

CALCIUM CHLORIDE- calcium chloride injection
HF Acquisition Co LLC, DBA HealthFirst

10% CALCIUM CHLORIDE INJECTION, USP 1 g/10 mL (100 mg/ mL) (1.4 mEq/mL) LUER-JET™ SYR

SPL UNCLASSIFIED

10% Calcium Chloride
Injection, USP Rx Only

1 g/10 mL (100 mg/mL)

Represents 27 mg (1.4 mEq) Ca⁺⁺/mL

A HYPERTONIC SOLUTION IN A 10 ML SINGLE DOSE SYRINGE FOR PROMPT
INTRAVENOUS INJECTION.

CAUTION: This solution must not be injected intramuscularly or subcutaneously.
Administer only by slow injection (not to exceed 1 mL/minute)

DESCRIPTION

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 single dose 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 CaCl₂ • 2H₂O (dihydrate) and is described as white, odorless fragments or granules freely soluble in water.

CLINICAL PHARMACOLOGY

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 operates 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%.

INDICATIONS & USAGE

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

CONTRAINDICATIONS

Calcium chloride is contraindicated for cardiac resuscitation in the presence of ventricular fibrillation or in patients with the risk of existing digitalis toxicity.

Calcium chloride is not recommended in the treatment of asystole and electromechanical dissociation.

WARNINGS

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.

PRECAUTIONS

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.

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

Pregnancy Category C: 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.

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.

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.

DRUG ABUSE AND DEPENDENCE

None known.

OVERDOSAGE

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.

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.

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.

The usual adult dosage in hypocalcemic disorders ranges from 200 mg to 1 g (2 -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.

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.

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.

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

To prevent needle-stick injuries, needles should not be recapped, purposely bent or broken by hand.

HOW SUPPLIED

10% CALCIUM CHLORIDE INJECTION, USP is supplied in the following dosage forms.
NDC 51662-1379-1

10% CALCIUM CHLORIDE INJECTION, USP 1 g/10 mL (100 mg/ mL) (1.4 mEq/mL) LUER-JET™ SYR

NDC 51662-1379-2

10% CALCIUM CHLORIDE INJECTION, USP 1 g/10 mL (100 mg/ mL) (1.4 mEq/mL) LUER-JET™ SYR in a POUCH

NDC 51662-1379-3

10% CALCIUM CHLORIDE INJECTION, USP 1 g/10 mL (100 mg/ mL) (1.4 mEq/mL) LUER-JET™ SYR in a Pouch, 10 Pouches per Case

HF Acquisition Co LLC, DBA HealthFirst
Mukilteo, WA 98275

Also supplied in the following manufacture supplied dosage forms

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

NDC No.	Stock No.	Container Size	Needle
76329-3304-1	3304	10 mL	None

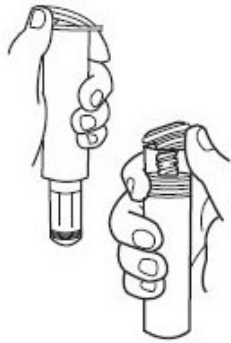
One shrink wrapped package containing 10 unit cartons, each containing a Luer-Jet™ Luer-Lock Prefilled Syringe.

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

Syringe Assembly Directions:

USE ASEPTIC TECHNIQUE

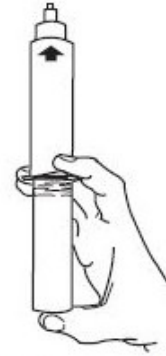
Do not assemble until ready to use.



1. Remove protective caps.



2. Thread vial into injector
3 half turns, or until
stopper is pierced by
metal cannula.*
**DO NOT PUSH VIAL INTO
INJECTOR; THIS MAY CAUSE
MISALIGNMENT.**



3. Remove cover and expel
air before injection.

***CAUTION: IMPROPER ENGAGING MAY CAUSE GLASS BREAKAGE AND SUBSEQUENT INJURY.**

CLINICAL STUDIES

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.

SPL UNCLASSIFIED

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International Medication Systems, Ltd. Rev. 2-19

South El Monte, CA 91733 USA


An Amphastar Pharmaceuticals Company

6933040G

PRINCIPAL DISPLAY PANEL - SYRING LABEL

10 mL Rx Only
Single Dose


NDC 76329-3304-1
2.04 mOsmol / mL / pH 6.3 (5.5 to 7.5)
Contains no more than 1,000 mcg/L of aluminum
For Intravenous use. Usual dosage: See insert.
Sterile nonpyrogenic. Caution: Do not inject
intramuscularly or subcutaneously.

