CHROMIUM- chromic chloride injection, solution
Hospira, Inc.

CHROMIUM
Chromic Chloride
Injection, USP
40 mcg/10 mL (4 mcg/mL)

FOR I.V. USE ONLY AFTER DILUTION
Plastic Vial
Rx Only

DESCRIPTION

Chromium 4 mcg/mL (Chromic 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 20.5 mcg chromic chloride, hexahydrate 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/or sodium hydroxide for pH adjustment. The osmolarity is 0.308 mOsm/mL (calc.).

Chromic Chloride, USP is chemically designated chromic chloride, hexahydrate $CrCl_3 \cdot 6H_2O$, a 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

Trivalent chromium is part of glucose tolerance factor, an essential activator of insulin-mediated reactions. Chromium helps to maintain normal glucose metabolism and peripheral nerve function.

Providing chromium during TPN helps prevent deficiency symptoms including impaired glucose tolerance, ataxia, peripheral neuropathy and a confusional state similar to mild/moderate hepatic encephalopathy.

Serum chromium is bound to transferrin (siderophilin) in the beta globulin fraction. Typical blood levels for chromium range from 1 to 5 mcg/liter, but blood levels are not considered a meaningful index of tissue stores. Administration of chromium supplements to chromium-deficient patients can result in normalization of the glucose tolerance curve from the diabetic-like curve typical of chromium deficiency. This response is viewed as a more meaningful indicator of chromium nutriture than serum chromium levels.

Excretion of chromium is via the kidneys, ranging from 3 to 50 mcg/day. Biliary excretion via the small intestine may be an ancillary route, but only small amounts of chromium are believed to be excreted in this manner.

INDICATIONS AND USAGE

Chromium 4 mcg/mL (Chromic Chloride Injection, USP) is indicated for use as a supplement to intravenous solutions given for TPN. Administration helps to maintain chromium serum levels and to prevent depletion of endogenous stores and subsequent deficiency symptoms.

CONTRAINDICATIONS

None known.

WARNINGS

Direct intramuscular or intravenous injection of Chromium 4 mcg/mL (Chromic Chloride Injection, USP) is contraindicated, as the acidic pH of the solution may cause considerable tissue irritation.

Severe kidney disease may make it necessary to reduce or omit chromium and zinc doses because these elements are primarily eliminated in the urine.

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. Chromium 4 mcg/mL (Chromic 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.

In assessing the contribution of chromium supplements to maintenance of glucose homeostasis, consideration should be given to the possibility that the patient may be diabetic.

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.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Laboratory Tests

Because chromium is present in the bloodstream in microgram quantities, routine measurement is impractical. If necessary, samples can be sent to a reference laboratory for assay.

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Long-term animal studies to evaluate the carcinogenic potential of Chromium 4 mcg/mL (Chromic 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 Chromium 4 mcg/mL (Chromic Chloride Injection, USP) is administered to a nursing woman.

Pediatric Use

See DOSAGE and ADMINISTRATION section. Safety and effectiveness in children have not been established.

Pregnancy

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

ADVERSE REACTIONS

None known.

DRUG ABUSE AND DEPENDENCE

None known.

OVERDOSAGE

Trivalent chromium administered intravenously to TPN patients has been shown to be nontoxic when given at dosage levels of up to 250 mcg/day for two consecutive weeks.

Reported toxic reactions to chromium include nausea, vomiting, ulcers of the gastrointestinal tract, renal and hepatic damage, convulsions and coma. The acute LD_{50} for intravenous trivalent chromium in rats was reported as 10 to 18 mg/kg.

DOSAGE AND ADMINISTRATION

Chromium 4 mcg/mL (Chromic Chloride Injection, USP) contains 4 mcg chromium/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 is 10 to 15 mcg chromium/day (2.5 to 3.75 mL/day). The metabolically stable adult with intestinal fluid loss may require 20 mcg chromium/day (5 mL/day), with frequent monitoring of blood levels as a guideline for subsequent administration. For pediatric patients, the suggested additive dosage is 0.14 to 0.20 mcg/kg/day (0.035 to 0.05 mL/kg/day).

