COPPER- cupric chloride injection, solution
Hospira, Inc.

COPPER
0.4 mg/mL

Cupric Chloride

Injection, USP

FOR I.V. USE ONLY AFTER DILUTION

Plastic Vial R_x only

DESCRIPTION

Copper (Cupric Chloride Injection, USP) 0.4 mg/mL is a sterile, nonpyrogenic solution intended for use as an additive to intravenous solutions for total parenteral nutrition (TPN). Each mL of solution contains 1.07 mg cupric chloride, dihydrate 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 0.327 mOsmol/mL (calc.).

Cupric chloride, USP is chemically designated cupric chloride, dihydrate ($CuCl_2 \bullet 2H_2O$), a crystalline compound freely 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

Copper is an essential nutrient which serves as a cofactor for serum ceruloplasmin, an oxidase necessary for proper formation of the iron carrier protein, transferrin. Copper also helps maintain normal rates of red and white blood cell formation.

Providing copper during TPN helps prevent development of the following deficiency symptoms: Leukopenia, neutropenia, anemia, depressed ceruloplasmin levels, impaired transferrin formation, secondary iron deficiency and osteoporosis.

Normal serum copper values range from 80 to 163 mcg/dl (mean, approximately 110 mcg/dl). The serum copper level at which deficiency symptoms appear is not precisely defined.

In the plasma, about 7% of copper is bound to albumin and amino acids. In the liver, about 93% of copper is bound to ceruloplasmin and released to the serum. The daily

turnover of copper through ceruloplasmin is approximately 0.5 mg. Copper is primarily excreted through the bile and into the gastrointestinal tract where it is not reabsorbed. Copper is also eliminated through the kidneys.

INDICATIONS AND USAGE

Copper (Cupric Chloride Injection) is indicated for use as a supplement to intravenous solutions given for TPN. Administration helps to maintain copper serum levels and to prevent depletion of endogenous stores and subsequent deficiency symptoms.

CONTRAINDICATIONS

Copper (Cupric Chloride Injection) is contraindicated in patients with hypersensitivity to copper (see ***WARNINGS: Hypersensitivity Reactions***).

WARNINGS

Hepatic Accumulation

Copper is primarily eliminated in the bile and excretion is decreased in patients with cholestasis and/or cirrhosis. Hepatic accumulation of copper has been reported in autopsies of patients receiving long-term parenteral nutrition containing copper at dosages higher than recommended.

Administration of copper to patients with cholestasis and/or cirrhosis may cause hepatic accumulation of copper. Administration of copper to patients with Wilson disease, an inborn error of copper metabolism with a defect in hepatocellular copper transport, may cause both increased hepatic accumulation of copper and aggravation of the underlying hepatocellular degeneration.

For patients with cholestasis, biliary dysfunction, or cirrhosis, monitor hepatic and biliary function during long-term administration of Cupric Chloride Injection. If a patient develops signs or symptoms of hepatobiliary disease during the use of Cupric Chloride Injection, obtain serum concentrations of copper and ceruloplasmin, and adjust the dose as indicated (see ***PRECAUTIONS: Hepatic Impairment***).

Hypersensitivity Reactions

Postmarket safety reporting has identified copper hypersensitivity in women receiving copper-containing intrauterine devices, providing evidence that patients may experience hypersensitivity reactions when exposed to this metal. If hypersensitivity reactions (e.g., pruritis, angioedema, dyspnea, rash, urticaria) occur in patients receiving Cupric Chloride Injection in parenteral nutrition, discontinue the product, and initiate appropriate medical treatment (see ***CONTRAINDICATIONS***).

Aluminum Toxicity

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

Laboratory Tests

Twice monthly serum assays for copper and/or ceruloplasmin are suggested for monitoring copper concentrations in long-term TPN patients. As ceruloplasmin is a cuproenzyme, ceruloplasmin assays may be depressed secondary to copper deficiency.

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Long-term animal studies to evaluate the carcinogenic potential of Copper 0.4 mg/mL (Cupric Chloride Injection) 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 Copper 0.4 mg/mL (Cupric Chloride Injection) is administered to a nursing woman.

Pediatric Use

The safety and effectiveness of Cupric Chloride Injection have been established in pediatric patients receiving parenteral nutrition (see ***DOSAGE AND ADMINISTRATION***).

Pregnancy

Animal reproduction studies have not been conducted with cupric chloride. It is also not known whether cupric chloride can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Cupric 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.

Hepatic Impairment

Copper is primarily excreted in the bile. Excretion is decreased in patients with cholestasis and/or cirrhosis (see ***CLINICAL PHARMACOLOGY***). Hepatic accumulation of copper has been reported with long-term administration of parenteral nutrition at dosages higher than recommended (*see* ***WARNINGS: Hepatic Accumulation***). For patients with cholestasis or cirrhosis, monitor hepatic and biliary function during long-term administration of Cupric Chloride Injection. If a patient develops signs or symptoms

of hepatobiliary disease during use of Cupric Chloride Injection, obtain serum concentrations of copper and ceruloplasmin.

ADVERSE REACTIONS

None known.

