CALCIUM CHLORIDE - calcium chloride injection
International Medication Systems, Limited

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.

CALCIUM CHLORIDE
INJECTION, USP, 10%

13.6 mEq (1 g) per 10 mL
100 mg (1.36 mEq)/ mL
Osmolarity approximately 2050 mOsmol/L

DESCRIPTION

Calcium Chloride Injection, USP, 10%, is a sterile aqueous solution containing, in each mL, 100 mg (1.36 mEq) calcium chloride. The pH of the solution may have been adjusted with hydrochloric acid and / or calcium hydroxide, when necessary. The air above the liquid in the individual containers has been displaced by flushing with nitrogen during the filling operation. The preparation contains no antimicrobial preservatives and is intended as a single-dose vial; once the unit is assembled and used, any remaining portion of the solution must be discarded with the entire unit.

Calcium Chloride, USP, contains two molecules of water of hydration and is chemically designated as $CaCl_2 \cdot 2H_20$.

CLINICAL PHARMACOLOGY

Calcium is the fifth most abundant element in the body, the major fraction of which is found in the bony structure. Calcium plays important physiological roles; it is essential for the functional integrity of the nervous and muscular systems; it is necessary for normal cardiac function; and it is one of the factors involved in the mechanism of blood coagulation.

INDICATIONS AND USAGE

Calcium Chloride Injection, USP, 10% is indicated:

In the treatment of hypocalcemia in conditions requiring a prompt increase in plasma calcium levels (e.g., neonatal tetany and tetany due to parathyroid deficiency, vitamin D deficiency and alkalosis) and for prevention of hypocalcemia during exchange transfusions.

As adjunctive therapy in the management of acute symptoms in lead colic.

In the treatment of magnesium intoxication due to overdosage of magnesium sulfate.

In severe hyperkalemia, to combat deleterious effects on electrocardiographic (ECG) function, pending correction of the potassium level in the extracellular fluid.

In cardiac resuscitation, particularly after open heart surgery, when epinephrine fails to improve weak or ineffective myocardial contractions.

CONTRAINDICATIONS

Calcium chloride is contraindicated for cardiac resuscitation in the presence of ventricular fibrillation.

WARNINGS

Calcium chloride should be injected into a large vein very slowly, as it may cause peripheral vasodilatation and a cutaneous burning sensation. A moderate fall in blood pressure due to vasodilatation may attend the injection. Since calcium chloride is an acidifying salt, it is usually undesirable in the treatment of hypocalcemia or renal insufficiency.

PRECAUTIONS

General

Calcium Chloride Injection, USP, 10% 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.

Solutions should be warmed to body temperature. 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 care must be taken to avoid injection into the myocardial tissue.

Drug Interactions

Because of the danger involved in the simultaneous use of calcium salts and drugs of the digitalis group, a digitalized patient should not receive an intravenous injection of a calcium compound unless the indications are clearly defined.

Calcium salts should not generally be mixed with carbonates, phosphates, sulfates or tartrates in parenteral admixtures.

ADVERSE REACTIONS

Rapid I.V. 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 vasodilation as well as a local “burning” sensation, and there may be a moderate fall in blood pressure.

DOSAGE AND ADMINISTRATION
FOR INTRACARDIAC OR INTRAVENOUS USE ONLY

INJECT SLOWLY

Calcium Chloride Injection, USP, 10%, 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.

INTRACARDIAC USE

For cardiac resuscitation, inject into the ventricular cavity, not into the heart muscle.

Usual Adult Dosage: 200 to 800 mg (2 to 8 mL) when injected into the ventricular cavity.

Pediatric Dosage: 0.2 mL/kg of body weight.

INTRAVENOUS USE
Hypocalcemic Disorders

Usual Adult Dosage: 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.

Pediatric Dosage: 0.2 mL /kg of body weight. Maximum 1-10 mL/day.

Magnesium Intoxication
Initial Adult Dose: 500 mg (5 mL) administered promptly and the patient observed for signs of recovery before further doses are given.

Hyperkalemic ECG Disturbances of Cardiac Function
Dosage should be adjusted by constant monitoring of ECG changes during administration.

HOW SUPPLIED

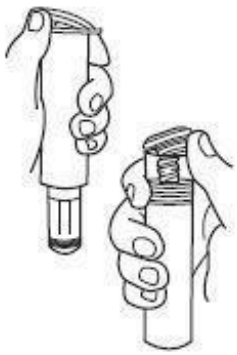
CALCIUM CHLORIDE INJECTION, USP, 10%

In unit-use packages containing a Luer-Jet™ Luer-Lock Prefilled Syringe.