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

HOW SUPPLIED

Chromium (Chromic Chloride Injection, USP) is supplied as follows:

Unit of Sale	**Concentration**
NDC 0409-4093-01 Tray of 25 Single-dose plastic vials	40 mcg/10 mL (4 mcg/mL)

Store at 20 to 25ºC (68 to 77ºF). [See USP Controlled Room Temperature.]

Hospira

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

LAB-1065-3.0

Revised: 4/2021

PRINCIPAL DISPLAY PANEL - 10 mL Vial Label

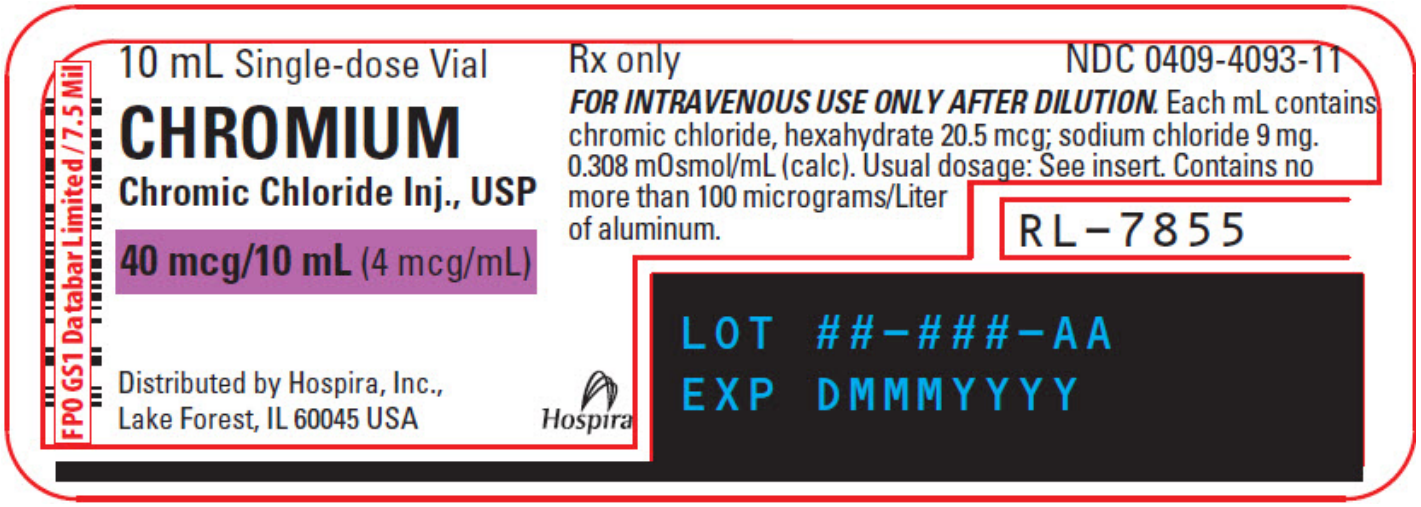
10 mL Single-dose Vial

CHROMIUM
Chromic Chloride Inj., USP

40 mcg/10 mL (4 mcg/mL)

