CALCIUM CHLORIDE- calcium chloride injection injection, solution
Medical Purchasing Solutions, LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use 10% CALCIUM CHLORIDE INJECTION, USP safely and effectively. See full prescribing information for 10% CALCIUM CHLORIDE INJECTION, USP.

10% CALCIUM CHLORIDE INJECTION, USP for Intravenous Injection

Initial U.S. Approval: 2019

INDICATIONS AND USAGE

(3)
10% Calcium Chloride Injection, USP is indicated for the treatment of hypocalcemia in those conditions requiring a prompt increase in plasma calcium levels. (3)

CONTRAINDICATIONS

Calcium chloride is contraindicated for cardiac resuscitation in the presence of ventricular fibrillation or in patients with the risk of existing digitalis toxicity. (4)
Calcium chloride is not recommended in the treatment of asystole and electromechanical dissociation. (4)

ADVERSE REACTIONS

Rapid injection may cause the patient to complain of tingling sensations, a calcium taste, a sense of oppression or "heat wave".
Injections of calcium chloride are accompanied by peripheral vasodilatation as well as a local "burning" sensation and there may be a moderate fall in blood pressure.
Should perivascular infiltration occur, I.V. administration at that site should be discontinued at once. Local infiltration of the affected area with 1% procaine hydrochloride, to which hyaluronidase may be added, will often reduce venospasm and dilute the calcium remaining in the tissues locally. Local application of heat may also be helpful.
To report SUSPECTED ADVERSE REACTIONS, contact Medefil, Inc., at 1-630-682-4600 or www.medefilinc.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

10% Calcium Chloride Injection, USP is administered only by slow intravenous injection (not to exceed 1 mL/min), preferably in a central or deep vein. (14)
The usual precautions for intravenous therapy should be observed. If time permits, the solution should be warmed to body temperature. The injection should be halted if the patient complains of any discomfort; it may be resumed when symptoms disappear. Following injection, the patient should remain recumbent for a short time. (14)
The usual adult dosage in hypocalcemic disorders ranges from 200 mg to 1 g (2 to 10 mL) at intervals of 1 to 3 days depending on the response of the patient and/or results of serum ionized calcium determinations. Repeated injections may be required because of rapid excretion of calcium. (14)
The pediatric dosage in hypocalcemic disorders ranges from 2.7 to 5.0 mg/kg hydrated calcium chloride (or 0.136 to 0.252 mEq elemental calcium per kg, or 0.027 to 0.05 mL of 10% Calcium Chloride Injection per kg). No data from clinical trials is available about repeated dosages, though textbook references recommend repeat dosages q 4 to 6 hours. (14)
Caution: 10% Calcium Chloride Injection consists of 1 gram of calcium chloride in a 10 mL syringe, or 100 mg/mL. This concentration represents 27 mg or 1.4 mEq of elemental calcium per mL. Thus, one 10 mL syringe provides 270 mg of elemental calcium. The dosage recommendation in various references is given either as amount of calcium chloride or amount of elemental calcium, and often it is not specified. Ionized calcium concentrations should be measured, to assist in dosage adjustment. (14)
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. See PRECAUTIONS. (14)
To prevent needle-stick injuries, needles should not be recapped, purposely bent or broken by hand. (14)

Revised: 9/2019

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

10% Calcium Chloride Injection, USP is a sterile, nonpyrogenic, hypertonic solution. Each mL contains 100 mg (1.4 mEq/mL) of calcium chloride, dihydrate (1.4 mEq each of Ca++ and Cl−) in water for injection. It is provided in a 10 mL Unit of Use Syringe to facilitate prompt intravenous injection. The solution contains no bacteriostat, antimicrobial agent or added buffer and is intended for use only as a single-dose injection. The pH of 10% Calcium Chloride Injection, USP is 5.5 to 7.5 when diluted with water for injection to make a 5% solution. May contain hydrochloric acid and/or sodium hydroxide for pH adjustment. The osmolar concentration is 2.04 mOsmol/mL (calc.). 10% Calcium Chloride Injection, USP is oxygen sensitive.

