prophylaxis of acid aspiration during general anesthesia	Recommended dose of **PROMEP IV** is 40mg to be given slowly (over a period of 5 minutes) as an intravenous injection, in the evening before surgery and a further 40mg one hour before surgery.

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

INSTRUCTIONS FOR USE:
Injection:
For IV injection, reconstitute **PROMEP IV** (Omeprazole) with 10mL sterile water for injection to make a 10mL solution containing 4mg/mL omeprazole approximately. ***No other solvents for IV injection should be used.***
After reconstitution, **PROMEP IV** (Omeprazole) 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 IV infusion, reconstitute **PROMEP IV** (Omeprazole) with 10mL sterile water for injection to make a 10mL solution containing 4mg/mL omeprazole approximately. Next add the 10mL 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 light.
The reconstituted and diluted solutions should not be used if it contains visible particulate matter.

INCOMPATIBILITIES
Infusions with low pH should not be used for diluting **PROMEP IV** (Omeprazole) as fading and discoloration of solution can occur.

CONTRAINDICATIONS:
-With known hypersensitivity to active, substituted benzimidazoles or to any component of the formulation.
-Concomitantly with nelfinavir.

PRECAUTIONS:
General:
-When gastric ulcer is suspected, the possibility of malignancy should be excluded as treatment may alleviate symptoms and delay diagnosis.
-Decreased gastric acidity due to any means including proton pump inhibitors, increases gastric counts of bacteria normally present in the gastrointestinal tract. Treatment with acid-reducing drugs may lead to a slightly increased risk of gastrointestinal infections, such as Salmonella and Campylobacter.
Pregnancy:
PROMEP IV (Omeprazole) can be used during pregnancy.
Nursing Mothers:
PROMEP IV (Omeprazole) is excreted in breast milk but is not likely to influence the child when therapeutic doses are used.

DRUG INTERACTIONS:
-Omeprazole decreases absorption of ***ketoconazole & itraconazole*** due to decreased intragastric acidity when use concomitantly. With ***voriconazole***, the plasma concentration of both drugs may be increased and a reduced dose of omeprazole is recommended.
-Plasma concentrations of ***diazepam, citalopram, imipramine, clomipramine, phenytoin*** & ***warfarin*** may be increased and a dose reduction could be needed when given concomitantly with omeprazole.
-An interaction is observed between ***clopidogrel*** and omeprazole. As a precaution, concomitant use of omeprazole and clopidogrel should be discouraged.
-Concomitant administration of omeprazole with ***saquinavir, tacrolimus*** *and* ***digoxin*** resulted in increased plasma levels of these drugs. Careful monitoring and caution should be exercised.
-Omeprazole like other PPIs should not be co-administered with ***atazanavir***.
-***Inhibitors of CYP2C19 or CYP3A4*** (such as clarithromycin) results in an approximate 30% Increase in peak plasma concentrations of omeprazole and an increase in its mean half-life from 1.2 hours to 1.6 hours
-***Inducers of CYP2C19 or CYP3A4*** (such as rifampicin and St John's wort) decreases omeprazole serum levels by increasing omeprazole rate of metabolism.

ADVERSE REACTIONS:
Omeprazole is well tolerated and the adverse reactions have generally been mild and reversible.
Common: headache, diarrhea, constipation, abdominal pain, nausea/vomiting and flatulence.
Uncommon: dizziness, somnolence, insomnia and vertigo, increased liver enzymes, urticaria, rash and/or pruritis.
Rare: depression, gynecomastia, dry mouth, stomatitis, gastrointestinal candidiasis, Leukopenia, thrombocytopenia, agranulocytosis, encephalopathy in patients with pre-existing severe liver disease, hepatitis with or without jaundice, hepatic failure, increased liver enzymes, myalgia, impotence, breast disorders, photosensitivity, stevens-Johnson syndrome, alopecia, hypersensitivity reactions.
Gastro-duodenal carcinoids have been reported in patients with Zollinger-Ellison syndrome on long-term treatment with omeprazole.

OVERDOSAGE:
Treatment:
No specific antidote for omeprazole overdosage is known. Omeprazole is extensively protein bound and is, therefore, not readily dialyzable. In the event of overdosage, treatment should be symptomatic and supportive.

INSTRUCTIONS:
-Store below 25˚C.
-Protect from light & moisture.
-Keep out of reach of children.
To be sold on prescription of a registered medical practitioner.

HOW SUPPLIED:
PROMEP IV (Omeprazole) 40mg lyophilized powder for injection is available as 1 vial plus 10mL sterile water for injection.

خوراک:ڈاکٹری ہدایات کے مطابق استعمال کریں۔
ہدایات: دوا کو ۲۵ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

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