DRUG ABUSE AND DEPENDENCE

None known.

OVERDOSAGE

Acute copper toxicity has been reported in patients with oral, intravenous, or subcutaneous administration. Clinical manifestations included metallic taste, nausea, vomiting, diarrhea, abdominal pain, neurological signs, such as encephalopathy, and multi-organ failure involving kidney, liver, blood, and cardiovascular systems, which may be fatal. Chelating agents, such as D-penicillamine, can be used for treatment of acute toxicity. Long-term administration of parenteral copper above the recommended dosage may result in significant accumulation of copper in the liver, brain, and other tissues with possible organ damage (see ***WARNINGS: Hepatic Accumulation***).

DOSAGE AND ADMINISTRATION

- Copper (Cupric Chloride Injection) contains 0.4 mg of copper per mL and is administered intravenously only after dilution. The additive should be diluted in a volume of fluid not less than 100 mL.
- For the adult receiving TPN, the suggested additive dosage of copper is 0.3 to 0.5 mg/day.
- For pediatric patients, the suggested additive dosage of copper is 20 mcg/kg/day (0.05 mL/kg/day) up to a maximum of 500 mcg/day.
- This product is not appropriate for patients weighing less than 4 kg due to the inability to measure the appropriate amount of the product.
- Do not administer Copper (Cupric Chloride Injection) intramuscularly because the acidic pH of the solution may cause considerable tissue irritation.

Copper (Cupric Chloride Injection) 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. The solution contains no preservatives; discard the unused portion immediately after the admixture procedure is completed.

Copper (Cupric Chloride Injection) should be inspected visually for particulate matter and discoloration prior to administration. Do not use unless the solution is clear, and the seal is intact.

Cupric ion may degrade ascorbic acid in TPN solutions. In order to avoid this loss of ascorbate, multivitamin additives should be added to TPN solutions immediately prior to infusion. Alternatively, the multivitamin additive may be added to one container of TPN

solution, followed by copper in a subsequent container.

HOW SUPPLIED

Copper 0.4 mg/mL (Cupric Chloride Injection, USP) is supplied as follows:

Unit of Sale	Concentration
NDC 0409-4092-01 Tray containing 25 - 10 mL Single-dose Plastic Vials	4 mg/10 mL (0.4 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-1067-3.0

Revised: 06/2025

PRINCIPAL DISPLAY PANEL - 10 mL Vial Label

10 mL Single-dose Vial
NDC 0409-4092-11

COPPER
Rx only

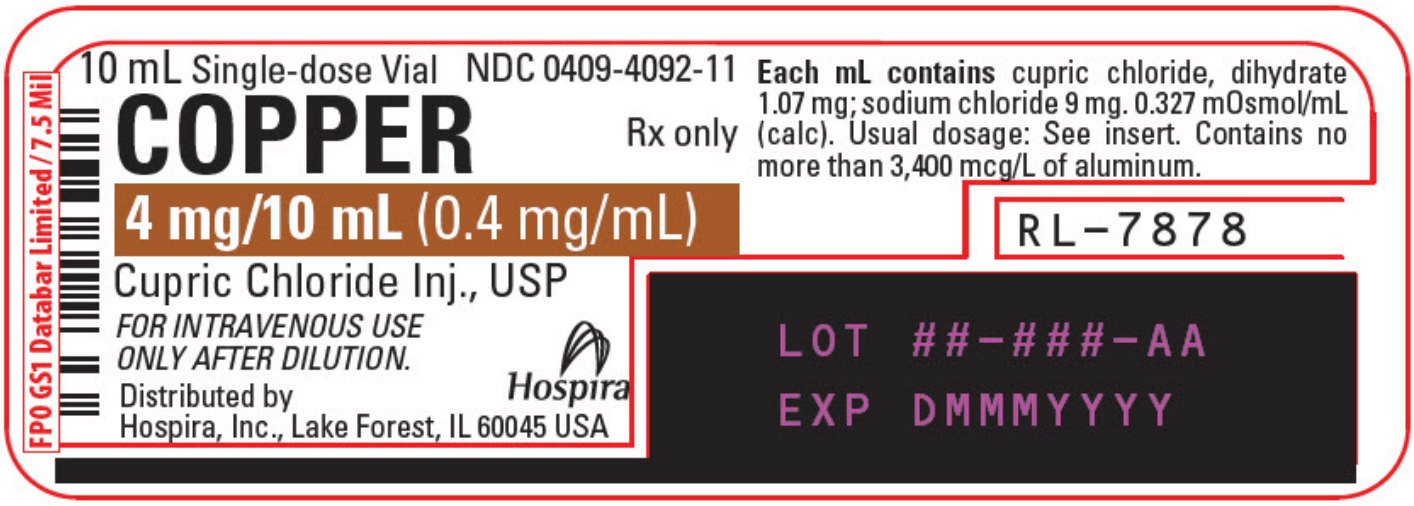
4 mg/10 mL (0.4 mg/mL)

Cupric Chloride Inj., USP

FOR INTRAVENOUS USE
ONLY AFTER DILUTION.

