MANGANESE SULFATE- manganese 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.

MANGANESE SULFATE INJECTION, USP

Rx Only

STERILE, NONPYROGENIC, TRACE ELEMENT ADDITIVE
FOR IV USE AFTER DILUTION
(MANGANESE 0.1 mg/mL)
PRESERVATIVE FREE

DESCRIPTION

Manganese Sulfate Injection, USP is a sterile, nonpyrogenic solution intended for use as an additive to solutions for Total Parenteral Nutrition (TPN). Each mL contains 0.308 mg of Manganese Sulfate Monohydrate, USP, Water for Injection q.s. pH adjusted with Sulfuric Acid. It delivers elemental manganese 0.1 mg/mL. It is a single dose preservative free vial. Discard any unused portion.

CLINICAL PHARMACOLOGY

Manganese is an activator for enzymes such as polysaccharide polymerase, liver arginase, cholinesterase and pyruvate carboxylase. Providing manganese during TPN prevents development of the following deficiency symptoms: nausea and vomiting, weight loss, dermatitis and changes in growth and color of hair.

INDICATIONS AND USAGE

Manganese Sulfate Injection, USP is indicated for use as a supplement to intravenous solutions given for Total Parenteral Nutrition (TPN). Administration helps to maintain plasma levels and to prevent depletion of endogenous stores and subsequent deficiency symptoms.

CONTRAINDICATIONS

Manganese Sulfate Injection, USP should not be given undiluted by direct injection into a peripheral vein because of the potential for infusion phlebitis.

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

Manganese is eliminated via the bile. The possibility of manganese retention should be considered in patients with biliary tract obstruction. Decreasing or omitting manganese supplements entirely may be necessary for such patients. However, ancillary routes of manganese excretion include pancreatic juice, or reabsorption into the lumen of the duodenum, jejunum or ileum.

Use in Pregnancy

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

ADVERSE REACTIONS

Adverse reactions to manganese at the dosage levels recommended have not been reported.

DOSAGE AND ADMINISTRATION

Manganese Sulfate Injection, USP provides 0.1 mg manganese/mL. For the metabolically stable adult receiving TPN, the suggested additive dosage level for manganese is 0.15 to 0.8 mg/day. For pediatric patients, a dosage level of 2 to 10 mcg manganese/kg/day is recommended.

Aseptic addition of Manganese Sulfate Injection, USP to the TPN solution under a laminar flow hood is recommended. Manganese is physically compatible with the electrolytes and vitamins usually present in the amino acid/dextrose solution used for TPN. Periodic monitoring of manganese plasma levels is suggested as a guideline for subsequent administration.

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

OVERDOSAGE

Manganese toxicity has not been reported in patients receiving TPN. Neither have reports of manganese toxicity from excessive intake in foods and/or beverages been published.

HOW SUPPLIED

Manganese Sulfate Injection, USP 0.1 mg/mL

NDC 0517-6410-25 10 mL SDV 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).

IN6410

Rev. 1/09

MG #14479

AMERICAN
REGENT, INC.
SHIRLEY, NY 11967

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - Container Label

NDC 0517-6410-25

MANGANESE SULFATE INJECTION, USP

Manganese 1 mg/10 mL

(0.1 mg/mL)

10 mL SINGLE DOSE VIAL

Trace Element Additive

FOR IV USE AFTER DILUTION

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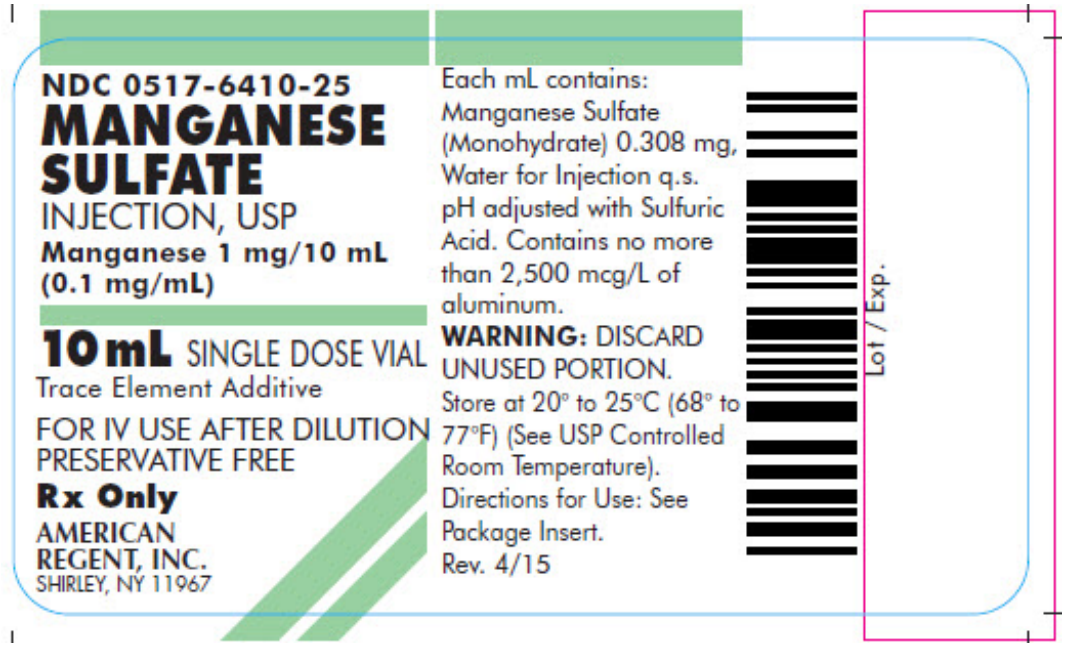

