Manganese
0.1 mg/mL

Manganese Chloride

Injection, USP

FOR I.V. USE ONLY AFTER DILUTION

Plastic Vial

Rx only

DESCRIPTION

Manganese 0.1 mg/mL (Manganese Chloride Injection, USP) is a sterile, nonpyrogenic solution intended for use as an additive to intravenous solutions for total parenteral nutrition (TPN). Each mL of solution contains 0.36 mg manganese chloride, tetrahydrate and 9 mg sodium chloride. The solution contains no bacteriostat, antimicrobial agent or added buffer. The pH is 2.0 (1.5 to 2.5); product may contain hydrochloric acid and sodium hydroxide for pH adjustment. The osmolarity is 0.313 mOsmol/mL (calc.).

Manganese Chloride, USP is chemically designated manganese chloride, tetrahydrate ($MnCl_2 \cdot 4H_2O$), a deliquescent, crystalline compound soluble in water.

Sodium Chloride, USP is chemically designated NaCl, a white, crystalline compound freely soluble in water.

The semi-rigid vial is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers. The small amount of water vapor that can pass through the plastic container wall will not significantly alter the drug concentration.

CLINICAL PHARMACOLOGY

Manganese is an essential nutrient which serves as an activator for enzymes such as polysaccharide polymerase, liver arginase, cholinesterase and pyruvate carboxylase. Providing manganese during TPN helps prevent development of deficiency symptoms such as nausea and vomiting, weight loss, dermatitis and changes in growth and color of hair.

Under conditions of minimal intake, 20 mcg manganese/day is retained. Manganese is bound to a specific transport protein, transmanganin, a beta-1-globulin. Manganese is widely distributed but concentrates in the mitochondria rich tissues such as brain, kidney, pancreas, and liver. Assays for manganese in whole blood result in concentrations ranging from 6 to 12 mcg/manganese/liter.

Excretion of manganese occurs mainly through the bile, but in the event of obstruction, ancillary excretion routes include pancreatic juice, or return into the lumen of the duodenum, jejunum, or ileum. Urinary excretion of manganese is negligible.

INDICATIONS AND USAGE

Manganese 0.1 mg/mL (Manganese Chloride Injection, USP) is indicated for use as a supplement to intravenous solutions given for TPN.

Administration helps to maintain manganese serum levels and to prevent depletion of endogenous stores and subsequent deficiency symptoms.

CONTRAINDICATIONS

None known.

WARNINGS

Direct intramuscular or intravenous injection of Manganese 0.1 mg/mL (Manganese Chloride Injection, USP) is contraindicated as the acidic pH of the solution (pH 2.0) may cause considerable tissue irritation.

Liver and/or biliary tract dysfunction may require omission or reduction of copper and manganese doses because these elements are primarily eliminated in the bile.

WARNING: 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

General

Do not use unless solution is clear and seal is intact.

Manganese 0.1 mg/mL (Manganese Chloride Injection, USP) should only be used in conjunction with a pharmacy directed admixture program using aseptic technique in a laminar flow environment; it should be used promptly and in a single operation without any repeated penetrations. Solution contains no preservatives; discard unused portion immediately after admixture procedure is completed.

Laboratory Tests

Serum manganese levels can be measured periodically at the discretion of the investigator. Because of the low serum concentration normally present, samples will usually be analyzed by a reference laboratory.

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Long-term animal studies to evaluate the carcinogenic potential of Manganese 0.1 mg/mL (Manganese Chloride Injection, USP) have not been performed, nor have studies been done to assess mutagenesis or impairment of fertility.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Manganese 0.1 mg/mL (Manganese Chloride Injection, USP) additive is administered to a nursing woman.

Pediatric Use

(See ***DOSAGE AND ADMINISTRATION*** section.) Safety and effectiveness in pediatric patients have not been established.

Pregnancy

Animal reproduction studies have not been conducted with manganese chloride. It is also not known whether manganese chloride can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Manganese chloride should be given to a pregnant woman only if clearly indicated.

Geriatric Use

An evaluation of current literature revealed no clinical experience identifying differences in response between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS

None known.

DRUG ABUSE AND DEPENDENCE

None known.

OVERDOSAGE

Manganese toxicity in TPN patients has not been reported.

DOSAGE AND ADMINISTRATION

Manganese 0.1 mg/mL (Manganese Chloride Injection, USP) contains 0.1 mg manganese/mL and is administered intravenously only after dilution. The additive should be administered in a volume of fluid not less than 100 mL. For the adult receiving TPN, the suggested additive dosage for manganese is 0.15 to 0.8 mg/day (1.5 to 8 mL/day). For pediatric patients, a dosage of 2 to 10 mcg manganese/kg/day (0.02 to 0.1 mL/kg/day) is recommended.

Periodic monitoring of manganese plasma levels is suggested as a guideline for subsequent administration.

Parenteral products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. (See ***PRECAUTIONS***.)

HOW SUPPLIED

Manganese 0.1 mg/mL (Manganese Chloride Injection, USP) is supplied in 10 mL Plastic Vials.

Unit of Sale	Concentration
NDC 0409-4091-01 25 in a carton	1 mg/10 mL (0.1 mg/mL)

Store at 20 to 25°C (68 to 77°F) [See USP Controlled Room Temperature.]

Distributed by Hospira, Inc., Lake Forest, IL 60045 USA

LAB-1068-2.0

Revised: 4/2018