4.75”

7.15”

Pantosol 40mg Injection

(Pantoprazole Sodium)

پینٹوسول ۴۰ ملی گرام انجیکشن

(پینٹوپرازول سوڈیم)

COMPOSITION:

PANTOSOL Injection 40mg

Each vial contains:

Pantoprazole (as sodium sesquihydrate)
powder for solution for injection.....40mg

(BP Specifications)

DESCRIPTION:

PANTOSOL contains pantoprazole as an active ingredient. Pantoprazole is a proton pump inhibitor and causes long lasting inhibition of gastric acid secretion and used in the treatment of peptic ulcers.

MODE OF ACTION:

Pantoprazole is a proton pump inhibitor (PPI) that suppresses the final step in gastric acid production by forming a covalent bond to two sites of the (H^+,K^+ - ATPase) enzyme system at the secretory surface of the gastric parietal cell. This effect is dose- related and leads to inhibition of both basal and stimulated gastric acid secretion irrespective of the stimulus.

INDICATIONS:

• For the eradication of H. pylori in patients with peptic ulcer (in combination with antibiotics and drugs indicated for the removal of H. pylori), gastric ulcers, duodenal ulcers, moderate to severe reflux esophagitis, Zollinger Ellison syndrome.

• Pantoprazole injectable is indicated for short term treatment (7-10 days) of patients with gastroesophageal reflux disease (GERD) and a history of erosive esophagitis.

• Pantoprazole injection is indicated for the treatment of pathological hypersecretory conditions associated with Zollinger Ellison syndrome or other neoplastic conditions.

DOSAGE & ADMINISTRATION:

➢ **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 7-10 days. Safety and efficacy of Pantoprazole I.V. for injection as a treatment of patients with GERD and a history of erosive esophagitis for more than 10 days has not been demonstrated.

• **Fifteen minute infusion:**

Pantoprazole I.V. for injection is to be reconstituted with 10 ml of 0.9% sodium chloride injection USP, further to be mixed with 100 ml of 5% dextrose injection, USP, 0.9% sodium chloride injection USP or ringer's lactate injection USP to a final concentration of approximately 0.4 mg/ml.

The reconstituted solution may be stored for upto 6 hours at room temperature. Both the reconstituted solution and the admixed solution do not need to be protected from light.

Pantoprazole injection admixtures need to be administered intravenously over a period of approximately 15 minutes at a rate of approximately 7ml/min.

• **Two minute infusion:**

Pantoprazole I.V. for injection is to be reconstituted with 10 ml of 0.9% sodium chloride injection USP, to a final concentration of approximately 4 mg/ml. The reconstituted solution may be stored for upto 24 hours at room temperature prior to IV Infusion and does not need to be protected from light.

Pantoprazole injection needs to be administered intravenously over a period of 2 minute.

➢ **Pathological hypersecretion associated with Zollinger- Ellison Syndrome:**

The dosage of Pantoprazole injection in patients with pathological hypersecretory conditions associated with Zollinger Ellison syndrome or other neoplastic conditions varies with individual patients. The recommended Intravenous adult dosage is 80 mg 12 hourly.

The dosing frequency can be adjusted to individual patient needs based on the acid output measurements. Those patients who need higher dosage, 80mg Intravenously every 8 hour is expected to maintain acid output below 10mEq/h. Daily doses higher than 240 mg or administered for more than 6 days have not been studied.

Switching from oral to I.V. and from I.V. to oral formulations of gastric acid inhibitors should be performed in a manner so that the effect of acid secretion remains suppressed.

Patients of Zollinger Ellison syndrome may be vulnerable to clinical complications of increased acid production after a short period of loss of effective inhibition.

• **Fifteen minute infusion:**

Each Pantoprazole vial needs to be reconstituted with 10 ml of 0.9% sodium chloride injection USP. The contents of two vials are combined and further diluted with 80 ml of 5% dextrose injection USP, 0.9% sodium chloride injection USP, or ringer's lactate injection USP, to a total volume of 100 ml with a final concentration of approximately 0.8 mg/ml.

The reconstituted solution may be stored for upto 6 hours at room temperature.

Protection from light is not required for both solutions.

Pantoprazole injection should be administered intravenously over a period of 15 minutes at a rate of approximately 7ml/min.

• **Two minute infusion:**

Pantoprazole I.V. for injection is to be reconstituted with 10 ml of 0.9% sodium chloride injection USP, per vial to a final concentration of approximately 4 mg/ml.

The reconstituted solution may be stored for upto 24 hours at room temperature does not need protected from light.

Total volume from both the vials should be administered intravenously over a period of 2 minutes.

• **Technique to Prepare:**

Add 0.9% sodium chloride into the lyophilized powder of Pantoprazole vial and mix thoroughly. Transfer the dissolved solution into the infusion bag.

➢ **Method of Reconstitution**

• **Injection**

Reconstitute the dry powder by adding 10ml of 0.9% w/v sodium chloride solution for injection and shake vigorously. Reconstituted solution should be

administered within 24 hours after preparation.

