

CALCIUM CHLORIDE- calcium chloride injection, solution
American Regent, Inc.

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%

Rx Only

100 mg/mL (13.6 mEq Calcium/10 mL)

FOR INTRAVENOUS USE ONLY

Osmolarity 2.04 mOsmol/mL

DESCRIPTION

Each mL contains: Calcium Chloride Dihydrate 100 mg in Water for Injection q.s. pH (range 5.5-7.5) adjusted with Hydrochloric Acid and/or Sodium Hydroxide. Each 10 mL contains 13.6 mEq Calcium and 13.6 mEq Chloride. The molecular weight is 147.02 and the molecular formula is $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$. Sterile, nonpyrogenic.

CLINICAL PHARMACOLOGY

Calcium is the fifth most abundant element in the body; the major fraction is in bone. It is essential for the functional integrity of the nervous and muscular systems, for normal cardiac contractility and the coagulation of blood. It also functions as an enzyme cofactor and affects the secretory activity of endocrine and exocrine glands.

INDICATIONS AND USAGE

Calcium Chloride is indicated in the immediate treatment of hypocalcemic tetany. Other therapy, such as parathyroid hormone or vitamin D, may be indicated according to the etiology of the tetany. It is also important to institute oral calcium therapy as soon as practicable. Calcium salts have been used as adjunctive therapy in a number of conditions, including the following:

- Insect bites or stings, such as Black Widow Spider bites.
Sensitivity reactions, particularly when characterized by urticaria.
As an aid in the treatment of depression due to overdosage of magnesium sulfate.
As an aid in the management of the acute symptoms in lead colic.
In cardiac resuscitation, particularly after open heart surgery, calcium chloride has been used when epinephrine has failed to improve weak or ineffective myocardial contractions.

CONTRAINDICATIONS

In cardiac resuscitation, the use of calcium chloride is contraindicated in the presence of ventricular fibrillation.

If neonates are required, or expected to require, treatment with calcium-containing IV solutions, including continuous calcium-containing infusions such as parenteral nutrition, ceftriaxone sodium injection is contraindicated because of the risk of precipitation of ceftriaxone-calcium.

A small number of cases of fatal outcomes in which a crystalline material was observed in the lungs and kidneys at autopsy have been reported in neonates receiving calcium containing fluids and ceftriaxone.

In some of these cases, the same intravenous infusion line was used for both calcium-containing fluids and ceftriaxone and in some a precipitate was observed in the intravenous infusion line. At least one fatality has been reported in a neonate in whom calcium-containing fluids and ceftriaxone were administered at different time points via different intravenous lines; no crystalline material was observed at autopsy in this neonate. There have been no similar reports in patients other than neonates.

WARNINGS

This solution is suitable only for intravenous use. Calcium chloride solution injection into muscle or into subcutaneous or perivascular tissue may cause severe necrosis and sloughing. Intravenous injections of this drug must be made with great care to avoid leakage into the perivascular tissue.

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

To avoid undesirable reactions that may follow intravenous administration of calcium chloride, the rate of injection should not exceed 0.5 mL to 1 mL per minute.

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.

Interaction with Calcium-Containing Products:

Do not use diluents containing calcium to reconstitute ceftriaxone vials or to further dilute a reconstituted vial for IV administration because a precipitate can form. Precipitation of ceftriaxone-calcium can also occur when calcium-containing solutions are mixed with ceftriaxone in the same IV administration line. Calcium-containing IV solutions, including continuous calcium-containing infusions such as parenteral nutrition must not be administered simultaneously with ceftriaxone via a Y-site. However, in patients other than neonates, calcium-containing solutions and ceftriaxone may be administered sequentially of one another if the infusion lines are thoroughly flushed between infusions with a compatible fluid. *In vitro* studies using adult and neonatal plasma from umbilical cord blood demonstrated that neonates have an increased risk of precipitation of ceftriaxone-calcium.

There have been no reports of an interaction between oral calcium-containing products and ceftriaxone or interaction between calcium-containing products (IV or oral) and intramuscular ceftriaxone.

PREGNANCY

Safety for use in pregnancy has not been established. Use of calcium chloride in women of childbearing potential requires that anticipated benefits be weighed against possible hazards.

DOSAGE AND ADMINISTRATION

The usual adult dose of this preparation varies from 5 to 10 mL at intervals of 1 to 3 days.