Stock No. 3304 NDC 76329-3304-1 10 mL

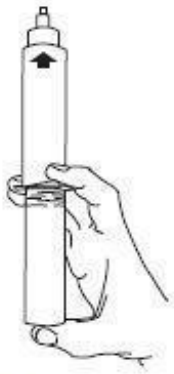
Ten cartons per package.

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.

Store at controlled room temperature 15° to 30°C (59° to 86°F).

Rx Only

INTERNATIONAL MEDICATION SYSTEMS, LIMITED So. El Monte, CA 91733, U.S.A. Rev. 2-13
An Amphastar Pharmaceuticals Company

PRINCIPLE DISPLAY PANEL: Syringe Label

Osmolarity approx. 2050 mOsmol per liter (calc.)

FOR SLOW INTRAVENOUS USE ONLY

SEE INSERT / SINGLE DOSE

NO PRESERVATIVE ADDED

IMS, LIMITED

Rx Only

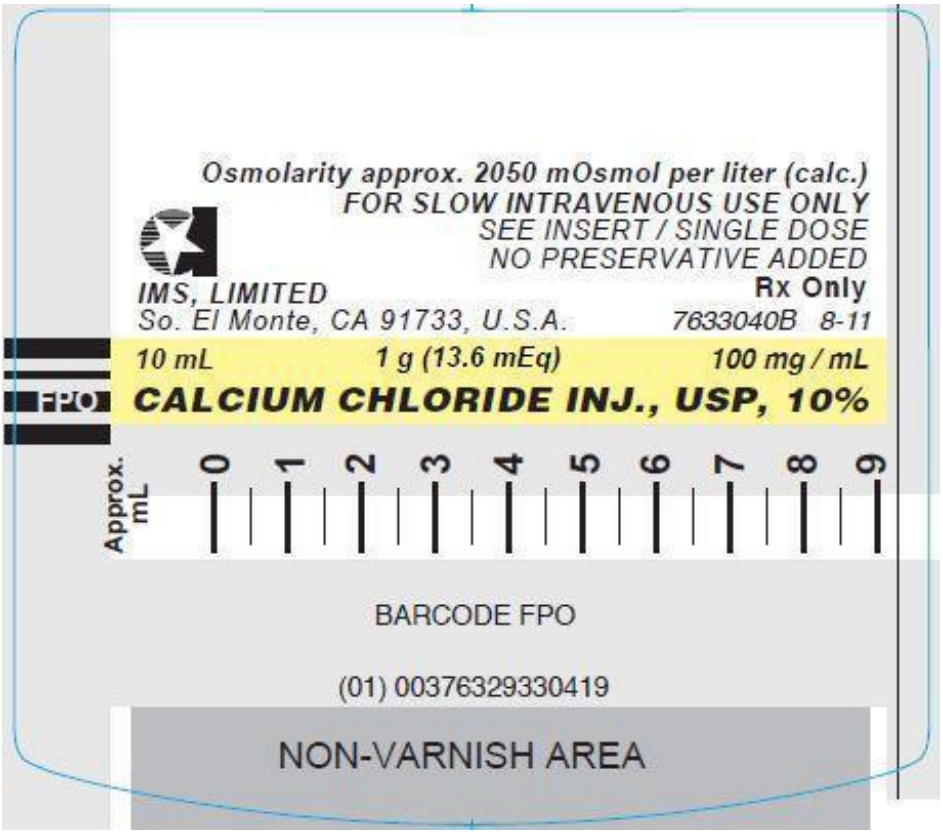
So. El Monte, CA 91733, U.S.A.

7633040B 8-11

10 mL 1 g (13.6 mEq) 100 mg / mL

CALCIUM CHLORIDE INJ., USP, 10%

Approx. mL 0 1 2 3 4 5 6 7 8 9



PRINCIPLE DISPLAY PANEL: Carton

Luer-Lock Prefilled Syringe

Rx only

NDC 76329-3304-1

STOCK NO. 3304

CALCIUM CHLORIDE INJ. USP, 10%

1.36 mEq/ mL (100 mg/ mL)

