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

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

10% CALCIUM CHLORIDE INJECTION, USP 1gram (100mg/mL) SYR

SPL UNCLASSIFIED

100 mg/mL Rx only
Represents 27 mg (1.4 mEq) Ca++/mL
ABBOJECT® Syringe
A HYPERTONIC SOLUTION IN A 10 ML
UNIT OF USE SYRINGE FOR PROMPT
INTRAVENOUS INJECTION.
CAUTION: This solution must not be injected
intramuscularly or subcutaneously.

DESCRIPTION

10% Calcium Chloride Injection, USP is a sterile, nonpyrogenic, hypertonic solution containing 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 is administered only by intravenous or intraventricular cavity injection as a calcium replenisher.

The solution contains no bacteriostat, antimicrobial agent or added buffer and is intended only for use as a single-dose injection. As per USP testing, when diluted with water for injection to make a 5% solution, the pH of calcium chloride injection is 6.3 (5.5 to 7.5). 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) 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 (1) for the treatment of hypocalcemia in those conditions requiring a prompt increase in blood plasma calcium levels, (2) in the treatment of magnesium intoxication due to overdosage of magnesium sulfate and (3) to combat the deleterious effects of hyperkalemia as measured by electrocardiographic (ECG), pending correction of the increased potassium level in the extracellular fluid.

10% Calcium Chloride Injection, USP also may be used in cardiac resuscitation when weak or inadequate contractions return following defibrillation or when epinephrine injection has failed to strengthen myocardial contractions.

CONTRAINDICATIONS

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

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. If injected into the ventricular cavity in cardiac resuscitation, it must not be injected into the myocardial tissue.

Pregnancy: 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 reproduction capacity. Calcium chloride should be given to a pregnant woman only if clearly needed.

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 & DEPENDENCE

None known.

DOSAGE & ADMINISTRATION

10% Calcium Chloride Injection, USP is administered only by slow intravenous injection (not to exceed 1 mL/min) and/or in cardiac resuscitation, by injection into the ventricular cavity. It must not be injected into the myocardium.

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 500 mg to 1 g (5 to 10 mL) at intervals of 1 to 3 days, depending on the response of the patient and/or results of serum calcium determinations. Repeated injections may be required because of rapid excretion of calcium.

In magnesium intoxication, an initial adult dose of 500 mg (5 mL) should be administered promptly and the patient observed for signs of recovery before further doses are given.

In hyperkalemic ECG disturbances of cardiac function, the dosage of calcium chloride injection should be titrated by constant monitoring of ECG changes during administration.

In cardiac resuscitation, the usual adult dosage ranges from 500 mg to 1 g (5 to 10 mL) intravenously, or from 200 to 800 mg (2 to 8 mL) when injected into the ventricular cavity.

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.

OVERDOSAGE

oo 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.

HOW SUPPLIED

10% CALCIUM CHLORIDE INJECTION is supplied in the following dosage forms.
NDC 51662-1209-1
10% CALCIUM CHLORIDE INJECTION, USP 1gram (100mg/mL) SYR

NDC 51662-1209-2
10% CALCIUM CHLORIDE INJECTION, USP 1gram (100mg/mL) SYR, 1 SYRINGE PER POUCH

NDC 51662-1209-3

10% CALCIUM CHLORIDE INJECTION, USP 1gram (100mg/mL) SYR, 1 SYRINGE PER POUCH, 10 POUCHES PER CASE

HF Acquisition Co LLC, DBA HealthFirst
Mukilteo, WA 98275

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

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LIFESHIELD® is the trademark of ICU Medical, Inc.

