CHROMIC CHLORIDE- chromic chloride injection, solution
Archis Pharma LLC

Chromic Chloride Injection, USP
40 mcg/10mL(4 mcg/mL) Archis Pharma LLC
FOR I.V. USE ONLY AFTER DILUTION
Glass Vial
Rx only

DESCRIPTION

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.

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

Chromic Chloride Injection is indicated for use as a supplement to intravenous solutions

given for total parenteral nutrition (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 Chromic Chloride Injection 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. Chromic 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. 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 Chromic 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 Chromic Chloride Injection 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 LD50 for intravenous trivalent chromium in rats was reported as 10 to 18 mg/kg.

DOSAGE AND ADMINISTRATION

Chromic Chloride Injection 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**.)

Discard unused portion.

HOW SUPPLIED

Chromic Chloride Injection, USP is supplied as follows:

Unit of Sale	Concentration
NDC 72819-235-16 Carton of 25 Single-dose vials	40 mcg/10 mL (4 mcg/mL)

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

Distributed by:
Archis Pharma LLC
15 Corporate Place South, Suite 108
Piscataway, NJ 08854 U.S.A.

Rev.: 11/2024
PI-CRC-00

LEIA-327.00
10625

Principal Display Panel Text for Container Label:

NDC 72819- **235**-06

Chromic Chloride Injection, USP 4 mg/mL

10 mL Single-dose Vials

Rx only

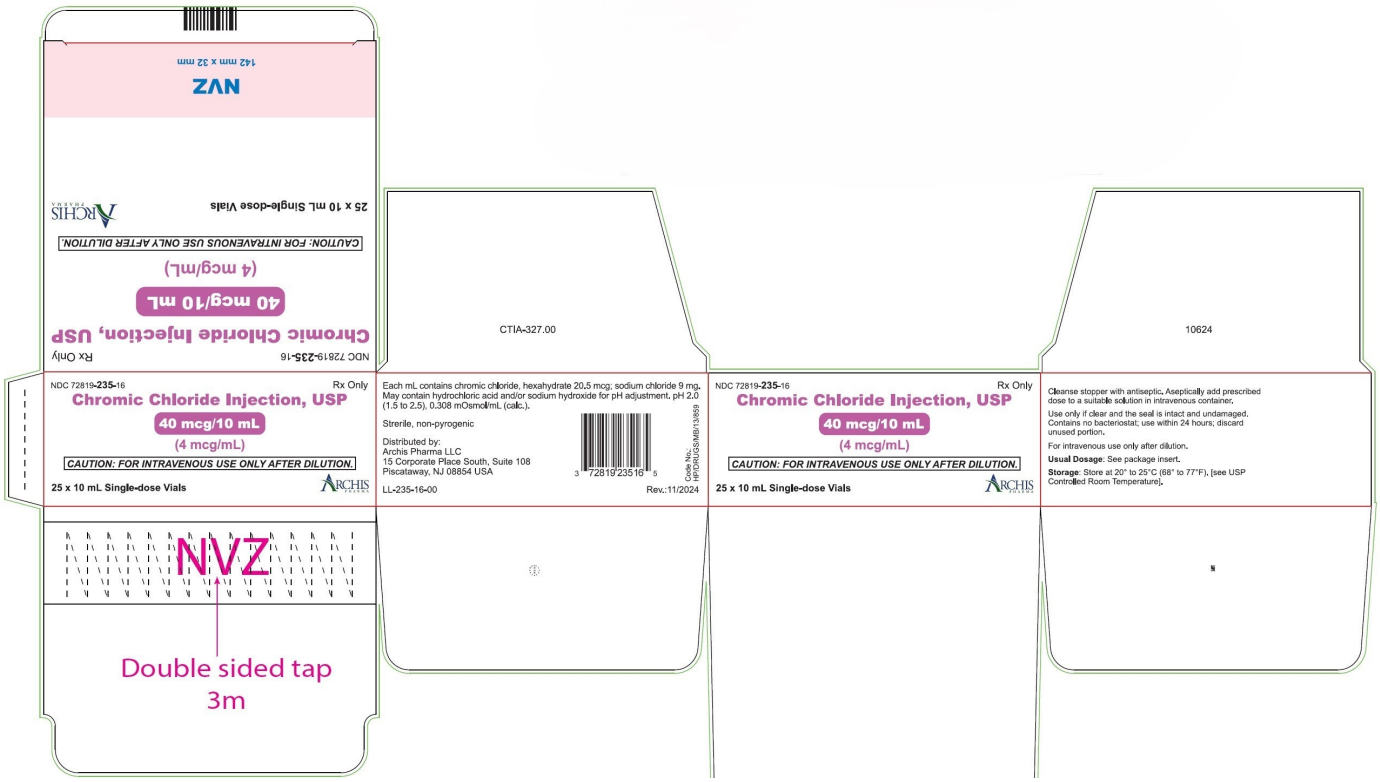
Principal Display Panel Text for Carton Label:

NDC 72819- **235**-16

Chromic Chloride Injection, USP 4 mg/mL

10 mL Single-dose vials in package of 25

Rx only



CHROMIC CHLORIDE

chromic chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72819-235
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:72819-235-16	25 in 1 PACKAGE	01/25/2025	
1	NDC:72819-235-06	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
ANDA	ANDA218538	01/25/2025	

Labeler - Archis Pharma LLC (026836212)

Registrant - RK Pharma INC., (116901480)

Establishment

Name	Address	ID/FEI	Business Operations
Immacule Lifesciences Private Limited		650694503	manufacture(72819-235)

Revised: 1/2025 Archis Pharma LLC