Piramal Critical Care is a world leader in inhaled anesthetics, intrathecal therapy, and generic injectables, with a strong presence in more than 100 countries.

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Piramal Critical Care

Pantoprazole Sodium for Injection, USP

For Intravenous Infusion Only

Available through the wholesaler or distributor of your choice:

10 single-dose vials per carton, saleable unit NDC # 66794-258-41

WHOLESALER/DISTRIBUTOR	CATALOG NUMBER
ABC Wholesale	10283685
Cardinal	5873476
McKesson	2852614
Morris and Dickson	314203

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Indication and Important Safety Information you should know about Pantoprazole Sodium for Injection, USP

DESCRIPTION:
Pantoprazole sodium for injection is a proton pump inhibitor (PPI) for INTRAVENOUS use only after reconstitution. Pantoprazole 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 [20mg to 120mg].

Qualitative and Quantitative Composition: Pantoprazole sodium for injection is supplied in a single-dose vial as a white to off white freeze-dried powder for reconstitution containing 40 mg of pantoprazole.

Pharmaceutical Form: Powder for solution for injection.

Therapeutic Indications: Pantoprazole sodium for injection is indicated for short-term treatment (7 to 10 days) of adult patients with gastroesophageal reflux disease (GERD) and a history of erosive esophagitis (EE). Safety and efficacy of pantoprazole sodium for injection as a treatment of patients with GERD and a history of EE for more than 10 days have not been demonstrated.

Dosage and Administration: GERD associated with EE: The recommended adult dosage is 40 mg given once daily by intravenous infusion for 7 to 10 days.

Pathological Hypersecretion Conditions, including ZE (Zollinger-Ellison) Syndrome: The recommended adult dosage is 80 mg administered every 12 hours by intravenous infusion. For information on how to adjust dosing for individual patient needs, see the full prescribing information.

Administration: Only for intravenous infusion. The intravenous infusion can be administered over 2 minutes or 15 minutes. For information on how to prepare and administer for each indication, see the full prescribing information. **[For additional information, please refer to the full prescribing information]**

CONTRAINDICATIONS:

Patients with a known hypersensitivity to any component of the formulation or to substituted benzimidazoles. Patients receiving rilpivirine-containing products.

WARNINGS AND PRECAUTIONS:

Gastric Malignancy: In adults, symptomatic response to therapy with pantoprazole sodium for injection does not preclude the presence of gastric malignancy 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 of severe cutaneous adverse reactions or other signs of hypersensitivity and consider further evaluation. Cutaneous and Systemic Lupus Erythematosus: Mostly cutaneous; new onset or exacerbation of existing disease; discontinue pantoprazole sodium for injection 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. **[For additional information regarding, please refer to the full prescribing information]**

Drug Interactions: Monitoring and interventions like modified dosages would be required in drugs like Antiretroviral, Warfarin, Clopidogrel, Methotrexate, Drugs, dependent on Gastric pH for absorption [like iron salts, erlotinib, dasatinib, nilotinib, mycophenolate mofetil, ketoconazole/ itraconazole], interactions with investigations of Neuroendocrine Tumors and urine tests for tetrahydrocannabinol. **[For additional information regarding, please refer to the full prescribing information]**

Usage in Pregnancy: Available data from published observational studies did not demonstrate an association of major malformations or other adverse pregnancy outcomes with pantoprazole. **Lactation:** Pantoprazole has been detected in breast milk of a nursing mother after a single 40 mg oral dose of pantoprazole. There were no effects on the breastfed infant (see data). There is no data on pantoprazole effects on milk production. **Usage in Children:** The safety and effectiveness of pantoprazole sodium for injection have not been established in pediatric patients. **[For additional information regarding, please refer to the full prescribing information]**

ADVERSE REACTIONS: Most common adverse reactions (>2%) are: headache, diarrhea, nausea, abdominal pain, vomiting, flatulence, dizziness, and arthralgia. **[For additional information, please refer to the full prescribing information]**

PREPARATION OF SOLUTION:

For 15-minute infusion: Reconstitute each pantoprazole sodium vial with 10 mL of 0.9% Sodium Chloride Injection, USP. Combine both vials and dilute with 80 mL of 5% Dextrose Injection or 0.9% Sodium Chloride Injection, USP, or Lactated Ringer's Injection, USP, to reach 100 mL with a final concentration of around 0.8 mg/mL. Visually inspect diluted solution for particulate matter and discoloration before and during administration. Administer intravenously over 15 minutes at a rate of about 7 mL/min. Do not freeze the solution and discard any unused portion. **Storage:** The reconstituted solution may be stored for up to 6 hours at room temperature prior to further dilution. The admixed solution may be stored at room temperature and must be used within 24 hours from the time of initial reconstitution. Both the reconstituted solution and the admixed solution do not need to be protected from light. **For 2-minute Infusion:** Reconstitute pantoprazole sodium for injection with 10 mL of 0.9% Sodium Chloride Injection, USP, per vial to a final concentration of approximately 4 mg/mL. Inspect the diluted pantoprazole sodium for injection solution visually for particular matter and discoloration prior to and during administration. Administer the total volume from both vials intravenously over a period of at least 2 minutes. **Storage:** The reconstituted solution may be stored for up to 24 hours at room temperature prior to intravenous infusion and does not need to be protected from light. **[For additional information, please refer to the full prescribing information]**

HOW SUPPLIED:

Pantoprazole sodium for injection is supplied in a single-dose vial as a white to off-white freeze-dried powder for reconstitution containing 40 mg of pantoprazole.

Pantoprazole sodium for injection is available as follows:

NDC Number: NDC 66794-258-41 **Strength:** 40 mg/vial pantoprazole **Package Size:** 10 vials

Storage and Handling

Store pantoprazole sodium for injection at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Protect from light.

- **Full prescribing information of Pantoprazole Sodium for Injection, USP can be seen at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0696b10c-972b-9dcf-e063-6294a90a1034&audience=consumer**
- **Adverse events should be reported to Piramal Critical Care at http://pcc-chex.force.com/SiteComplaintForm.**
- **You are encouraged to report adverse events of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.**

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