Pansos

Pantoprazole

COMPOSITION

Pansos 20 Tablet: Each enteric-coated tablet contains Pantoprazole Sodium Sesquihydrate USP equivalent to Pantoprazole 20 mg.
Pansos 40 Tablet: Each enteric-coated tablet contains Pantoprazole Sodium Sesquihydrate USP equivalent to Pantoprazole 40 mg.
Pansos 40 IV Injection: Each vial contains sterile lyophilized cake or powder of Pantoprazole Sodium Sesquihydrate USP equivalent to Pantoprazole 40 mg and each ampoule contains 10 ml of 0.9% Sodium Chloride BP Injection.

PHARMACOLOGY

Pansos (Pantoprazole) is a proton pump inhibitor that suppresses the final step in gastric acid production by covalently binding to the H^+/K^+ATPase enzyme system at the surface of the gastric parietal cell. This effect leads to inhibition of both basal and stimulated gastric acid secretion, irrespective of the stimulus that persists longer than 24 hours.

INDICATIONS

Pansos is indicated for the following:
- Duodenal ulcers, Gastric ulcers.
- Short-term treatment of erosive esophagitis associated with gastroesophageal reflux disease (GERD).
- Maintenance of healing of erosive esophagitis.
- Pathological hypersecretory conditions including Zollinger-Ellison (ZE) syndrome.
- Prevention of gastroduodenal ulcers induced by NSAIDs.

DOSAGE AND ADMINISTRATION

Tablets

Short-term treatment of erosive esophagitis associated with GERD: For adults, 40 mg once daily for up to 8 weeks. For children (≥5 years), 20 mg (≥ 15 kg to < 40 kg) or 40 mg (≥ 40 kg) once daily for up to 8 weeks.
Maintenance therapy for healing of erosive esophagitis: For adults, 40 mg once daily. Controlled studies did not extend beyond 12 months.
Pathological hypersecretory conditions including Zollinger-Ellison syndrome: For adults, 40 mg twice daily.
Swallow the tablet whole, with or without food in the stomach. Concomitant administration of antacids does not affect the absorption of tablets.

IV INJECTION/ INFUSION

GERD associated with EE and gastric/ duodenal ulcers: 40 mg once daily by intravenous route for 7 to 10 days.
Pathological hypersecretion conditions, including ZE syndrome: 80 mg every 12 hours by intravenous route. If a higher dosage is needed, 80 mg IV every 8 hours.

Preparation, Administration and Storage:
For a 40 mg IV injection dose, reconstitute the vial's content with 10 ml 0.9% sodium chloride injection and then withdraw the dose to administer through an intravenous route for at least 2 minutes. To administer intravenously over 15 minutes (7 ml/ min), the reconstituted solution of each vial is admixed to 5% Dextrose injection, or 0.9% Sodium Chloride Injection or Lactated Ringer's Solution to make it 100 ml diluted solution. For an 80 mg dose, a proportionate amount of vial content should be used.

Inspect the reconstituted solution visually for particulate matter and discoloration prior to and during administration. Administer it intravenously through a dedicated line or a Y-site. Flush the intravenous line before and after administration of Pantoprazole with either 5% Dextrose Injection, 0.9% Sodium Chloride Injection, or Lactated Ringer's Solution.

This initial reconstituted solution may be stored at room temperature for up to 6 hours. The further diluted solution may be stored at room temperature and must be used within 24 hours from the time of initial reconstitution. Do not freeze and no need to be protected from light.

CONTRAINDICATIONS

It is contraindicated in patients with hypersensitivity to any component of the formulation or any substituted benzimidazole.

WARNING AND PRECAUTION

Gastric Malignancy: In adults, symptomatic response to therapy with **Pansos** IV does not preclude the presence of gastric malignancy. So, consider additional follow-up and diagnostic testing.
Injection Site Reactions: Thrombophlebitis is associated with the administration of intravenous Pantoprazole.
Potential Exacerbation of Zinc Deficiency: Consider zinc supplementation in patients who are prone to zinc deficiency. Caution should be used when other EDTA containing products are also co-administered intravenously.
Acute Tubulointerstitial Nephritis: Discontinue treatment and evaluate patients.
Clostridium difficile-Associated Diarrhea: PPI therapy may be associated with increased risk.
Bone Fracture: Long term and multiple daily dose PPI therapy may be associated with an increased risk for osteoporosis related fractures of the hip, wrist or spine.
Severe Cutaneous Adverse Reactions: Discontinue at the first signs or symptoms.
Cutaneous and Systemic Lupus Erythematosus: Discontinue **Pansos** IV and refer to specialist for evaluation.
Hepatic Effects: Elevations of transaminases observed.
Hypomagnesemia and Mineral Metabolism: Reported rarely with prolonged treatment with PPIs.
Fundic Gland Polyps: Risk increases with long term use, especially beyond one year. Use the shortest duration of therapy.

SIDE EFFECTS

The most common side effects (>2%) are headache, diarrhea, nausea, abdominal pain, vomiting, flatulence, dizziness, and arthralgia.

USE IN PREGNANCY AND LACTATION

As a precautionary measure, it is preferable to avoid the use of Pantoprazole during pregnancy.
It should only be used during lactation if the benefit clearly outweighs the potential risks.

USE IN CHILDREN AND ADOLESCENTS

The safety and effectiveness of **Pansos** for pediatric uses other than EE have not been established.

DRUG INTERACTIONS

Antiretrovirals (Rilpivirine, Atazanavir and Nelfinavir): Concomitant use with Pantoprazole is contraindicated.
Warfarin: Concomitant use may increase INR and prothrombin time.
Methotrexate: Concomitant use may elevate and prolong serum concentrations of methotrexate and/or its metabolite.
Iron salts, Erlotinib, Dasatinib, Nilotinib, Mycophenolate Mofetil, Ketoconazole/Itraconazole: Pantoprazole can reduce the absorption of other drugs due to its effect on reducing intragastric acidity.
Interactions with Investigations of Neuroendocrine Tumors: The increased CgA level may cause false positive results in diagnostic investigations for neuroendocrine tumors.
False Positive Report in Urine Tests for THC: There have been reports of false positive urine screening tests for tetrahydrocannabinol (THC) in patients receiving PPIs.

OVERDOSAGE

In case of overdosage, treatment should be symptomatic and supportive.

STORAGE

Store below 30°C temperature in a cool & dry place. Protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Pansos 20 Tablet: Each box contains 50 tablets in Alu-Alu blister pack.
Pansos 40 Tablet: Each box contains 50 tablets in Alu-Alu blister pack.
Pansos 40 IV Injection: Each combipack contains one vial containing sterile lyophilized cake or powder of Pantoprazole Sodium Sesquihydrate USP equivalent to Pantoprazole 40 mg and one ampoule of 10 ml 0.9% Sodium Chloride BP Injection. It also contains a sterile disposable syringe (10 ml).

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NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.