60.8mm

140.5mm

SOMEP IV 40mg

سومیپ آئی وی

(Esomeprazole)

۴۰ ملی گرام

Lyophilized powder for IV Injection & Infusion

(انجکشن اور انفیوژن)

DESCRIPTION:
The active ingredient in **SOMEP IV** lyophilized powder for injection/infusion is esomeprazole sodium. Esomeprazole is the S-isomer of omeprazole, which is a mixture of the S- and R-isomers. It inhibits gastric acid secretion more effectively than omeprazole.

QUALITATIVE & QUANTITATIVE COMPOSITION:
SOMEP IV (Esomeprazole) is available as:
SOMEP IV 40mg
Each vial contains:
Esomeprazole sodium equivalent to esomeprazole.............40mg

CLINICAL PHARMACOLOGY:

MECHANISM OF ACTION:
Esomeprazole is a weak base and is concentrated and converted to the active form in the highly acidic environment of the secretory canaliculi of the parietal cell, where it inhibits the enzyme H^+K^+-ATPase - the acid pump and inhibits both basal and stimulated acid secretion. By acting specifically on the proton pump, esomeprazole blocks the final step in acid production, thus reducing gastric acidity.

PHARMACOKINETICS:

Distribution:
The apparent volume of distribution at steady state in healthy subjects is approximately 0.22L/kg body weight. Esomeprazole is 97% bound to plasma proteins.

Metabolism:
Esomeprazole is completely metabolized in the liver by the cytochrome P450 system (CYP). The major part of the metabolism of esomeprazole is dependent on the CYP2C19, responsible for the formation of the hydroxy- and desmethyl metabolites of esomeprazole. The remaining part is dependent on CYP3A4, responsible for the formation of esomeprazole sulphone, the main metabolite in plasma.

Elimination:
Esomeprazole is excreted as metabolites primarily in urine but also in feces. Less than 1% of the parent drug is excreted in urine. Esomeprazole is completely eliminated from plasma and there is no accumulation during once daily administration. The plasma elimination half-life of intravenous esomeprazole is approximately 1.1 to 1.4 hours and is prolonged with increasing dose of intravenous esomeprazole.

Special Populations:

Hepatic Insufficiency:
The metabolism of esomeprazole in patients with mild to moderate liver dysfunction may be impaired. The metabolic rate is decreased in patients with severe liver dysfunction resulting in a doubling of the total exposure of esomeprazole. Esomeprazole or its major metabolites do not show any tendency to accumulate with once daily dosing.

INDICATIONS:
SOMEP IV (Esomeprazole) is indicated for gastric anti-secretory treatment when the oral route is not possible:
- For short term treatment of gastro-esophageal reflux disease in patients with esophagitis and/or severe symptoms of reflux.
- Healing of gastric ulcers associated with NSAID therapy.
- Prevention of gastric and duodenal ulcers associated with NSAID therapy, in patients at risk.

DOSAGE & ADMINISTRATION:

Indications	Dosage
Short term treatment of GERD with a history of Erosive Esophagitis	20mg or 40mg **SOMEP IV** once daily by intravenous injection (no less than 3 minutes) or intravenous infusion (10 to 30 minutes) upto 10 days
Healing of gastric ulcers associated with NSAID therapy	20mg once daily
Prevention of gastric and duodenal ulcers associated with NSAID therapy	20mg once daily

Hepatic Insufficient Patients:
Dose adjustment is not required in patients with mild to moderate liver impairment. For patients with severe liver impairment, a maximum daily dose of 20mg **SOMEP IV** (Esomeprazole) should not be exceeded.

Elderly:
Dose adjustment is not required in the elderly.

INSTRUCTIONS FOR USE:
SOMEP IV (Esomeprazole) for Injection should not be administered concomitantly with any other medications through the same intravenous site and/or tubing. The intravenous line should always be flushed with 0.9% sodium chloride solution for injection, Lactated Ringer's injection or 5% dextrose injection both prior to and after administration of **SOMEP IV** (Esomeprazole) for injection.

