

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

*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.*

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**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  $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$ .

**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.

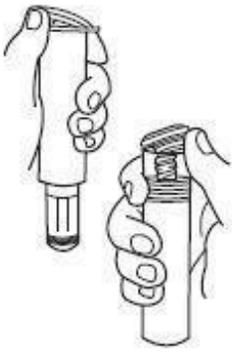
Stock No. 3304    NDC 76329-3304-1    10 mL

Ten cartons per package.

#### **Syringe Assembly Directions:**

#### **USE ASEPTIC TECHNIQUE**

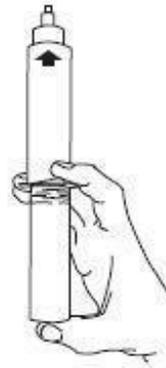
**Do not assemble until ready to use.**



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

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**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

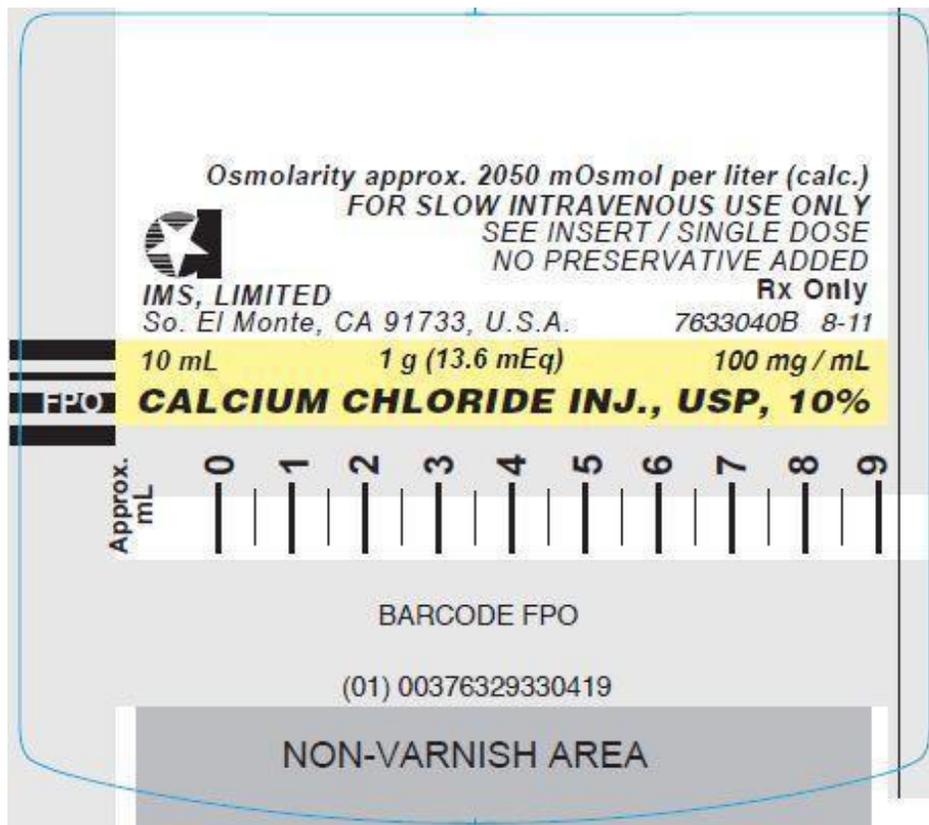
So. El Monte, CA 91733, U.S.A.

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)