• **Infusion**

Reconstitute the dry powder by adding 10ml of 0.9% w/v sodium chloride solution for injection and further dilute it with 100ml of 5% dextrose injection, 0.9% sodium chloride injection or lactate Ringer injection.

PHARMACOKINETICS:

• **Absorption**

Pantoprazole is rapidly absorbed and the maximal plasma concentration is achieved even after one single 40mg oral dose. On average at about 2.5 h the maximum serum concentrations of about 2 - 3 µg/ml are achieved, and these values remain constant after multiple administration.

Pharmacokinetics do not vary after single or repeated administration. In the dose range of 10 to 80mg, the plasma kinetics of pantoprazole are linear after intravenous administration.

Peak serum concentrations Cmax increases proportionally to intravenous doses from 10mg to 80mg.

Pantoprazole injection administration shows a reduction in serum concentration with terminal elimination half-life of approximately one hour.

In CYP2C19 extensive metabolizers with normal liver function receiving 40 mg dose over a constant rate of 15 minutes, the peak plasma concentration is 5.52±1.42mcg/ml. The total clearance is 7.6-14 liters/hr and volume of distribution is 11-23.6 L.

Distribution:

Pantoprazole's serum protein binding is about 98 %, primarily to albumin. Volume of distribution is 11-23.6L.

Metabolism:

Pantoprazole is extensively metabolized in the liver through the cytochrome P 450 system. The main pathway is demethylation by CYP2C19, with sulphation. Pantoprazole metabolites have no significant pharmacologic activity.

Elimination:

Approximately 71% of the dose is excreted via urine and 18% in the feces via biliary excretion.

PRECAUTIONS:

• Pantosol should be used with caution in patients with liver or kidney disease or of any drug allergy.

• It should be used only when clearly needed during pregnancy. Avoid use during lactation.

• The elderly may be especially sensitive to this drug, so use with caution.

SIDE EFFECTS:

Safety profile with Pantoprazole Injectable:

Intravenous Pantoprazole has been studied in clinical trials in patients with GERD, erosive esophagitis, Zollinger Ellison syndrome and patients involved in other disorders.

Side effects occurring in >1% of patients treated with I.V. Pantoprazole include abdominal pain, headache, reaction at injection site, constipation, dyspepsia, nausea, diarrhea, insomnia, dizziness and rhinitis, leukopenia, hyponatremia, urticaria etc.

DRUG INTERACTIONS:

Pantoprazole is metabolized through the cytochrome P450 system, primarily CYP2C19 and CYP3A4 isoenzymes and subsequently undergoes Phase II conjugation. Based on the studies evaluating possible interactions of Pantoprazole with other drugs, no dose adjustment is needed with concomitant use of the following: theophylline, cisapride, antipyrine, caffeine, carbamazepine, diazepam, diclofenac, naproxen, piroxicam, digoxin, ethanol, glyburide, oral contraceptives like, levonorgestrel/ethinyl estradiol, metoprolol, nifedipine, phenytoin, warfarin, midazolam, metronidazole or amoxicillin. Clinically same interactions with other drugs with identical metabolic pathways are not expected. When co-administered with Pantoprazole, adjustment of the dosage of Pantoprazole or such drugs may not be necessary.

No interaction seen with concomitant administered antacids.

There are reports of increased INR and prothrombin time in patients receiving proton pump inhibitors, including Pantoprazole and warfarin concomitantly. Increases in INR and prothrombin time can lead to abnormal bleeding and death. Due to profound and long lasting inhibition of gastric acid secretion, Pantoprazole may interfere with absorption of drugs where gastric pH is an important determinant of their bio-availability like, ketoconazole, ampicillin, esters and iron salts.

CONTRAINDICATIONS:

Pantoprazole IV is contraindicated in patients with known hypersensitivity to any component of the formulation.

Use in Pregnancy

Pregnancy category B.

The trials subjected to animals are not always predicted of human response. There are no adequate and well controlled studies in pregnant females; therefore this drug should only be used in pregnancy if at all clearly needed.

Use in Nursing Mothers

Pantoprazole excretion in human milk has been detected in a study of a single nursing mother after 40 mg oral dose. Clinical relevance of this finding is not known. Many drugs which are excreted in human milk have the potential for serious adverse reactions in nursing infants. Based on the potential for tumorigenicity shown for Pantoprazole in rodent carcinogenicity studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the benefit of the drug to the mother.

STORAGE&INSTRUCTIONS:

Store between 15-25°C. Protect from heat, sunlight & moisture. Do not freeze.Keep away from the reach of children.

To be sold on the prescription of a registered medical practitioner only.

HOW SUPPLIED

PANTOSOL Injection 40mg

1vial + 10ml 0.9% w/v sodium chloride solution for injection.

خوراک وطریقہ استعمال:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔

دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

Manufactured by:
PHARMASOL
PRIVATE LIMITED
Plot # 549, Sundar Industrial Estate, Lahore, Pakistan.