

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-I-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.

2

#### 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 Category C.* 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.

#### 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

5

#### INDICATIONS AND USAGE

Manganese 0.1 mg/mL (Manganese Chloride Injection, USP) is indicated for use as a supplement to intravenous solutions given for total parenteral nutrition (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 (2) 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

3

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 (List No. 4091).

Store at controlled room temperature 15° to 30° C (59° to 86° F) (see USP).

©Abbott 2002 58-6218-R5-Rev. April, 2002 Printed in USA  
ABBOTT LABORATORIES, NORTH CHICAGO, IL 60064, USA

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.

4

# MANGANESE

## 0.1 mg/mL

### Manganese Chloride Injection, USP

FOR I.V. USE ONLY AFTER DILUTION

Plastic Vial

 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<sub>2</sub> • 4H<sub>2</sub>O), 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

#### Abbott Packaging Graphics Art

LIST NO.	4091
COMMOD. NO.	58-6218
LCRN	24163
DATE	6/9/00
LABEL EDITOR	VanSant
DATE PREPARED	5/10/02
STUDIO REFERENCE	DD 1137-10
ARTIST	TG

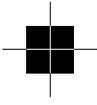
#### FORMULA and LABEL CONTROL D-39B, APPROVAL

APPROVED BY

DATE  
\*NOT VALID UNLESS FINAL PROOFS CARRY D-39B APPROVAL SIGNATURE

COLOR

 PMS Black



10 mL Vial

# MANGANESE

0.1 mg/mL

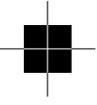
Manganese Chloride Inj., USP

FOR I.V. USE ONLY AFTER DILUTION. **Rx** only

ABBOTT LABORATORIES, NORTH CHICAGO, IL 60064, USA

NDC 0074-4091-01  
Each mL contains manganese chloride, tetrahydrate 0.36 mg; sodium chloride 9 mg, 0.313 mOsmol/mL (calc. pH 2.0 (1.5 to 2.5). Usual dosage: See insert. Contains no more than 100 mcg/L of aluminum.

Lot/Exp.



<b>Abbott Packaging Graphics Art</b>	
LIST NO.	4091
COMMOD. NO.	58-2137
LCRN	24163
DATE	6/9/00
LABEL EDITOR	VanSant
DATE PREPARED	5/10/02
STUDIO REFERENCE	DB 5706-03
ARTIST	TG
<b>FORMULA and LABEL CONTROL D-39B, APPROVAL</b>	
APPROVED BY	
DATE	
*NOT VALID UNLESS FINAL PROOFS CARRY D-39B APPROVAL SIGNATURE	
<b>COLOR</b>	
	PMS Black
	PMS 221

 10 mL Single-dose

25 Units/**NDC 0074-4091-01**

# MANGANESE

## 0.1 mg/mL

Manganese Chloride Injection, USP

ABBOTT LABORATORIES, NORTH CHICAGO, IL 60064, USA

**CAUTION: FOR INTRAVENOUS  
USE ONLY AFTER DILUTION.**

 only



(01) 1 030074 409101 0

Store at controlled room temperature 15° to 30°C (59° to 86°F) (see USP).

Cleanse stopper with antiseptic. Aseptically add prescribed dose to a suitable solution in I.V. container. Use only if clear and seal is intact and undamaged. Contains no bacteriostat; use promptly; discard unused portion.  
For I.V. use only after dilution. Usual dosage: See insert.



97

 10 mL Single-dose  
**MANGANESE**  
0.1 mg/mL  
Manganese Chloride Injection, USP  
 only  
**CAUTION: FOR INTRAVENOUS  
USE ONLY AFTER DILUTION.**  
25 Units/**NDC 0074-4091-01**  
ABBOTT LABORATORIES, NORTH CHICAGO, IL 60064, USA

©Abbott 2002

59-0778-2/R3-4/02

Printed in USA

Each mL contains manganese chloride, tetrahydrate. Sterile, nonpyrogenic.  
0.36 mg; sodium chloride 9 mg.  
Contains hydrochloric acid and may contain sodium hydroxide for pH adjustment.  
0.313 mOsmol/mL (calc.).  
pH 2.0 (1.5 to 2.5)

### Abbott Packaging Graphics Art

LIST NO.	4091
COMMOD. NO.	59-0778
LCRN	24163
DATE	6/9/00
LABEL EDITOR	VanSant
DATE PREPARED	5/10/02
STUDIO REFERENCE	DC 2176-06
ARTIST	TG

### FORMULA and LABEL CONTROL D-39B, APPROVAL

APPROVED BY

DATE  
\*NOT VALID UNLESS FINAL  
PROOFS CARRY D-39B  
APPROVAL SIGNATURE

### COLORS

 PMS Black