

PRESCRIBING INFORMATION

Calcium Chloride Injection USP

100 mg/mL
(represents 27 mg [0.7 mmol or 1.4 mEq] Ca^{++} /mL)

Hypertonic solution for intravenous injection

Calcium Replenisher

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ACTION AND CLINICAL PHARMACOLOGY

Calcium is the fifth most abundant element in the body and the major fraction is in the bone 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 physiologic 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 AND CLINICAL USES

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 electrocardiography (ECG), pending correction of the increased potassium level in the extracellular fluid.

Calcium Chloride Injection USP may also 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

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.

PRECAUTIONS

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, intravenous 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.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Too rapid injection may produce lowering of blood pressure and cardiac syncope. Persistent hypercalcemia from over dosage 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**).

DOSAGE AND ADMINISTRATION

Caution: This solution must not be injected intramuscularly or subcutaneously.

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.

To prevent needle-stick injuries, needles should not be recapped, purposely bent or broken by hand.

PHARMACEUTICAL INFORMATION

Description

Calcium Chloride Injection USP is a sterile, nonpyrogenic, hypertonic solution containing 100 mg/mL (0.7 mmol/mL or 1.4 mEq/mL) of calcium chloride, dihydrate (0.7 mmol/mL or 1.4 mEq/mL of Ca^{++} and 1.4 mmol/mL or 1.4 mEq/mL of Cl^-) in Water for Injection USP. It is provided in a 10 mL single-use syringe to facilitate intravenous injection. The solution is administered only by intravenous or intraventricular cavity injection as a calcium replenisher.

The solution contains no bacteriostat, antimicrobial agent nor added buffer (except for pH adjustment) and is intended only for use as a single-use injection. When smaller doses are required, the unused portion should be discarded. 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 mOsm/mL (calc.).

Calcium Chloride USP dihydrate is chemically designated $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$ (dihydrate) white, odourless fragments or granules freely soluble in water.

STORAGE RECOMMENDATIONS

Store between 20 and 25°C. Protect from freezing. Avoid excessive heat.

Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration, whenever solution and container permit.

Do not use unless the solution is clear and the container or seal is intact. Discard if the solution contains a precipitate.

Single-use; discard unused portion.

AVAILABILITY OF DOSAGE FORMS

Calcium Chloride Injection USP is supplied in single-use containers as follows:

Container	Size	Needle
LifeShield [®] Abboject [®] Syringe ¹	10 mL	20-gauge
Ansyr [®] Syringe ²	10 mL	Luer lock

1: LifeShield[®] Abboject[®] Syringe: Flexible and reliable, the ready-to-use LifeShield[®] Abboject[®] syringe minimizes errors and protects caregivers and patients alike. It can be used for needle-free or shrouded needle access. The design features two pieces - a calibrated glass drug vial and a matching plastic syringe barrel with integral injector needle. Medication, fluid path, and needle are sterile and nonpyrogenic if caps and needle cover are undisturbed and package intact.

2: Ansyr[®] Syringe: The Ansyr[®] syringe is a proprietary delivery option offering one-piece, polypropylene plastic construction with a needle-free male luer lock adapter. Ansyr[®] syringes are available prefilled with a wide range of emergency medications. Graduated markings on the syringe barrel conform to ISO standards and clearly show any drug remaining. Medication and fluid path are sterile and nonpyrogenic if protective cover is undisturbed and package intact.