PACKAGE LABEL PRINCIPAL DISPLAY PANEL - Carton Labeling

NDC 0517-6410-25
25 x 10 mL
SINGLE DOSE VIALS

MANGANESE SULFATE INJECTION, USP

Manganese 1 mg/10 mL
(0.1 mg/mL)

10 mL SINGLE DOSE VIAL

Trace Element Additive

FOR IV USE AFTER DILUTION. PRESERVATIVE FREE

Rx Only

Each mL contains: Manganese Sulfate (Monohydrate) 0.308 mg, Water for Injection q.s.
pH adjusted with Sulfuric Acid. Sterile, nonpyrogenic.
WARNING: DISCARD UNUSED PORTION. 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). Directions for Use: See

Package Insert.

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SHIRLEY, NY 11967

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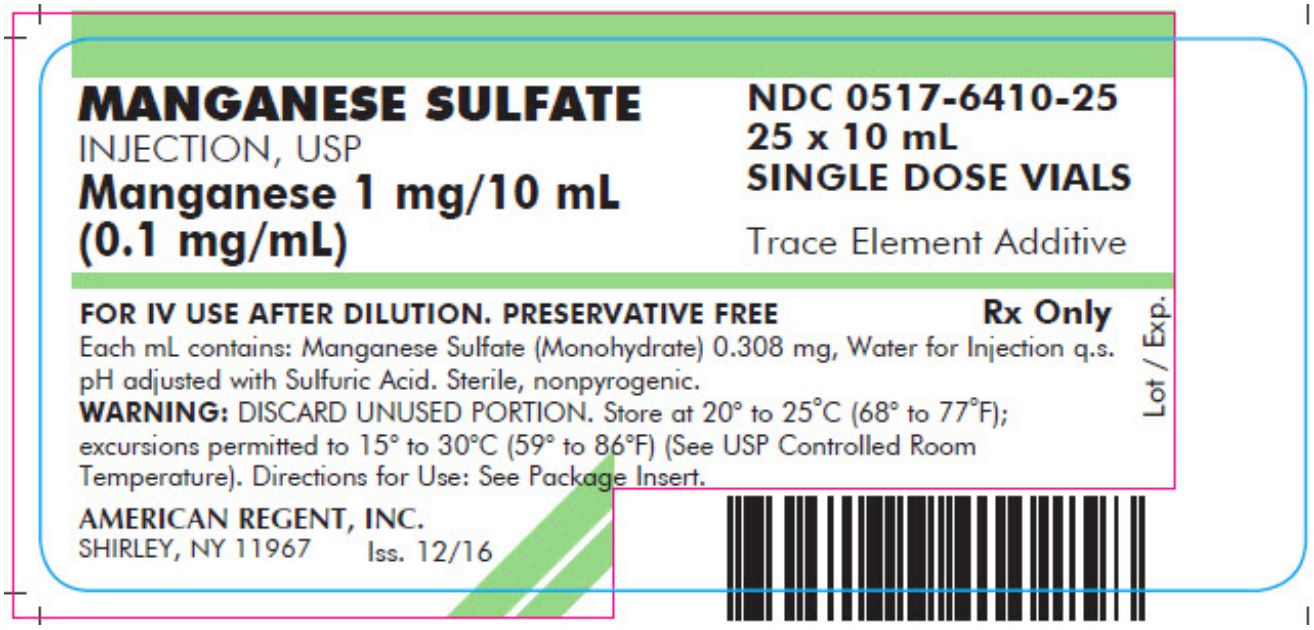

Serialization Label

MANGANESE SULFATE

manganese sulfate injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0517-6410
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MANGANESE SULFATE (UNII: W00LYS4T26) (MANGANESE CATION (2+) - UNII:H6EP7W5457)	MANGANESE CATION (2+)	0.1 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:0517-6410-25	25 in 1 TRAY	09/30/1990	
1		10 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(0517-6410) , MANUFACTURE(0517-6410)

Revised: 12/2019 American Regent, Inc.