ZINC SULFATE- zinc sulfate injection, solution
American Regent, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

CONCENTRATED ZINC SULFATE INJECTION, USP

Rx Only

STERILE, NONPYROGENIC TRACE ELEMENT ADDITIVE FOR INTRAVENOUS USE AFTER DILUTION

(Zinc 5 mg/mL)

DESCRIPTION

Concentrated Zinc Sulfate Injection, USP is a sterile, non-pyrogenic solution intended for use as an additive to solutions for Total Parenteral Nutrition (TPN). Each mL contains Zinc Sulfate (Anhydrous) 12.32 mg, Water for Injection q.s. pH adjusted with Sulfuric Acid. It contains no preservatives. Discard unused portion. It delivers elemental zinc 5 mg per mL.

CLINICAL PHARMACOLOGY

Zinc has been identified as a cofactor for over 70 different enzymes, including alkaline phosphatase, lactic dehydrogenase and both RNA and DNA polymerase. Zinc facilitates wound healing, helps maintain normal growth rates, normal skin hydration and the senses of taste and smell.

Providing zinc during TPN prevents development of the following deficiency symptoms: Parakeratosis, hypogeusia, anorexia, dysosmia, geophagia, hypogonadism, growth retardation and hepatosplenomegaly. At plasma levels below 20 mcg zinc/100 mL, dermatitis followed by alopecia has been reported for TPN patients.

INDICATIONS AND USAGE

Concentrated Zinc Sulfate Injection, USP is indicated for use as a supplement to intravenous solutions given for TPN. Administration helps to maintain plasma levels and to prevent depletion of endogenous stores.

CONTRAINDICATIONS

Concentrated Zinc Sulfate Injection, USP should not be given undiluted by direct injection into a peripheral vein because of the likelihood of infusion phlebitis and the potential to increase renal loss of zinc from a bolus injection.

WARNINGS

This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels

associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

PRECAUTIONS

Administration of zinc in the absence of copper may cause a decrease in serum copper levels. Periodic determination of serum copper as well as zinc are suggested as a guideline for subsequent zinc administration. Zinc is eliminated via the intestine and kidneys. The possibility of retention should be considered in patients with malfunctioning excretory routes.

ADVERSE REACTIONS

The amount of zinc present in Concentrated Zinc Sulfate Injection, USP is very small, symptoms of toxicity from zinc are considered unlikely to occur.

USE IN PREGNANCY

Safety for use in pregnancy has not been established. Use of zinc in women of childbearing potential requires that anticipated benefits be weighed against possible hazards.

DOSAGE AND ADMINISTRATION

Concentrated Zinc Sulfate Injection, USP provides 5 mg zinc/mL. For metabolically stable adults receiving TPN, the suggested intravenous dosage is 2.5 to 4 mg zinc/day. An additional 2 mg zinc/day is suggested for acute catabolic states. For the stable adult with fluid loss from the small bowel, an additional 12.2 mg zinc/liter of small bowel fluid lost, or an additional 17.1 mg zinc/kg of stool or ileostomy output is recommended. Frequent monitoring of zinc blood levels is suggested for patients receiving more than the usual maintenance dosage level of zinc.

For full term infants and children up to 5 years of age, 100 mcg zinc/kg/day is recommended. For premature infants (birth weight less than 1500 g) up to 3 kg in body weight, 300 mcg zinc/kg/day is suggested.

Aseptic addition of Concentrated Zinc Sulfate Injection, USP to the TPN solution under a laminar flow hood is recommended. Zinc is physically compatible with the electrolytes and vitamins usually present in the amino acid/dextrose solution used for TPN.

Parenteral drug products should be inspected visually for particulate matter and discoloration, whenever solution and container permit.

OVERDOSAGE

Symptoms of zinc overdosage resulting from oral ingestion of zinc sulfate in large amounts (30 and 44 grams, respectively) have resulted in death. Symptoms included nausea, vomiting, dehydration, electrolyte imbalances, dizziness, abdominal pain, lethargy and incoordination. Single intravenous doses of 1 to 2 mg zinc/kg body weight have been given to adult leukemic patients without toxic manifestations. Normal plasma levels for zinc vary from approximately 88 to 112 mcg/100 mL. Plasma levels sufficient to produce symptoms of toxic manifestations in humans are not known. Calcium supplements may confer a protective effect against zinc toxicity.