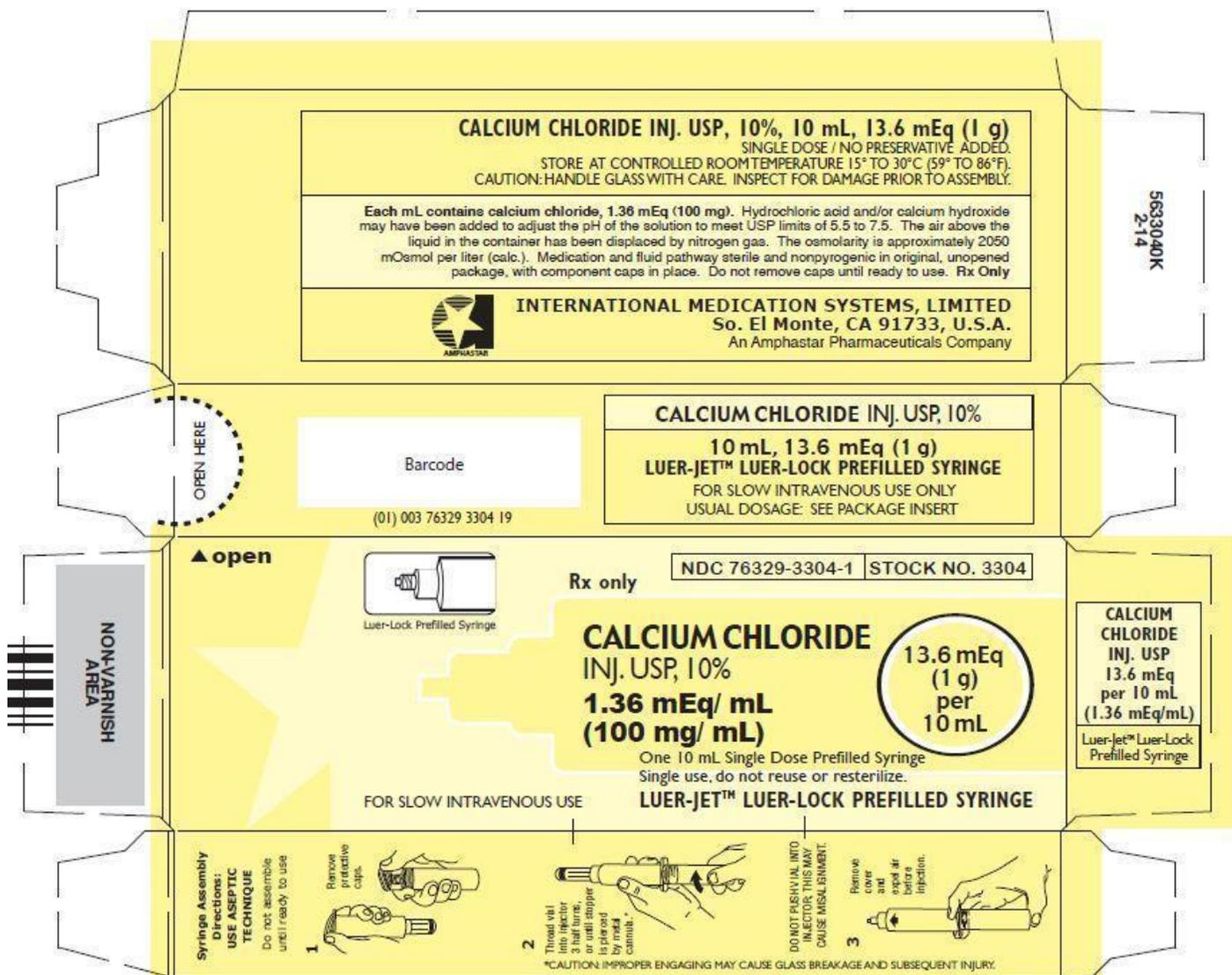
13.6 mEq (1 g) per 10 mL

One 10 mL Single Dose Prefilled Syringe

Single use, do not reuse or resterilize.

FOR SLOW INTRAVENOUS USE

LUER-JET™ LUER-LOCK PREFILLED SYRINGE



**PRINCIPAL DISPLAY PANEL: Outer package label**

NDC 71872-7044-1

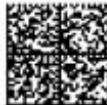
1 - Prefilled Syringe

Calcium Chloride Inj. USP, 10%

Rx Only



Rx only



(01) 0 0871872 70441 0  
(17) 000101  
(10) XXXX-XXXXXXX  
(21) 7044A000000

Calcium Chloride Inj. USP, 10%  
1.4 mEq/mL (100 mg/mL) 14 mEq (1 g) per 10 mL

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

LUER-JET™ LUER-LOCK PREFILLED SYRINGE. FOR SLOW INTRAVENOUS USE.  
Each mL contains calcium chloride, dihydrate 100mg. This concentration represents 27 mg or 1.4 mEq of elemental calcium per mL. May contain hydrochloric acid and/or sodium hydroxide for pH adjustment. pH 5.5 to 7.5. 2.04 mOsmol/mL. The air above the liquid in the container has been displaced by nitrogen gas. Medication and fluid pathway sterile and nonpyrogenic in original, unopened package, with component caps in place. Do not remove caps until ready to use.  
Usual dosage: See insert.

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

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

Manufactured by: International Medication Systems, Limited, An Amphastar Pharmaceuticals Company, So. El Monte, CA 91733, U.S.A.  
Manufacturer NDC: 76329-3304-01

Repackaged  
& Distributed By:



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

## CALCIUM CHLORIDE

calcium chloride injection

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:71872-7044(NDC:76329-3304)
<b>Route of Administration</b>	INTRAVENOUS, INTRAVENTRICULAR		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CALCIUM CHLORIDE</b> (UNII: M410D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CHLORIDE	100 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>CALCIUM HYDROXIDE</b> (UNII: PF5DZW74VN)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71872-7044-1	1 in 1 BAG	03/15/2018	

1		1 in 1 CARTON		
1		10 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
unapproved drug other			05/01/1973	

**Labeler** - Medical Purchasing Solutions, LLC (601458529)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Medical Purchasing Solutions, LLC		601458529	repack(71872-7044)

Revised: 5/2023

Medical Purchasing Solutions, LLC