Intravenous Injection (20mg or 40mg):
The Lyophilized powder should be reconstituted with 5mL of 0.9% sodium chloride solution for injection. Withdraw 5mL of the reconstituted solution and administer as an intravenous injection over no less than 3 minutes. The reconstituted solution should be stored at room temperature up to 30°C and administered within 12 hours after reconstitution.

Intravenous Infusion (20mg or 40mg):
A solution for intravenous infusion is prepared by first reconstituting the contents of one vial with 5mL of 0.9% sodium chloride solution for injection, Lactated Ringer's injection or 5% dextrose injection and further diluting the resulting solution to a final volume of 100mL. The solution (admixture) should be administered as an intravenous infusion over a period of 10 to 30 minutes. The admixture should be stored at room temperature up to 30°C and should be administered within the designated time period as listed in the table below.

Diluent	Administer within
0.9% sodium chloride solution for injection	12 hours
Lactated Ringer's injection	12 hours
5% dextrose injection	6 hours

Any unused solution should be discarded.

CONTRAINDICATIONS:
- Esomeprazole is contraindicated in patients with known hypersensitivity to the active substance esomeprazole or to other substituted benzimidazoles.
- Esomeprazole, like other PPIs, should not be administered with atazanavir.
- Contraindicated with nelfinavir.

PRECAUTIONS:

General:
-In the presence of any alarm symptoms (e.g., significant unintentional weight loss, recurrent vomiting, dysphagia, hematemesis or melaena) and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment with esomeprazole may alleviate symptoms and delay diagnosis.
- Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long term with PPIs such as esomeprazole.
- Dose reduction in patients with severe hepatic disease should be considered.
- Patients with severe renal insufficiency should be treated with caution when administered with esomeprazole IV.
- The safety and effectiveness of esomeprazole have not been established for pediatric patients.

Pregnancy:
Caution should be exercised when prescribing **SOMEP IV** to pregnant women.

Nursing Mothers:
SOMEP IV should not be used during breast- feeding.

DRUG INTERACTIONS:
- Esomeprazole inhibits acid secretion. Therefore, esomeprazole may interfere with the absorption of drugs ***(ketoconazole*** & ***itraconazole)*** where gastric Ph is important determinant of bioavailability.
- Esomeprazole inhibits CYP2C19. Thus, when esomeprazole is combined with drugs metabolised by CYP2C19, such as ***diazepam, citalopram, imipramine, clomipramine, phenytoin*** etc., the plasma concentrations of these drugs may be increased and a dose reduction could be needed.
- Patients treated with proton pump inhibitors and ***warfarin*** concomitantly may need to be monitored for increases in INR and prothrombin time.

ADVERSE REACTIONS:
The following adverse drug reactions have been reported during therapy of esomeprazole.
Common: Headache, abdominal pain, diarrhea, flatulence, nausea/vomiting, constipation.
Uncommon: Peripheral oedema, insomnia, dizziness, paresthesia, somnolence.
Rare: Leukopenia, thrombocytopenia, hypersensitivity reactions e.g., fever, angioedema and anaphylactic shock, hyponatremia, agitation, confusion, depression, taste disturbance, bronchospasm, stomatitis, gastrointestinal candidiasis, hepatitis with or without jaundice, alopecia, photosensitivity, arthralgia, myalgia, malaise, increased sweating.
Very rare: Aggression, hallucinations, hepatic failure, encephalopathy in patients with pre-existing liver disease, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN), muscular weakness, interstitial nephritis, gynecomastia.

OVERDOSAGE:
No specific antidote is known. Esomeprazole is extensively plasma protein bound and it is not expected to be removed by dialysis. In the event of overdosage, treatment should be symptomatic and supportive.

INSTRUCTIONS
- Store below 25°C.
- Protect from sunlight and moisture.
- Store in carton until the time of use.
- Vials can however, be stored, exposed to normal indoor light outside the box for up to 24 hours.
- Keep out of reach of children.

To be sold on prescription of a registered medical practitioner.

HOW SUPPLIED:
SOMEP IV (Esomeprazole) 40mg lyophilized powder for injection is available as 1 vial plus 5mL 0.9% sodium chloride solution for injection.

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

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