PRINCIPLE DISPLAY PANEL, SYRINGE

CALCIUM CHLORIDE 1 Gram/10 mL

10 mL Single-dose
NDC 0409-4928-34

10% CALCIUM CHLORIDE Inj., USP
1 Gram (100 mg/mL)
1.4 mEq Ca++/mL

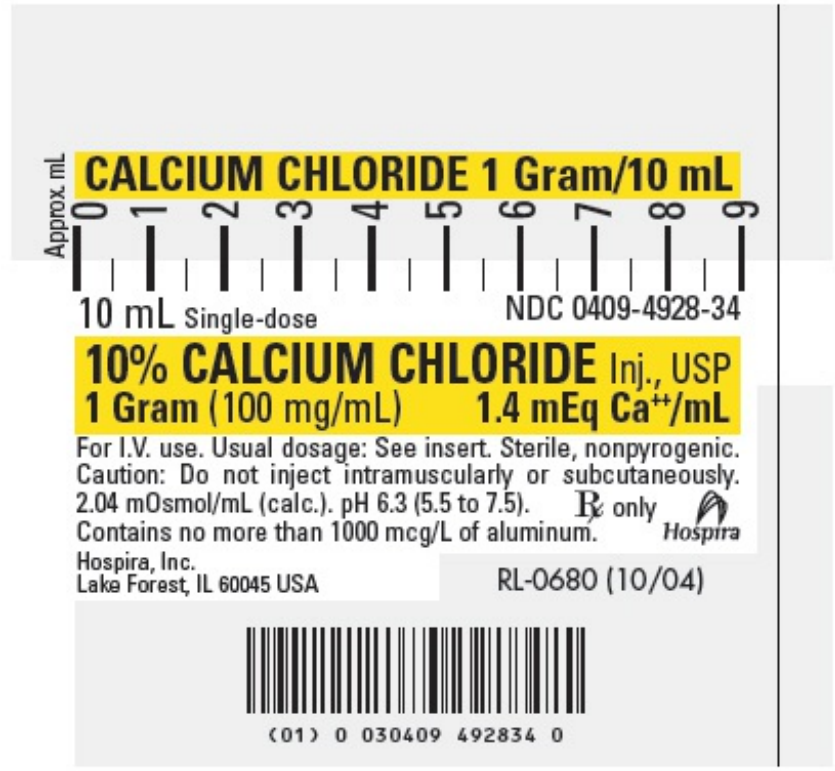
For I.V. use. Usual dosage: See insert. Sterile, nonpyrogenic.
Caution: Do not inject intramuscularly or subcutaneously.
2.04 mOsmol/mL (calc.). pH 6.3 (5.5 to 7.5).
Contains no more than 1000 mcg/L of aluminum.

Rx only

Hospira

Hospira, Inc.
Lake Forest, IL 60045 USA

RL-0680 (10/04)