Calcium Chloride, USP dihydrate is chemically designated $CaCl_2 \cdot 2H_2O$ (dihydrate) and is described as white, odorless fragments or granules freely soluble in water.

The plastic syringe is molded from a specially formulated polypropylene. Water permeates from inside the container at an extremely slow rate which will have an insignificant effect on solution concentration over the expected shelf life. Solutions in contact with the plastic container may leach our certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the syringe material.

Calcium is the fifth most abundant element in the body and the major fraction is in the bony structure. Calcium plays important physiological roles, many of which are poorly understood. It is essential for the functional integrity of the nervous and muscular systems. It is necessary for normal cardiac function and is one of the factors that operate in the mechanisms involved in the coagulation of blood.

Calcium chloride in water dissociates to provide calcium (Ca++) and chloride (Cl−) ions. They are normal constituents of the body fluids and are dependent on various physiological mechanisms for maintenance of balance between intake and output. Approximately 80% of body calcium is excreted in the feces as insoluble salts; urinary excretion accounts for the remaining 20%.

10% Calcium Chloride Injection, USP is indicated for the treatment of hypocalcemia in those conditions requiring a prompt increase in plasma calcium levels.

10% Calcium Chloride Injection, USP is irritating to veins and must not be injected into tissues, since severe necrosis and sloughing may occur. Great care should be taken to avoid extravasation or accidental injection into perivascular tissues.

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.

Do not administer unless solution is clear and seal is intact. Discard unused portion.

Because of its additive effect, calcium should be administered very cautiously to a patient who is digitalized or who is taking effective doses of digitalis or digitalis-like preparations.

Injections should be made slowly through a small needle into a large vein to minimize venous irritation and avoid undesirable reactions. It is particularly important to prevent a high concentration of calcium from reaching the heart because of the danger of cardiac syncope.

Studies with solutions in polypropylene syringes have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Safety and effectiveness are based on similar clinical conditions in children and adults.

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

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.

None known.

Too rapid injection may produce lowering of blood pressure and cardiac syncope. Persistent hypercalcemia from overdosage of calcium is unlikely because of rapid excretion. In the event of untoward effects from excessive calcium administration, the drug should be discontinued promptly, the patient re-evaluated and appropriate countermeasures instituted, if necessary. See PRECAUTIONS and ADVERSE REACTIONS.