 **IMS, LIMITED**
So. El Monte, CA 91733, U.S.A. 7633040E 5-15

10% Calcium Chloride Injection, USP
1 g/10 mL (100 mg/mL) 1.4 mEq/mL

Delivered mL

0 1 2 3 4 5 6 7 8 9


(01) 003 76329330419

NON-VARNISH AREA

PRINCIPAL DISPLAY PANEL - CARTON LABEL



PRINCIPAL DISPLAY PANEL - SERIALIZED LABELING



01) 00351622137910
17) 210930
21) 199833807583
10) CE075J9
see manufacturer's package insert
distributed by HF Acquisition Co., LLC
 Tukilteo, WA 98275



RX ONLY

(01) 003 76329330419



Luer-Lock Prefilled Syringe

10% Calcium Chloride Injection, USP
10 mL, 14 mEq (1 g)
LUER-JET™ LUER-LOCK PREFILLED SYRINGE
FOR SLOW INTRAVENOUS USE ONLY
USUAL DOSAGE: SEE PACKAGE INSERT

NDC 76329

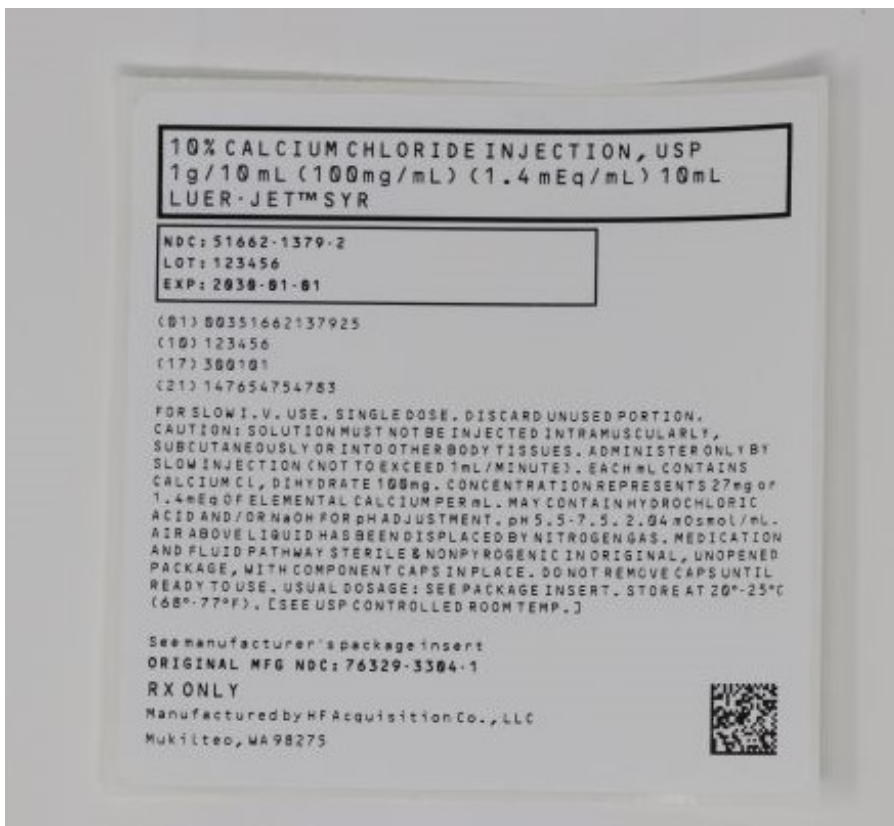
10% Calcium Chloride Injection, USP
1 g/10 mL (100 mg/mL)
(1.4 mEq/mL)

Single use, do not reuse or resterilize.
10 mL Single Dose LUER-JET™ LUER-LOCK Prefilled S

FOR SLOW INTRAVENOUS USE



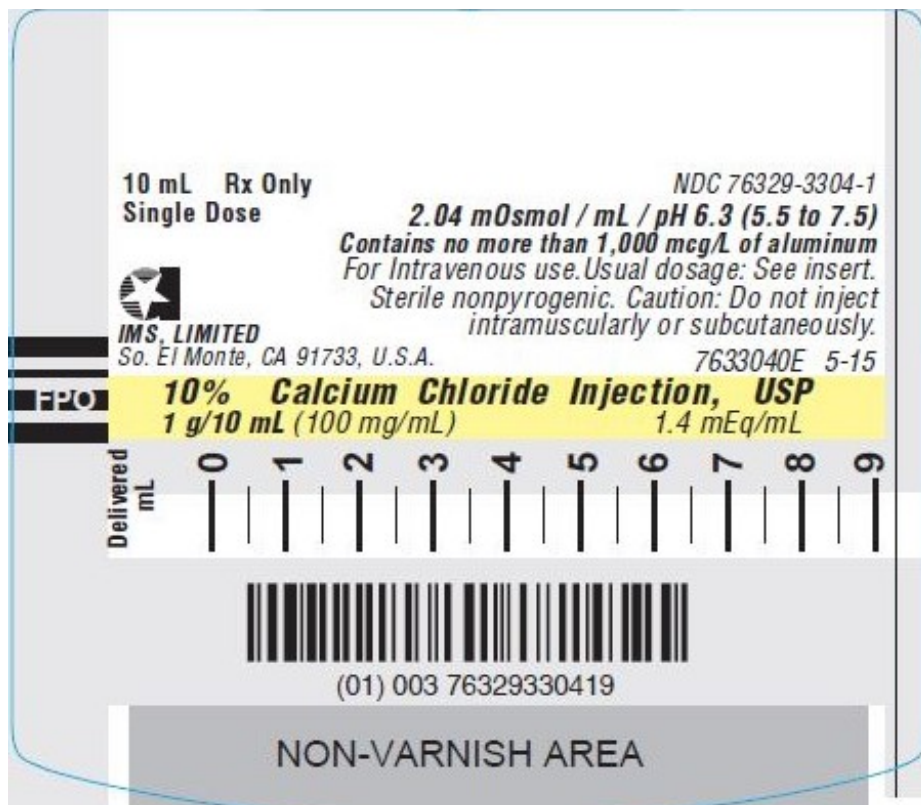
PRINCIPAL DISPLAY PANEL NDC 51662-1379-2 POUCH
POUCH LABELING