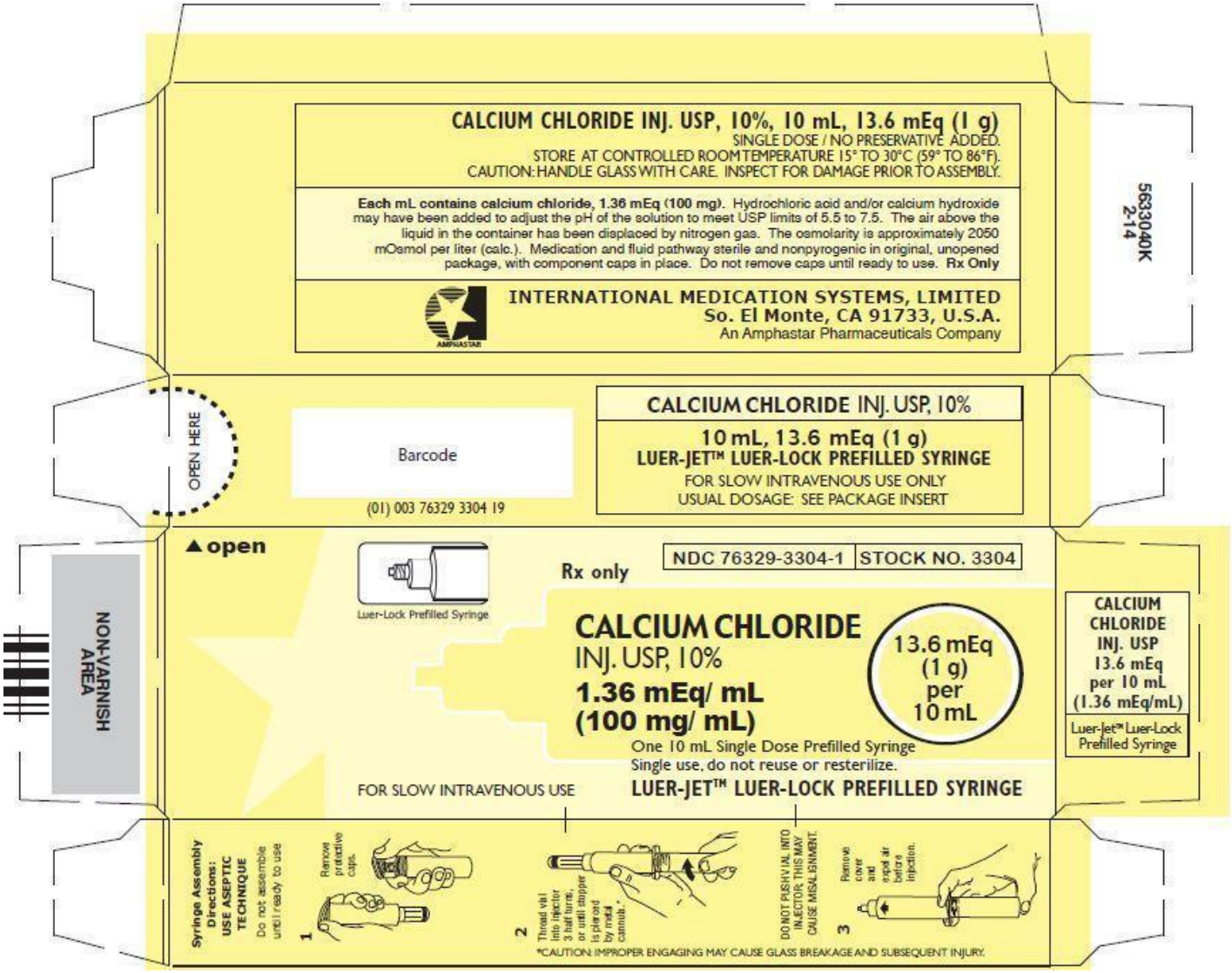
13.6 mEq (1 g) per 10 mL

One 10 mL Single Dose Prefilled Syringe

Single use, do not reuse or resterilize.

FOR SLOW INTRAVENOUS USE

LUER-JET™ LUER-LOCK PREFILLED SYRINGE



CALCIUM CHLORIDE

calcium chloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	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
Hydrochloric Acid (UNII: QTT17582CB)	
Calcium Hydroxide (UNII: PF5DZW74VN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76329-3304-1	10 in 1 PACKAGE	05/01/1973	
1		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
unapproved drug other		05/01/1973	

Labeler - International Medication Systems, Limited (055750020)

Establishment

Name	Address	ID/FEI	Business Operations
International Medication Systems, Limited		055750020	analysis(76329-3304) , manufacture(76329-3304) , label(76329-3304)

Revised: 11/2016 International Medication Systems, Limited