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

Pantoprazole for Injection

Pantocid i.v.

Description :
White to off white lyophilized cake in 10 ml colourless tubular glass vial with grey rubber stopper and blood red color flip off aluminium seal.

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Reconstituted Solution Appearance:
With 0.9% w/v sodium chloride solution: Clear colourless solution
With 5% dextrose solution: Clear colourless solution

Composition :
Each vial contains Pantoprazole Sodium Sesquihydrate equivalent to Pantoprazole 40mg as lyophilized powder.

Clinical Pharmacology :
Pantoprazole is a proton pump inhibitor, i.e., it inhibits specifically and dose proportionally the gastric H 1K - ATPase enzyme which is responsible for acid secretion in the parietal cells of the stomach.

Mechanism of Action :
Pantoprazole is a substituted benzimidazole which accumulates in the acidic environment of the parietal cells after absorption. There it is converted into the active form, a cyclic sulphonamide, which binds to the H^+/K^+ ATPase, thus inhibiting the proton pump and causing potent long-lasting suppression of basal and stimulated gastric acid secretion. As Pantoprazole acts distal to the receptor level, it can inhibit gastric acid secretion irrespective of the nature of the stimulus (acetylcholine, histamine or gastrin). Pantoprazole exerts its full effect only in a strongly acidic environment (pHc3), remaining mostly inactive at higher pH values.

Pharmacokinetics :
Pantoprazole shows linear pharmacokinetics. Pharmacokinetics do not vary after single or repeated administration. The plasma kinetics of Pantoprazole is linear after both oral and intravenous administration.

The total serum clearance of Pantoprazole is approximately 0.1 L/h/kg. The apparent volume of distribution is approximately 0.15 L/kg.

Pantoprazole's plasma protein binding is about 98%. The drug is almost exclusively metabolised in the liver. Renal elimination represents the major route of excretion (about 80%) for the metabolites of Pantoprazole; the rest are excreted in the faeces. The main metabolite in both the plasma and urine is desmethylpantoprazole which is conjugated with the Sulphate. The half-life of main metabolites (about 1.5 hours) is not much different than that of Pantoprazole.

The pharmacokinetics of Pantoprazole are not modified to any significant extent by renal impairment. But its metabolism and elimination may be impaired in patients with hepatic dysfunction.

Indication :
Pantocid I.V. is indicated for short term use for symptomatic improvement and healing of gastrointestinal diseases which require a reduction in acid secretion:
- Duodenal ulcer,
- Gastric ulcer
- Moderate and severe reflux oesophagitis
- Zollinger-Ellison syndrome and other pathological hypersecretory conditions.

Contra-indications :
Hypersensitivity to any of the constituents.

Warnings and Precautions:
It is an alternative in patients for whom oral administration of Pantoprazole is not indicated. 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.

The diagnosis of an inflammation of the oesophagus should be endoscopically confirmed. The liver enzyme values should be monitored. The treatment should be discontinued following the rise in liver enzymes.

Pantoprazole does not affect the ability to drive and use machines.

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 the potential risk.

Drug Interactions:
As with other acid secretion inhibitors, changes made in absorption may be observed when drugs whose absorption is pH dependent, e.g., ketoconazole, are taken concomitantly. Although studies have shown that Pantoprazole has no significant effect

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on cytochrome P450, an interaction of pantoprazole with other drugs or compounds which are metabolized using the same enzyme system cannot be excluded.
No clinically significant interactions were observed with a number of drugs including carbamazepine, caffeine, diazepam, diclofenac, digoxin, ethanol, glibenclamide, metoprolol, nifedipine, phenprocoumon, phenytoin, theophylline, warfarin, oral ontraceptive and concomitantly administered antacids.

Side effects:
Treatment with pantoprazole can occasionally lead to headache or diarrhoea. Rarely nausea/vomiting, abdominal pain, flatulence, constipation, allergic reactions such as skin rash and pruritus may occur. Individual cases of oedema, blurred vision, fever, dizziness, thrombophlebitis, depression or myalgia - subsiding after termination of therapy have been reported.

Overdosage:
There are no known symptoms of overdosage in human. 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 recommendations can be made.
Dosage:
The intravenous administration of **Pantocid I.V.** is recommended only if oral application is not appropriate.

For the long-term Management of Zollinger-Ellison-Syndrome and Other Pathological Hypersecretory conditions *t*he recommended daily dose at the beginning of the treatment is 80mg **Pantocid I.V.**. Thereafter, the dosage can be titrated up or down as needed using measurements of gastric acid secretion to guide. With dose above 80 mg daily, the dose should be divided and given twice daily. A temporary increase of dosage above 160 mg Pantoprazole is possible but should not be applied longer than the required for adequate acid control.

In case rapid acid control is required, a starting dose of 2x 80 mg **Pantocid I.V.** is sufficient to manage a decrease of acid output into the target range (<10 mEq/hr) within 1 hr in the majority of the patients. Transition from **Pantocid I.V.** to the oral formulation of **Pantocid** should be performed as soon as it is clinically justified.

The recommended intravenous dosage is one vial (40mg Pantoprazole) **Pantocid I.V.** per day.

Instructions and use/handling :
A ready-to-use solution is prepared by injecting 10 ml of physiological sodium chloride solution into the vial containing the dry substance. This solution may be administered directly or may be administered after mixing with 100 ml physiological sodium chloride solution or 5% glucose. **Pantocid I.V.** should not be prepared or mixed with solvents other than those sated. The solution should have a pH of 9.

After preparation the solution must be used within 12 h.
From a microbiological point of view the product should be used immediately. If not used immediately, in-use storage times & condition prior to use are the responsibility of the user and would normally not be longer than 12 hours at not more than 25°C.

The drug should be administered intravenously over 2-15 minutes.

Type and Duration of treatment :
As soon as oral therapy is possible, treatment with **Pantocid I.V.** should be discontinued and 40 mg Pantoprazole tabs should be administered instead.

Incompatibilities
Pantocid I.V., Powder for Injection is not compatible with acidic solutions.

Storage :
Store below 30°C, protected from light.

Shelf Life :
2 Years.

Presentation :
Pantocid I.V. is available in strength of 40mg in vial.

Date of revision: November, 2019

Manufacturer:

SUN PHARMA

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