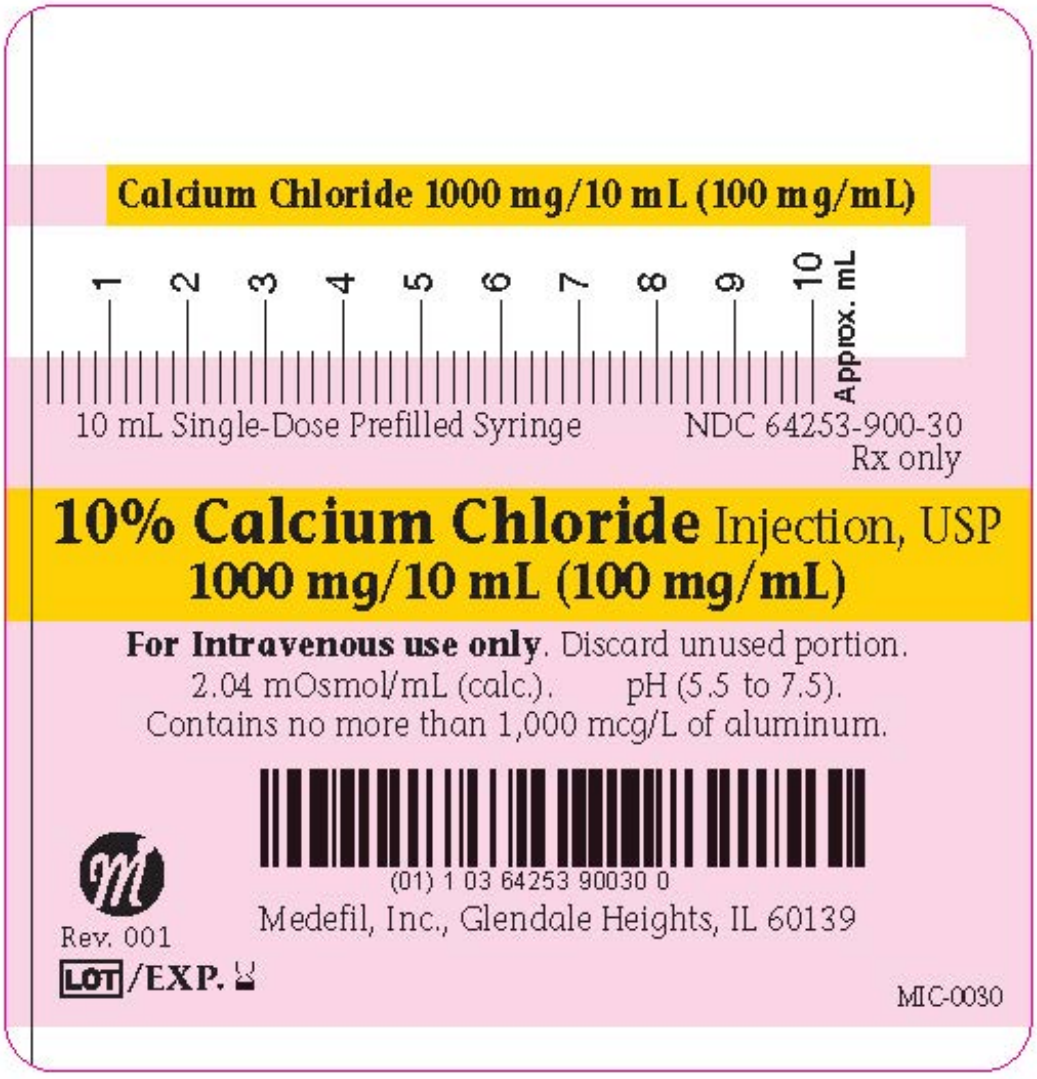
10% Calcium Chloride Injection, USP is supplied in single-dose containers as follows:

Unit of Sale	Container	Total Strength / Total Volume (Concentration)	Each	Needle
NDC 64253-900-36 10 mL Single-dose prefilled syringes, individually pouched, in a carton of 60s.	Plastic Syringe	1000 mg/10 mL (100 mg/mL)	NDC 64253-900-30 10mL fill in 12mL Syringe Single-dose prefilled syringes, individually pouched.	None

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Do not freeze.

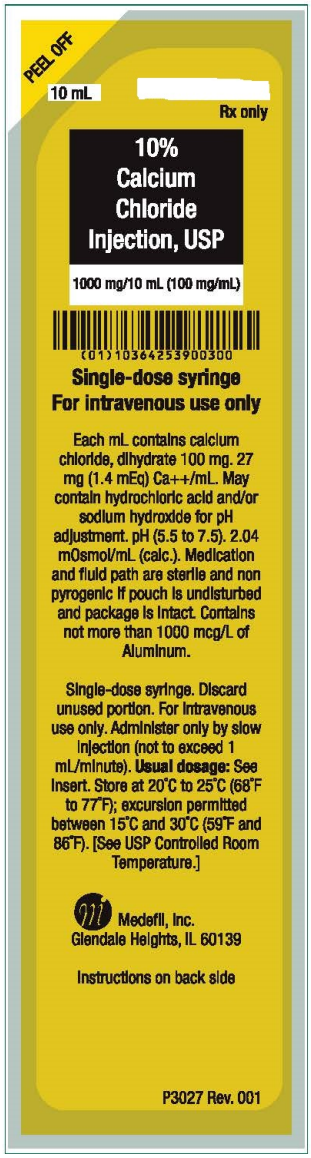
Medical literature also refers to the administration of calcium chloride in the treatment of magnesium intoxication due to overdosage of magnesium sulfate, and to combat the deleterious effects of hyperkalemia as measured by electrocardiogram (ECG), pending correction of the increased potassium level in the extracellular fluid. However, adequate well-controlled, randomized clinical studies have not been done to support these indications.

