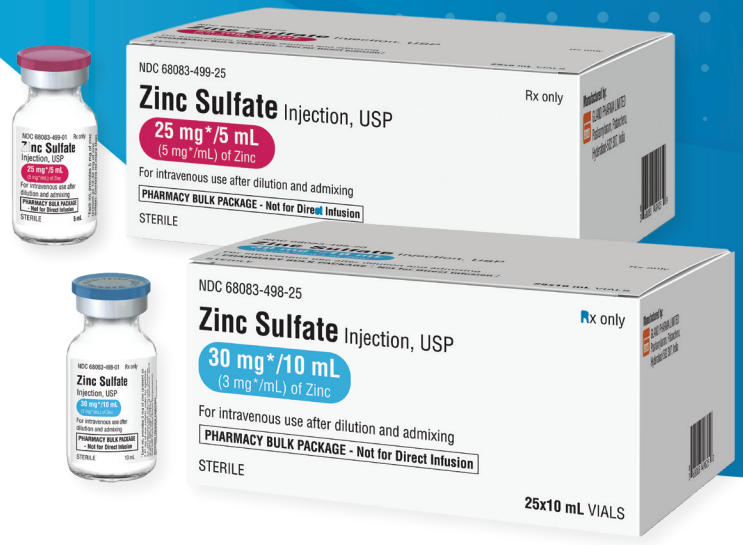
Piramal Critical Care

# ZINC SULFATE FOR INJECTION, USP

## FIRST TO MARKET GENERIC

Piramal's Zinc Sulfate Injection is available through the wholesaler or distributor of your choice.




| Wholesaler / Distributor Name | 25 Multi-Dose Vials in a carton: NDC 68083-499-25 Zinc Sulfate Injection, USP 25 mg/5 mL (5 mg/mL) Catalog Numbers | 25 Multi-Dose Vials in a carton: NDC 68083-498-25 Zinc Sulfate Injection, USP 30 mg/10 mL (3 mg/mL) Catalog Numbers |
|---|---|---|
| AmerisourceBergen | 023942 | 024042 |
| Cardinal | 5794052 | 5794060 |
| McKesson | 2626034 | 2626059 |
| Morris & Dickson | 228338 | 228395 |

### ABBREVIATED PRESCRIBING INFORMATION

#### PRODUCT NAME AND COMPOSITION:

Zinc Sulfate for Injection, an injectable solution.

*Please refer to the Full Prescribing Information (FPI) before prescribing.*

#### INDICATIONS:

Zinc Sulfate is a trace element indicated in adult and pediatric patients as a source of zinc for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

#### DOSAGE AND ADMINISTRATION:

**Important Administration Information**

Zinc Sulfate Injection is not for direct intravenous infusion. Prior to administration, Zinc Sulfate Injection must be transferred to a separate parenteral nutrition container, diluted and used as an admixture in parenteral nutrition solutions.

*See FPI for full details.*

Zinc Sulfate Injection provides 3 mg/mL, or 5 mg/mL of zinc.

Zinc Sulfate Injection in a concentration of 1 mg/mL is recommended for use in pediatric patients, particularly those weighing less than 12 kg.

The dosage of Zinc Sulfate Injection should be individualized, based on the patient's clinical condition, nutritional requirements, and the contribution of oral or enteral zinc intake.

**Adults:** The recommended adult dosage is 3 mg/day for metabolically stable patients, with potential need for higher daily dosage in monitored patients with small bowel fluid loss or excess stool or ileostomy output.

**Pediatrics:** The recommended dosage in pediatric patient's is shown by age and estimated weight. The doses in the table are general recommendations intended for most pediatric patients. However, based on clinical requirements, some patients may require a higher dosage.

| Population | Estimated Weight for Age | Recommended Daily Dosage |
|---|---|---|
| Pediatric Patients | 10 kg and above | 50 mcg/kg (up to 3 mg/day) |
| | 5 kg to less than 10 kg | 100 mcg/kg |
| Term Neonates | 3 kg to less than 5 kg | 250 mcg/kg[1] |
| Preterm Neonates | Less than 3 kg | 400 mcg/kg |

*1. Term neonates have higher requirements in the first 3 months of life*

Monitor zinc concentrations and signs and symptoms of zinc deficiency, especially in pediatric patients, during treatment. Zinc concentrations may vary depending on the assay used and the laboratory reference range. The collections, processing, and storage of the blood samples for zinc analysis should be performed according to the laboratory's sample requirements. Zinc concentrations in hemolyzed samples are falsely elevated due to release of zinc from erythrocytes. The lower end of the reported range in healthy adults in serum is 60 mcg/dL.
*See FPI for full details.*

## CONTRAINDICATIONS:

Known hypersensitivity to zinc.

## WARNINGS AND PRECAUTIONS:

**Pulmonary Embolism due to Pulmonary Vascular Precipitates:** If signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation.

**Vein Damage and Thrombosis:** Solutions with osmolarity of 900 mOsmol/L or more must be infused through a central catheter.

**Aluminum Toxicity:** Increase risk in patients with renal impairment, including preterm infants.

**Monitoring and Laboratory Tests:** Monitor fluid and electrolyte status, serum osmolarity, blood glucose, liver and kidney function, blood count and coagulation parameters throughout treatment.

**Copper Deficiency:** If signs and symptoms develop, interrupt treatment with Zinc Sulfate Injection and check zinc, copper, and ceruloplasmin levels.

**Hypersensitivity Reactions:** If reactions occur, discontinue Zinc Sulfate Injection and initiate appropriate medical treatment.
*See FPI for full details.*

## ADVERSE REACTIONS:

No zinc-related adverse reactions in patients receiving parenteral nutrition solutions containing zinc within the recommended dosage range have been reported.

*See FPI for full details.*

## OVERDOSAGE:

Symptoms of zinc overdosage may include hyperamylasemia, thrombocytopenia, anemia, vomiting and diarrhea. There is no known antidote for acute zinc toxicity. Management of zinc overdosage is supportive care based on presenting signs and symptoms.

*See FPI for full details.*

## HOW SUPPLIED/STORAGE AND HANDLING

- 30 mg/10 mL (3 mg/mL) of zinc in a 10 mL vial.
  (Each mL contains 3 mg of zinc present as 7.41 mg of zinc sulfate and WFI)
- 25 mg/5 mL (5 mg/mL) of zinc in a 5 mL vial.
  (Each mL contains 5 mg of zinc present as 12.32 mg of zinc sulfate and WFI)

Vial closure is not made with natural rubber latex.

Store at 20°C to 25°C (68°F to 77°F), excursions permitted to 15° to 30°C (59° to 86°F)

*See USP Controlled Room Temperature*
*See FPI for full details.*

**To report SUSPECTED ADVERSE REACTIONS, contact Piramal Critical Care at 1-888-822-8431 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

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