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

Hospira



PRINCIPAL DISPLAY PANEL - 10 mL Vial Tray

10 mL Single-dose Vial

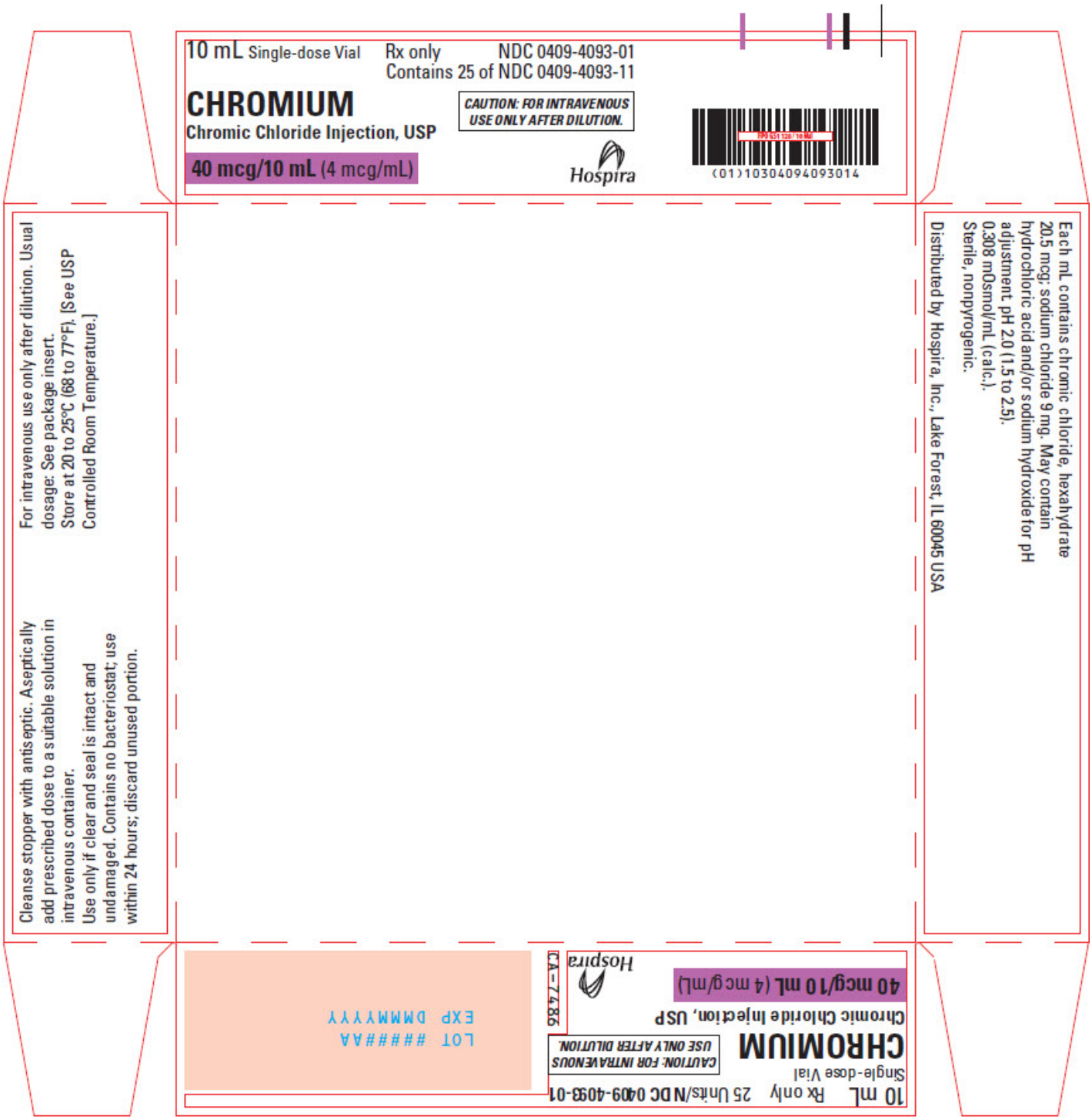
Rx only
NDC 0409-4093-01
Contains 25 of NDC 0409-4093-11

CHROMIUM
Chromic Chloride Injection, USP

40 mcg/10 mL (4 mcg/mL)

CAUTION: FOR INTRAVENOUS
USE ONLY AFTER DILUTION.

Hospira



CHROMIUM

chromic chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-4093
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety	

Ingredient Name	Basis of Strength	Strength
CHROMIC CHLORIDE (UNII: KB1PCR9DMW) (CHROMIC CATION - UNII:X1N4508KF1)	CHROMIC CATION	4 ug 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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-4093-01	25 in 1 TRAY	06/30/2005	
1	NDC:0409-4093-11	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	NDA018961	06/30/2005	

Labeler - Hospira, Inc. (141588017)

Establishment

Name	Address	ID/FEI	Business Operations
Hospira, Inc.		093132819	ANALYSIS(0409-4093) , MANUFACTURE(0409-4093) , PACK(0409-4093) , LABEL(0409-4093)

Establishment

Name	Address	ID/FEI	Business Operations
PPD Development, L.P.		838082055	ANALYSIS(0409-4093)

Establishment

Name	Address	ID/FEI	Business Operations
Hospira, Inc.		827731089	ANALYSIS(0409-4093)

Revised: 6/2021 Hospira, Inc.