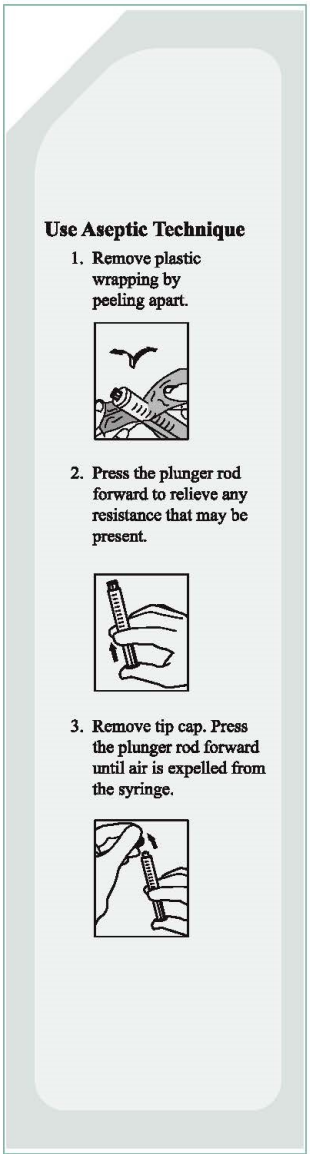
SYRINGE LABEL



Container Label

SYRINGE LABEL





PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - OUTER PACKAGE

NDC 71872-7193-1

RX Only

10% Calcium Chloride Injection, USP

1 x 10mL Single-Dose Prefilled Syringe

For Intravenous use only.

3 71872 71931 5

℞ only

(01) 0 03719?2 71931 5
(17) 000101
(10) XXXX-XXXXXX
(21) 7193AXXXXXX

10% Calcium Chloride Injection, USP

1000mg/10 mL (100 mg/mL) Single-Dose Prefilled Syringe

Qty: 1 vial Lot# XXXX-XXXXXX Exp: 01/01/1900

For Intravenous use only. Discard Unused Portion. Single-dose syringe.

Administer by slow intravenous injection only (not to exceed 1 mL/minute)

Usual Dosage: See insert. Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15 °C and 30°C (59°F and 86°F).
[See USP Controlled Room Temperature.]

Each mL contains calcium chloride, dihydrate 100mg. 27 mg (1.4mEq) Ca++/mL. May contain hydrochloric acid and/or sodium hydroxide for pH adjustment. pH (5.5 to 7.5). 2.04 mOsmol/mL (calc.) Contains no more than 1000 mcg/L of aluminium. Medication and fluid path are sterile and nonpyrogenic if protective cover is undisturbed and package is intact.

Manufactured by: Medefil, Inc. Glendale Heights, IL 60139
Manufacturer NDC: 64253-0900-36

Repackaged
& Distributed By:

Medical Purchasing Solutions
Scottsdale, AZ 85260
www.medicalpurchasingsolutions.com

Package Insert

Package Insert

CALCIUM CHLORIDE

calcium chloride injection injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71872-7193(NDC:64253-900)
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	100 mg in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71872-7193-1	1 in 1 BAG	01/10/2020	
1		10 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211553	08/22/2019	

Labeler - Medical Purchasing Solutions, LLC (601458529)

Establishment

Name	Address	ID/FEI	Business Operations
Medical Purchasing Solutions, LLC		601458529	repack(71872-7193)

Revised: 5/2023 Medical Purchasing Solutions, LLC