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

Hospira



PRINCIPAL DISPLAY PANEL - 10 mL Vial Tray

10 mL Single-dose Vial
NDC 0409-4092-01
Contains 25 of NDC 0409-4092-11

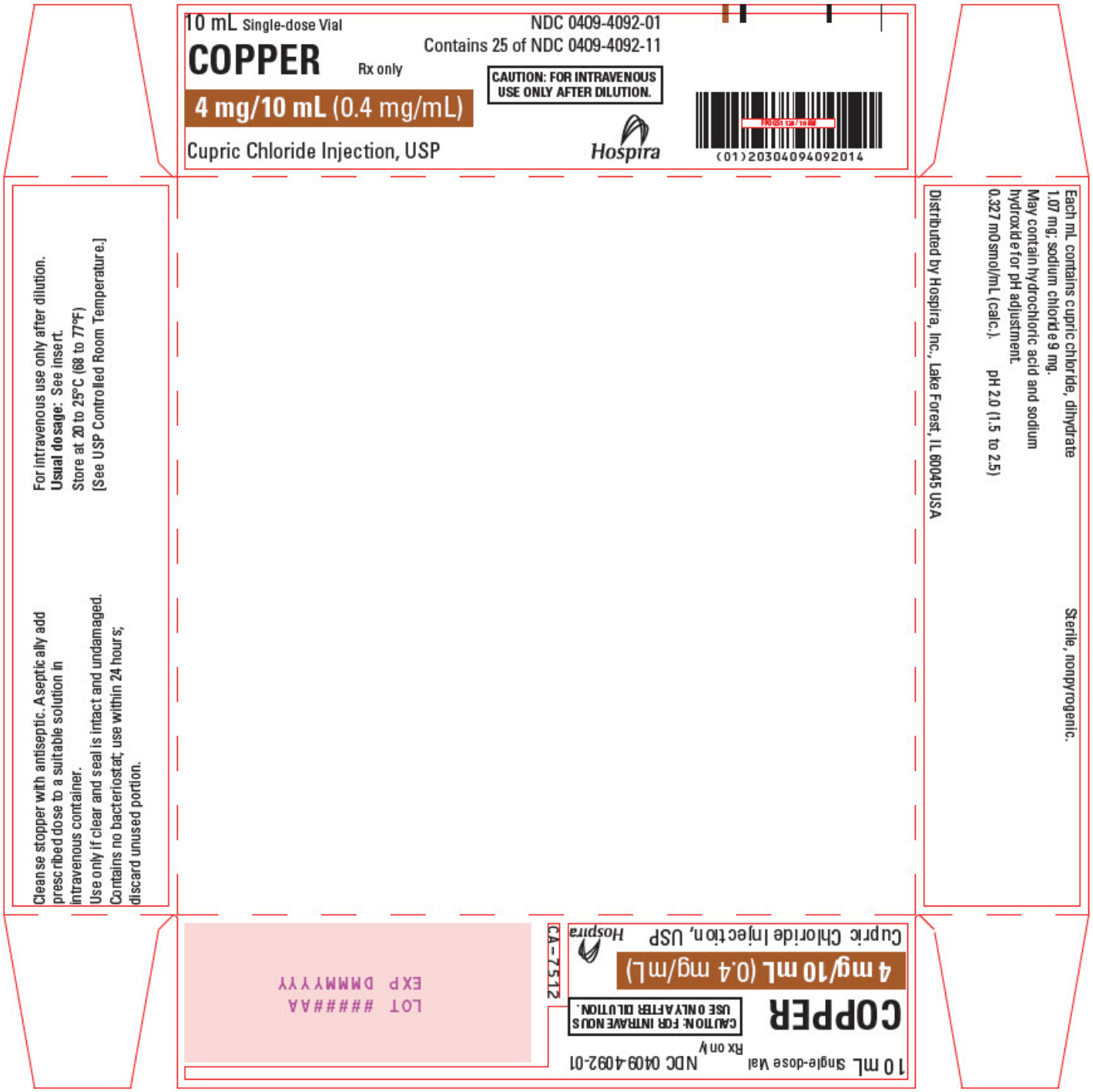
COPPER
Rx only

4 mg/10 mL (0.4 mg/mL)

CAUTION: FOR INTRAVENOUS
USE ONLY AFTER DILUTION.

Cupric Chloride Injection, USP

Hospira



COPPER

cupric chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-4092
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

CUPRIC CHLORIDE (UNII: S2QG84156O) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	0.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	9 mg in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-4092-01	25 in 1 TRAY	02/28/2005	
1	NDC:0409-4092-11	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
NDA	NDA018960	02/28/2005	

Labeler - Hospira, Inc. (141588017)

Establishment

Name	Address	ID/FEI	Business Operations
Hospira, Inc.		093132819	ANALYSIS(0409-4092) , MANUFACTURE(0409-4092) , PACK(0409-4092) , LABEL(0409-4092)

Establishment

Name	Address	ID/FEI	Business Operations
Hospira, Inc.		827731089	ANALYSIS(0409-4092)

Revised: 6/2025 Hospira, Inc.