Esomeprazole Sodium 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 either 0.9% Sodium Chloride Injection, Lactated Ringer's Injection, or 5% Dextrose Injection both prior to and after administration of Esomeprazole Sodium for Injection.

Treatment with Esomeprazole Sodium for Injection should be discontinued as soon as the patient is able to resume treatment with Esomeprazole Delayed-Release Capsules.

Safety and efficacy of Esomeprazole Sodium for Injection as a treatment of GERD patients with a history of erosive esophagitis for more than 10 days have not been demonstrated.

PREPARATIONS FOR USE:

Intravenous Injection (20 or 40 mg) over no less than 3 minutes
The freeze-dried powder should be reconstituted with 5 mL of 0.9% Sodium Chloride Injection. Withdraw 5 mL 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 (86°F) and administered within 12 hours after reconstitution. No refrigeration is required.
Intravenous Infusion (20 or 40 mg) over 10 to 30 minutes
A solution for intravenous infusion is prepared by first reconstituting the contents of one vial with 10 mL of 0.9% Sodium Chloride Injection, Lactated Ringer's Injection or 5% Dextrose Injection and further diluting the resulting solution to a final volume of 50 mL. 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 (86°F) and should be administered within the as listed in the below. No refrigeration is required.

* 0.9 % Sodium Chloride 12 hours
* Lactated ringers injection 12 hours
* 5 % Dextrose injection 6 hours

Esomeprazole Sodium 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 either 0.9% Sodium Chloride Injection, Lactated Ringer's Injection or 5% Dextrose Injection both prior to and after administration of Esomeprazole sodium for Injection.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

ADMINISTRATION IN CHILDREN.

AS product information allows for the use of adult doses of esomeprazole in children over 12 years.
In the doses, which may be given once daily for up to 8 weeks for the treatment of gastro-oesophageal reflux in children, are:

* 1 to 11 years: 10 mg
* 12 to 17 years: 20 or 40 mg

For healing erosive oesophagitis in children, the following doses based on body-weight are licensed in the USA to be given once daily for up to 8 weeks:

* Less than 20 kg: 10 mg
* 20 kg or over: 10 or 20 mg

PRECAUTIONS

Patients who are allergic to Benzimidazole-class drug are not allowed to use esomeprazole sodium. Patients of rare hereditary fructose intolerance, glucose-galactose absorption dysfunction, sucrase-isomaltase deficiency, and also lactation women are not allowed to use this drug.
Patients who have severe impaired liver or renal function, long-term treatment, malignant warning before using, and pregnant women should use with caution. When any warning symptoms (such as significant weight loss, recurrent vomiting, dysphagia, vomiting blood or black stools) happens, patients should be checked to exclude the possibility of malignant disorders (such as cancer) due to that treatment can worsen the symptoms and delay diagnosis. Long-term user should be regularly monitored.

NURSING MOTHER

The excretion of esomeprazole in milk has not been studied. However, omeprazole concentrations have been measured in breast milk of a woman following oral administration of 20 mg. Because esomeprazole is likely to be excreted in human milk, because of the potential for serious adverse reactions in nursing infants from esomeprazole, and because of the potential for tumorigenicity shown for omeprazole in rat carcinogenicity studies, 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.

OVERDOSAGE

The minimum lethal dose of esomeprazole sodium in rats after bolus administration was 310 mg/kg (about 62 times the human dose on a body surface area basis). The major signs of acute toxicity were reduced motor activity, changes in respiratory frequency, tremor, ataxia and intermittent clonic convulsions.