CARTON 2



SYRINGE



PRINCIPAL DISPLAY PANEL NDC 51662-1379-3 CASE

CASE LABELING

10% CALCIUM CHLORIDE INJECTION, USP
1g/10 mL (100mg/mL) (1.4 mEq/mL) 10mL
LUER-JET™ SYR (CASE OF 10)


NDC: 51662-1379-3
LOT: 123456
EXP: 2030-01-01

(01) 00351662137932
(10) 123456
(17) 300101
(21) 238996183127

FOR SLOW I.V. USE. SINGLE DOSE. DISCARD UNUSED PORTION.
CAUTION: SOLUTION MUST NOT BE INJECTED INTRAMUSCULARLY,
SUBCUTANEOUSLY OR INTO OTHER BODY TISSUES. ADMINISTER ONLY BY
SLOW INJECTION (NOT TO EXCEED 1mL/MINUTE). EACH mL CONTAINS
CALCIUM CL₂ DIHYDRATE 100mg. CONCENTRATION REPRESENTS 27mg of
1.4mEq OF ELEMENTAL CALCIUM PER mL. MAY CONTAIN HYDROCHLORIC
ACID AND/OR NaOH FOR pH ADJUSTMENT. pH 5.5-7.5. 2.64 osmol/mL.
AIR ABOVE LIQUID HAS BEEN DISPLACED BY NITROGEN GAS. MEDICATION
AND FLUID PATHWAY STERILE & NONPYROGENIC IN ORIGINAL, UNOPENED
PACKAGE, WITH COMPONENT CAPS IN PLACE. DO NOT REMOVE CAPS UNTIL
READY TO USE. USUAL DOSAGE: SEE PACKAGE INSERT. STORE AT 20°-25°C
(68°-77°F). [SEE USP CONTROLLED ROOM TEMP.]

See manufacturer's package insert
ORIGINAL MFG NDC: 76329-3304-1
RX ONLY
Manufactured by HF Acquisition Co., LLC
Nukilteo, WA 98275

CASE



SERIALIZED RFID LABELING

(01)00351662137932
(17)230919
(21)351662141212
(10)HF1234TESTING

SEE MANUFACTURE'S INSERT
DISTRIBUTED BY HF ACQUISITIONS CO., LLC
MUKILTEO, WA 98275

RX ONLY



**PRINCIPAL DISPLAY PANEL - 51662-1379-1 SERIALIZED LABELING
CORRECTED AND UPDATED as of 2-9-2023**

51662-1379-1 SERIALIZED LABELING as of 2-9-2023

(01) 00351662137918

(17) 210930

(21) 266493326472

(10) CE075J9



RX ONLY

See manufacturer's package insert
Distributed by HF Acquisition Co., LLC
Mukilteo, WA 98275

CALCIUM CHLORIDE

calcium chloride injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:51662-1379(NDC:76329-3304)
Route of Administration	INTRAVENOUS, INTRAVENTRICULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CHLORIDE	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51662-1379-1	1 in 1 CARTON	12/09/2019	
1		10 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:51662-	10 in 1 CASE	09/12/2022	

4	1379-3	10 in 1 CASE	09/12/2022	
2	NDC:51662-1379-2	1 in 1 POUCH		
2		1 in 1 CARTON		
2		10 mL in 1 SYRINGE; 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	ANDA203477	12/09/2019	

Labeler - HF Acquisition Co LLC, DBA HealthFirst (045657305)

Registrant - HF Acquisition Co LLC, DBA HealthFirst (045657305)

Establishment

Name	Address	ID/FEI	Business Operations
HF Acquisition Co LLC, DBA HealthFirst		045657305	relabel(51662-1379)

Revised: 1/2024

HF Acquisition Co LLC, DBA HealthFirst