PRINCIPLE DISPLAY PANEL, CARTON

10 mL

NDC 0409-4928-34

10%
CALCIUM
CHLORIDE
Injection, USP

1 gram (100 mg/mL)
represents 27 mg
(1.4 mEq) Ca++/mL

LifeShield®

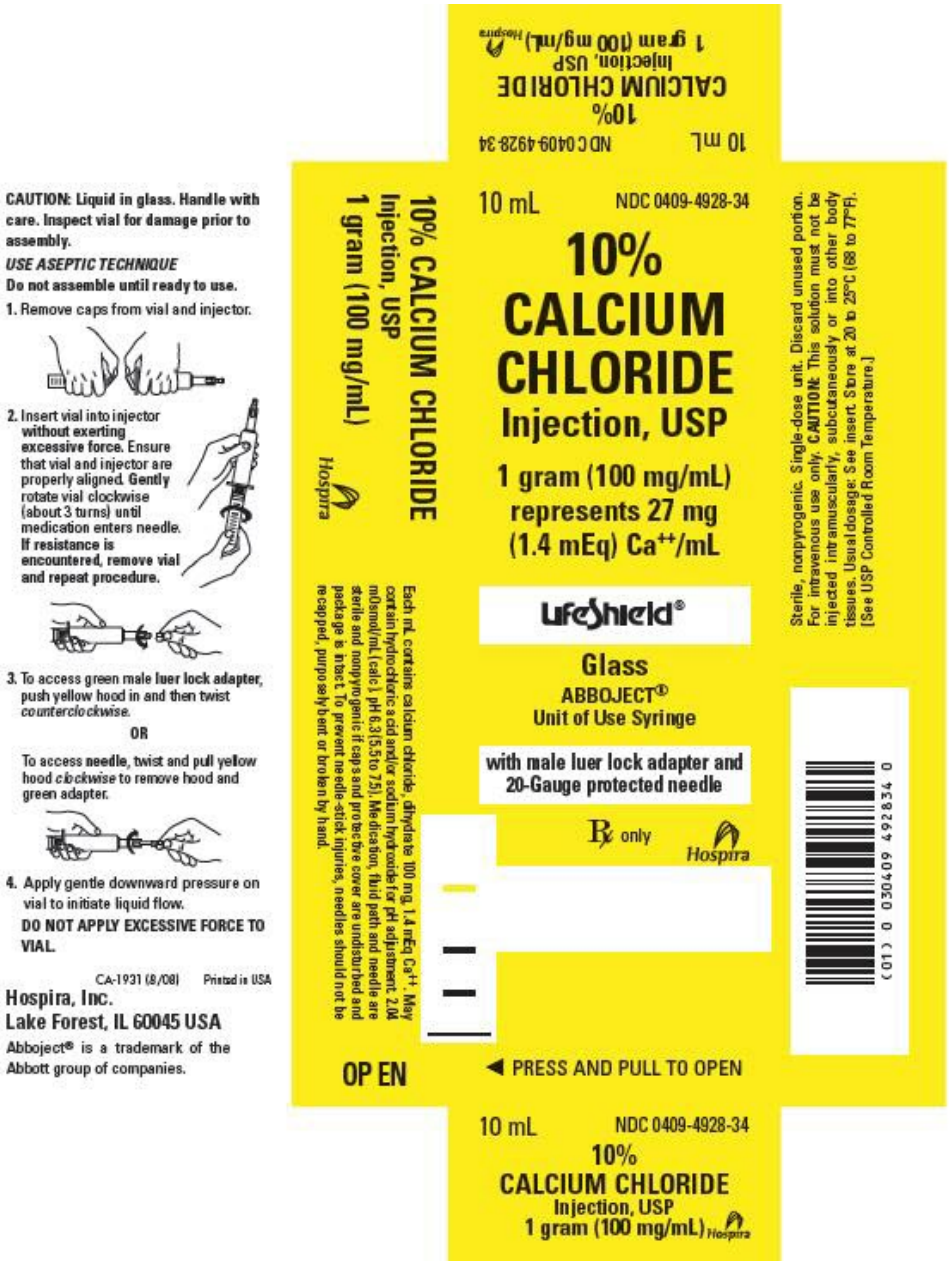
Glass
ABBOJECT®
Unit of Use Syringe

with male luer lock adapter and
20-Gauge protected needle

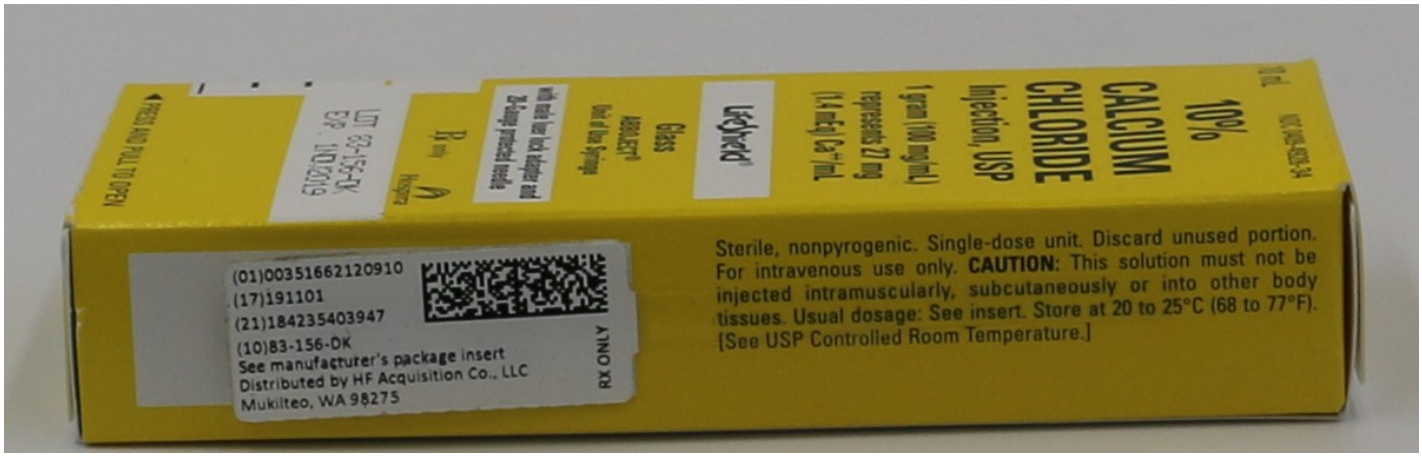
Rx only

Hospira

◀ PRESS AND PULL TO OPEN

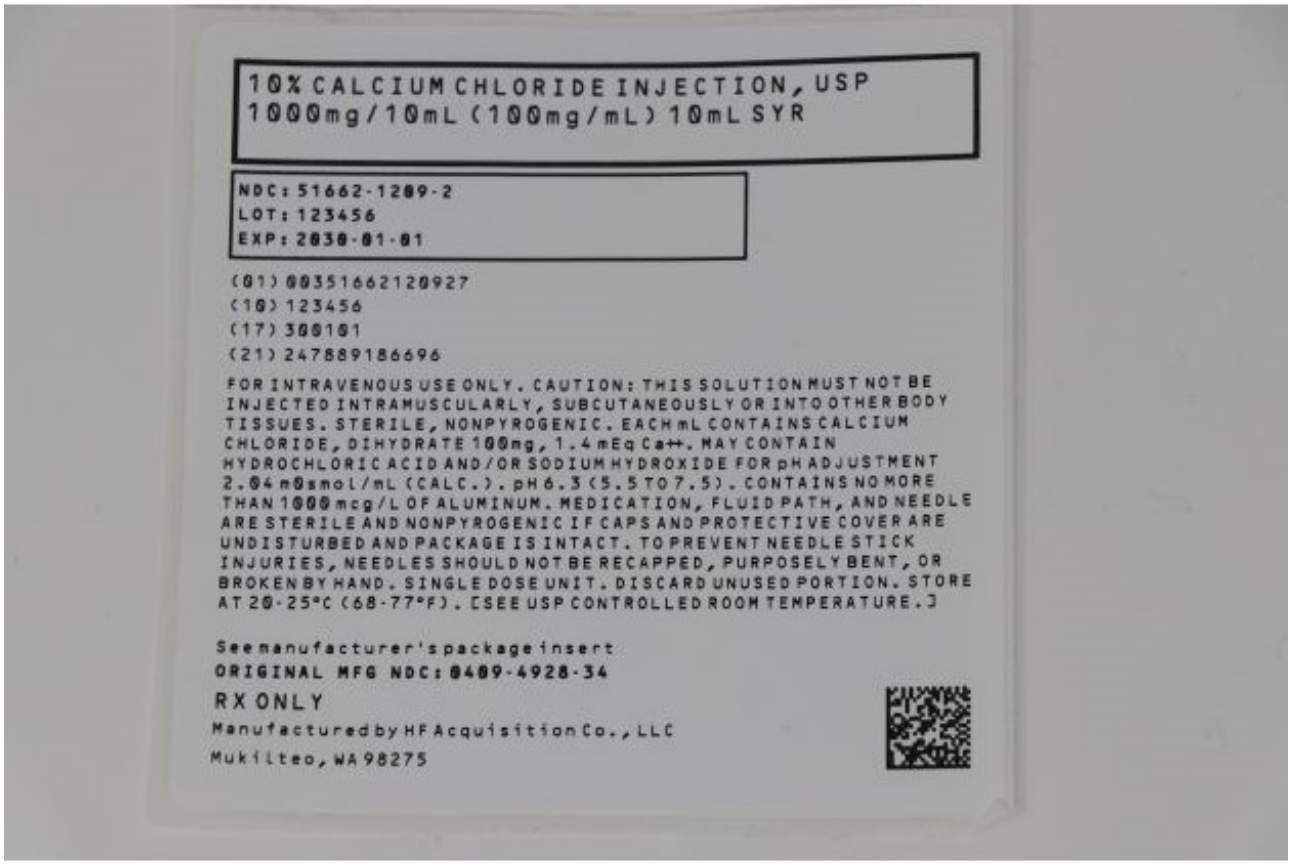


PRINCIPLE DISPLAY PANEL, SERIALIZED LABEL



PRINCIPAL DISPLAY PANEL - NDC 51662-1209-2 POUCH LABELING

NDC 51662-1209-2 POUCH LABELING



CARTON LABELING

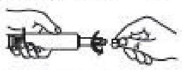
CAUTION: Liquid in glass. Handle with care. Inspect vial for damage prior to assembly.

USE ASEPTIC TECHNIQUE

Do not assemble until ready to use.

1. Remove caps from vial and injector.

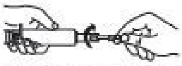
2. Insert vial into injector without exerting excessive force. Ensure that vial and injector are properly aligned. Gently rotate vial clockwise (about 3 turns) until medication enters needle. If resistance is encountered, remove vial and repeat procedure.



3. To access green male luer lock adapter, push yellow hood in and then twist *counterclockwise.*

OR

To access needle, twist and pull yellow hood *clockwise* to remove hood and green adapter.



4. Apply gentle downward pressure on vial to initiate liquid flow.
DO NOT APPLY EXCESSIVE FORCE TO VIAL.

CA-1931 (8/08) Printed in USA

Hospira, Inc.
Lake Forest, IL 60045 USA

Abboject® is a trademark of the Abbott group of companies.