Storage: - Store below 25 °C protect from light. .
Improper Storage may deteriorate the product
Medicine: - Keep out of reach of children.
Presentation: - Each pack contain Esomeprazole Sodium for Injection (40 mg) in a vial. And (0.9%) Sterile Sodium chloride injection 10 ml

Manufactured by:
AMERICAN REMEDIES
Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
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For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Rx Esomeprazole sodium for Injection

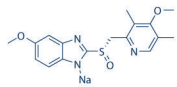
AMERICAN

ESOMECAN 40 Injection

For IV use only
Composition:-
Each Vial Contains:-
Esomeprazole Sodium (Sterile) (Lyophilized)
Eq. to Esomeprazole 40 mg

DESCRIPTION

Esomeprazole Sodium for Injection is a substituted sodium, 5-methoxy-2 (S)-4-mthoxy-3, 5-dimethylpyridin-2-yl)methylsulfiny1 benzimidazol-1-ide., a compound that inhibits gastric acid secretion. Its empirical formula is $C_{17}H_{18}N_3NaO_3S$, with a molecular weight of 367.4 the structural formula is:



Esomeprazole Sodium

PHARMACOLOGY

PHARMACOKINETICS

Esomeprazole is rapidly absorbed after oral doses, with peak plasma levels occurring after about 1 to 2 hours. It is acid labile and an enteric-coated formulation has been developed. Bioavailability of esomeprazole increases with both dose and repeated administration to about 68 and 89% for doses of 20 and 40 mg respectively. Food delays and decreases the absorption of esomeprazole, but this does not significantly change its effect on intragastric acidity. Esomeprazole is about 97% bound to plasma proteins. It is extensively metabolised in the liver by the cytochrome P450 isoenzyme CYP2C19 to hydroxy and desmethyl metabolites, which have no effect on gastric acid secretion. The remainder is metabolised by the cytochrome P450 isoenzyme CYP3A4 to esomeprazole sulfone. With repeated dosage, there is a decrease in first-pass metabolism and systemic clearance, probably caused by an inhibition of the CYP2C19 isoenzyme. However, there is no accumulation during once daily use. The plasma elimination half-life is about 1.3 hours. Almost 80% of an oral dose is eliminated as metabolites in the urine, the remainder in the faeces.

METABOLISM

Esomeprazole is extensively metabolized in the liver by the cytochrome P450 (CYP) enzyme system. The metabolites of esomeprazole lack antisecretory activity. The major part of esomeprazole's metabolism is dependent upon the CYP2C19 isoenzyme, which forms the hydroxy and desmethyl metabolites. The remaining amount is dependent on CYP3A4 which forms the sulphone metabolite. CYP2C19 isoenzyme exhibits polymorphism in the metabolism of esomeprazole, since some 3% of Caucasians and 15-20% of Asians lack CYP2C19 and are termed Poor Metabolizers. At steady state, the ratio of AUC in Poor Metabolizers to AUC in the rest of the population (Extensive metabolizers) is approximately 2.

Following administration of equimolar doses, the S- and R-isomers are metabolized differently by the liver, resulting in higher plasma levels of the S- than of the R-isomer.

EXCRETION

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

DRUG INTERACTIONS

Esomeprazole sodium can reduce the absorption of ketoconazole and itraconazole. When combined with the product, we should reduce the dosages of drugs metabolized by the enzyme CYP2C19 such as diazepam, citalopram, imipramine, clomipramine and phenytoin. When combined with the product or stop using this product, we should also monitor the plasma concentrations of phenytoin.
No interaction between the product and the amoxicillin, quinidine or warfarin was observed. No need for dose adjustment when combined with clarithromycin.
There is not too much clinical information of excess taking drug. But a single dose of 80 mg of this product has no adverse reactions. This product has no special antidote.

ADVERSE EFFECTS

Common adverse reactions (incidence of 1% to 10%) include headache, abdominal pain, diarrhea, gastrointestinal disorders, flatulence, nausea and vomiting, and constipation. Other adverse reactions (incidence of 0.1% to 1%) include dermatitis, itching, hives, dizziness, and dry mouth.

USES AND ADMINISTRATION

The recommended adult dose is either 20 or 40 mg esomeprazole given once daily by intravenous injection (no less than 3 minutes) or intravenous infusion (10 to 30 minutes).