HOW SUPPLIED

Concentrated Zinc Sulfate Injection, USP, 5 mg zinc/mL

NDC 0517-8105-25 5 mL Vials Packed in a box of 25

Store 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).

AMERICAN
REGENT, INC.
SHIRLEY, NY 11967

IN8105
Rev. 1/09
MG #14229

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

PRINCIPAL DISLAY PANEL – 5 mL Carton

CONCENTRATED ZINC SULFATE
INJECTION, USP

Zinc 25 mg/5 mL (5 mg/mL)

Trace Element Additive

NDC 0517-8105-25

25 x 5 mL SINGLE DOSE VIALS

FOR INTRAVENOUS USE AFTER DILUTION

PRESERVATIVE FREE

Rx Only

Each mL contains: Zinc Sulfate (Anhydrous) 12.32 mg, Water for Injection q.s.

pH adjusted with Sulfuric Acid, if necessary. Sterile, nonpyrogenic.

WARNING: DISCARD UNUSED PORTION.

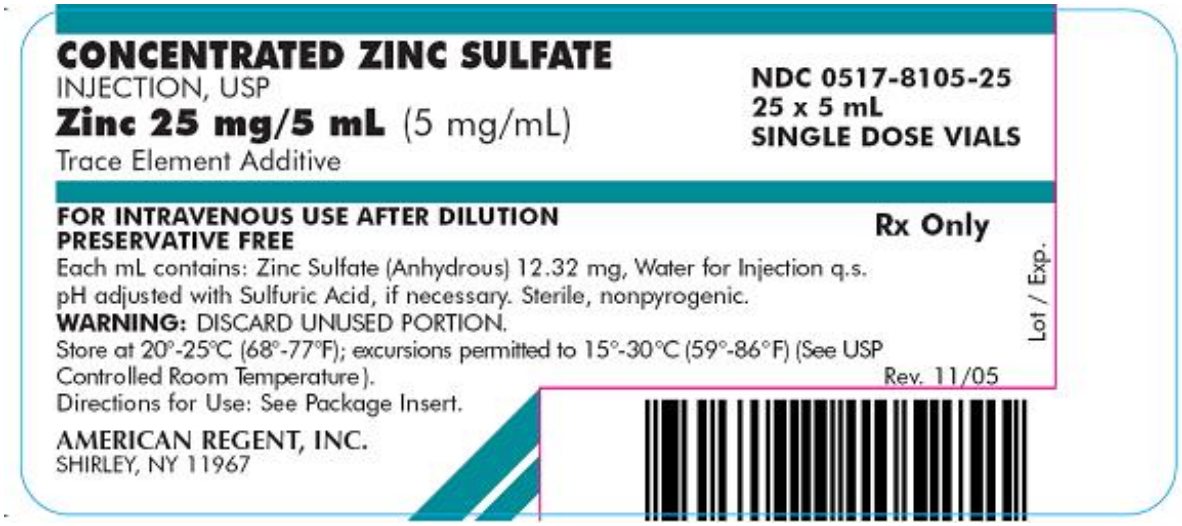
Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) (See USP

Controlled Room Temperature).

Directions for Use: See Package Insert.

AMERICAN REGENT, INC.
SHIRLEY, NY 11967

Rev. 11/05



Serialization Label

ZINC SULFATE zinc sulfate injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0517-8105
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC SULFATE ANHYDROUS (UNII: 0J6Z13X3WO) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SULFURIC ACID (UNII: O40UQP6WCF)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0517-8105-25	25 in 1 TRAY	09/30/1990	
1		5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		09/30/1990	

Labeler - American Regent, Inc. (002033710)

Establishment

Name	Address	ID/FEI	Business Operations
American Regent, Inc.		002033710	ANALYSIS(0517-8105) , MANUFACTURE(0517-8105)

Revised: 12/2019 American Regent, Inc.