10 mL NDC 0409-4928-34

10%
CALCIUM CHLORIDE
Injection, USP
1 gram (100 mg/mL)
Hospira

10% CALCIUM CHLORIDE
Injection, USP
1 gram (100 mg/mL)
Hospira

Each mL contains calcium chloride, dihydrate 100 mg, 1.4 mEq Ca^{++}. May contain hydrochloric acid and/or sodium hydroxide for pH adjustment. 2.04 mOsmol/mL (calc.). pH 6.3 (5.5 to 7.5). Medication, fluid path and needle are sterile and nonpyrogenic if caps and protective cover are undisturbed and package is intact. To prevent needle-stick injuries, needles should not be recapped, purposely bent or broken by hand.

OP EN

10 mL NDC 0409-4928-34

10%
CALCIUM CHLORIDE
Injection, USP

1 gram (100 mg/mL)
represents 27 mg
(1.4 mEq) Ca^{++}/mL

LifeShield®

Glass
ABBOJECT®
Unit of Use Syringe

with male luer lock adapter and 20-Gauge protected needle

℞ only

Hospira

◄ PRESS AND PULL TO OPEN

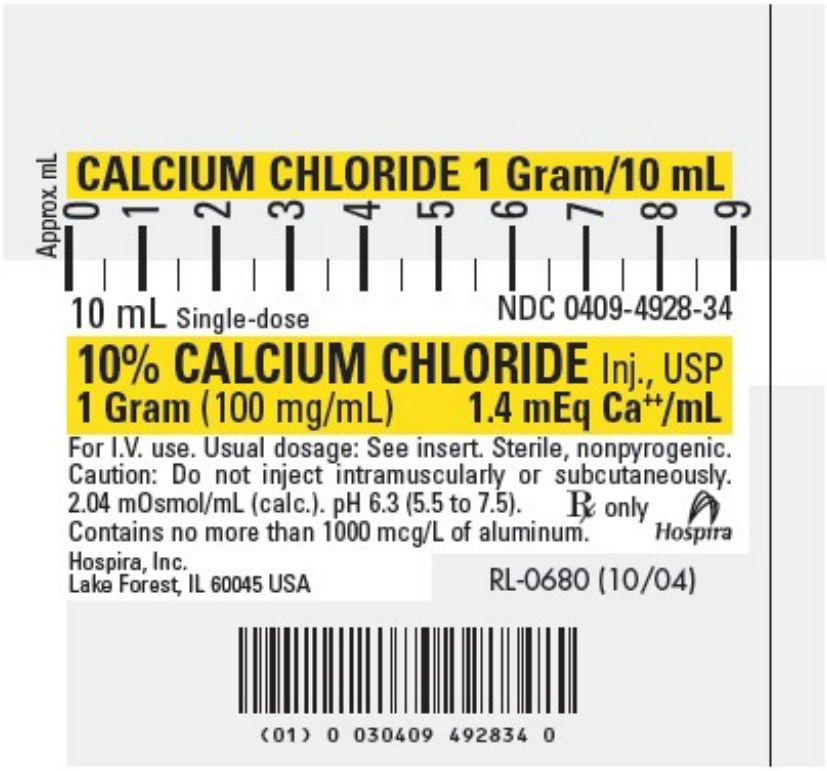
Sterile, nonpyrogenic. Single-dose unit. Discard unused portion. For intravenous use only. **CAUTION:** This solution must not be injected intramuscularly, subcutaneously or into other body tissues. Usual dosage: See insert. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

(01) 0 030409 492834 0

10 mL NDC 0409-4928-34

10%
CALCIUM CHLORIDE
Injection, USP
1 gram (100 mg/mL) Hospira

SYRINGE LABEL



PRINCIPAL DISPLAY PANEL - NDC 51662-1209-3 CASE LABELING

NDC 51662-1209-2 CASE LABELING

SERIALIZED CASE RFID LABELING

CALCIUM CHLORIDE

calcium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51662-1209(NDC:0409-4928)
Route of Administration	INTRAVENOUS, INTRAVENTRICULAR		

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51662-1209-1	1 in 1 CARTON	09/13/2018	
1		10 mL in 1 SYRINGE, GLASS; Type 1: Convenience Kit of Co-Package		
2	NDC:51662-1209-3	10 in 1 CASE	12/12/2022	
2	NDC:51662-1209-2	1 in 1 POUCH		
2		1 in 1 CARTON		
2		10 mL in 1 SYRINGE, GLASS; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/13/2018	

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(51662-1209)