MANGANESE SULFATE INJECTION, USP
Rx Only

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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.

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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).

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