In cardiac resuscitation, the usual dose is 2 to 4 mL injected into the ventricular cavity. Care should be

taken to avoid injection into the cardiac muscle.

Parenteral drug products should be inspected visually for particulate matter and discoloration, whenever solution and container permit.

TREATMENT OF OVERDOSAGE

Inadvertent systemic overloading with calcium ion can produce an acute hypercalcemic syndrome. The syndrome is characterized by weakness, lethargy, intractable nausea and vomiting, coma, and sudden death, and a markedly elevated plasma calcium level. It is suggested that details of treatment of this problem be obtained by reference to Harrison's Principles of Internal Medicine Sixth Edition, pg. 475, column 2, "Acute Hypercalcemic Syndrome".

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) (See USP Controlled Room Temperature).

HOW SUPPLIED

Calcium Chloride Injection, USP 10%. (No preservative added).

NDC 0517-2710-25 10 mL single dose vial packed in a box of 25

**AMERICAN
REGENT, INC.
SHIRLEY, NY 11967**

IN2710
Rev. 7/11

HEALTH CARE PROVIDER LETTER SECTION

Not available at this time.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

PRINCIPAL DISPLAY PANEL - 10 mL Container Label

NDC 0517-2710-25

CALCIUM CHLORIDE INJECTION, USP

10% (100 mg/mL)

(13.6 mEq Calcium/10 mL)

10 mL SINGLE DOSE VIAL

FOR IV USE ONLY

**AMERICAN REGENT, INC.
SHIRLEY, NY 11967**

Rev. 10/10

NDC 0517-2710-25
CALCIUM CHLORIDE
INJECTION, USP
10% (100 mg/mL)
(13.6 mEq Calcium/10 mL)

10 mL SINGLE DOSE VIAL
FOR IV USE ONLY

Rx Only

AMERICAN REGENT, INC.
SHIRLEY, NY 11967

Each mL contains: Calcium Chloride (Dihydrate) 100 mg, Water for Injection q.s. pH adjusted with Hydrochloric Acid and/or Sodium Hydroxide.

2.04 mOsmol/mL
Contains no more than 2,500 mcg/L of aluminum.

WARNING: DISCARD UNUSED PORTION.

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

Directions for Use: See Package Insert.
Rev. 10/10



Lot / Exp.

PRINCIPAL DISPLAY PANEL - 10 mL Carton Labeling

CALCIUM CHLORIDE INJECTION, USP

10% (100 mg/mL)

(13.6 mEq Calcium/10 mL)

NDC 0517-2710-25

25 x 10 mL

SINGLE DOSE VIALS

FOR INTRAVENOUS USE ONLY

Rx Only

Each mL contains: Calcium Chloride (Dihydrate) 100 mg, Water for Injection q.s. pH adjusted with Hydrochloric Acid and/or Sodium Hydroxide. **2.04 mOsmol/mL**

WARNING: DISCARD UNUSED PORTION. Sterile, nonpyrogenic.

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) (See USP Controlled Room Temperature).

Directions for Use: See Package Insert.

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Rev. 9/06

CALCIUM CHLORIDE
 INJECTION, USP
10% (100 mg/mL)
(13.6 mEq Calcium/10 mL)

NDC 0517-2710-25
25 x 10 mL
SINGLE DOSE VIALS

FOR INTRAVENOUS USE ONLY

Rx Only

Each mL contains: Calcium Chloride (Dihydrate) 100 mg, Water for Injection q.s.
 pH adjusted with Hydrochloric Acid and/or Sodium Hydroxide. **2.04 mOsmol/mL**

WARNING: DISCARD UNUSED PORTION. Sterile, nonpyrogenic.
 Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F)
 (See USP Controlled Room Temperature).
 Directions for Use: See Package Insert.

Lot / Exp.

AMERICAN
 REGENT, INC.
 SHIRLEY, NY 11967

Rev. 9/06



CALCIUM CHLORIDE

calcium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0517-2710
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM CHLORIDE (UNII: M410D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	100 mg in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0517-2710-25	25 in 1 TRAY	07/05/2017	
1		10 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG FOR USE IN DRUG SHORTAGE		07/05/2017	

Labeler - American Regent, Inc. (002033710)

Establishment

Name	Address	ID/FEI	Business Operations
American Regent, Inc.		002033710	ANALYSIS(0517-2710) , MANUFACTURE(0517-2710)

Revised: 12/2019

American Regent, Inc.