For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

℞ Pantoprazole for Injection IP

PANTRAMAX™ IV

Lyophilized Powder

Composition :
Each vial contains :
Pantoprazole Sodium I.P.
Eq. to Pantoprazole 40 mg
(A Sterile Lyophilized Powder)

Dosage Form/s
Powder for injection 40 mg

Pharmacology

Pharmacodynamics

Pantoprazole is a proton pump inhibitor (PPI) that suppresses the final step in gastric acid production by covalently binding to the (H^+,K^+)-ATPase enzyme system at the secretory surface of the gastric parietal cell. This effect leads to inhibition of both basal and stimulated gastric acid secretion irrespective of the stimulus. The binding to the (H^+,K^+)-ATPase results in a duration of antisecretory effect that persists longer than 24 hours for all doses tested.

Pharmacokinetics

Pantoprazole peak serum concentration (C_{max}) and area under the serum concentration-time curve (AUC) increase in a manner proportional to intravenous doses from 10 mg to 80 mg. Pantoprazole does not accumulate and its pharmacokinetics are unaltered with multiple daily dosing. Following the administration of Pantramax IV the serum concentration of pantoprazole declines biexponentially with a terminal elimination half-life of approximately one hour. In extensive metabolizers with normal liver function receiving a 40 mg dose of pantoprazole i.v. for injection by constant rate over 15 minutes, the peak concentration (C_{max}) is 5.52 μg/mL and the total area under the plasma concentration versus time curve (AUC) is 5.4 μg.hr/mL. The total clearance is 7.6-14.0 L/h and the apparent volume of distribution is 11.0-23.6 L, distributing mainly in extracellular fluid. The serum protein binding of pantoprazole is about 98%, primarily to albumin. Pantoprazole is extensively metabolized in the liver through the cytochrome P450 (CYP) system. The main metabolic pathway is demethylation, by CYP2C19, with subsequent sulfation; other metabolic pathways include oxidation by CYP3A4. After administration of a single intravenous dose of ^{14}C-labeled pantoprazole to healthy ,normal metabolizer subjects, approximately 71% of the dose was excreted in the urine with 18% excreted in the feces through biliary excretion. There was no renal excretion of unchanged pantoprazole.

Indications

- Pantramax IV is indicated for short-term treatment (7 to 10 days) of patients with gastroesophageal reflux disease (GERD) and a history of erosive esophagitis.
- Pantramax IV is indicated for the treatment of pathological hypersecretory conditions associated with Zollinger-Ellison Syndrome or other neoplastic conditions.

Dosage and Method of Administration

No dosage adjustment is necessary in patients undergoing hemodialysis.

Treatment of Gastroesophageal Reflux Disease Associated With a History of Erosive Esophagitis : The recommended adult dose is 40 mg pantoprazole given once daily by intravenous infusion for 7 to 10 days.

Pathological Hypersecretion Associated with Zollinger-Ellison Syndrome

The recommended adult dosage is 80 mg q12h. The frequency of dosing can be adjusted to individual patient needs based on acid output measurements. In those patients who need a higher dosage, 80 mg q8h is expected to maintain acid output below 10 mEq/h.

Daily doses higher than 240 mg or administered for more than 6 days have not been studied. Transition from oral to I.V. and from I.V. to oral formulations of gastric acid inhibitors should be performed in such a manner to ensure continuity of effect of suppression of acid secretion. Patients with Zollinger-Ellison Syndrome may be vulnerable to serious clinical complications of increased acid production even after a short period of loss of effective inhibition.

Contraindications

Pantramax IV is contraindicated in patients with known hypersensitivity to the formulation.

Warning and Precautions

Prior to the treatment of gastric ulcer, the possibility of malignancy should be excluded as treatment with pantoprazole may alleviate the symptoms of malignant ulcers and can thus delay diagnosis.In patients with renal impairment or in patients undergoing hemodialysis, no dosage adjustment is necessary. No dosage adjustment is needed in patients with mild to severe hepatic impairment.

Pregnancy & Lactation

During pregnancy, pantoprazole should not be used unless the benefit exceeds the potential risk. There is no information about the safety of pantoprazole during breast feeding in humans. During breast feeding, pantoprazole should not be used unless the benefit exceeds potential risk.

Drug interactions

No clinically relevant drug interactions have been reported so far. As compared to omeprazole, pantoprazole has a low affinity for the hepatic cytochrome P450 enzyme system. There was no induction of the P450-system when tested after chronic administration with antipyrine as a marker. Also, no inhibition of metabolism was observed after concomitant administration of pantoprazole with either antipyrine, diazepam, phenytoin, carbamazepine, nifedipine, theophyline, digoxin or oral contraceptives. Concomitant administration of pantoprazole with warfarin has no influence on warfarin's effects on coagulation factors. Coadministartion with other antacids does not lead to any interaction.

Side effects:

Treatment with pantoprazole can occasionally lead to headache or diarrhoea.Rarely nausea, stomach complaints, flatulence,skin eruption,itches and fainting may occur. Individual cases of edema formation,fever,thrombophlebitis,depression and blurred vision have been reported.

Overdosage:

There are no known symptoms overdosage in man, However, pantoprazole is very specific in action and no particular problems are anticipated. Doses of up to 240 mg i.v. were administered without adverse effects. As pantoprazole is excessively protein bound, it is not readily dialysable. Apart from symptomatic and supportive treatment , no specific therapeutic recommendation can be made.

Reconstitution:

The content of the vial needs to be reconstituted with 10 ml normal saline solution before injection. The recommended dose of pantoprazole should be administered either by slow i.v. injection or i.v. infusion over 2-15 minutes.For i.v. infusion, the ready- to- use solution should be prepared as described for i.v. injection. The ready-to-use solution should then be further diluted with 90 ml normal saline solution or 90 ml of 5% glucose solution or 10% glucose solution. The resulting potency of diluted solution is 0.4 mg/ml of pantoprazole. As with all parenteral admixtures, the reconsitituted or further diluted solution should be examined for change in colour, precipitation, haziness (or) leakage, the unused portion should be discarded. The reconstituted solution must be used within 6 hours of prepation.

Storage : Store protected from light and moisture, at a temperature not exceeding 25°C.

Keep all medicines out of reach of children.

Presentation: Vial of Pantoprazole 40 mg with 10 ml Sodium chloride inj. IP 0.9 % w/v.

Manufactured in India by:
Protech Telelinks
(A WHO-GMP Certified Co.)
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windlas

Marketed in India by :
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