

CALCIUM CHLORIDE INJECTION, USP 10%

Rx Only



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**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.

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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 Ceftriaxone Sodium Injection: 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.

USE IN 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.

ADMINISTRATION AND DOSAGE

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 OVERDOSE

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

IN2710
Rev. 7/11
MG #14274

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