10% Calcium Chloride Injection, USP

DESCRIPTION
10% calcium chloride injection is a sterile, nonpyrogenic, hypertonic solution. Each mL contains 100 mg (1.4 mEq/mL) of calcium chloride, dihydrate (1.4 mEq each of Ca++ and Cl−) in water for injection. It is provided in a 10 mL single-dose vial to facilitate prompt intravenous injection. The solution contains no bacteriostatic, antimicrobial agent or added buffer and is intended for use only as a single-dose injection. The pH of 10% calcium chloride injection is 6.3 (5.5 to 7.5) when diluted with water for injection to make a 5% solution. May contain hydrochloric acid and/or sodium hydroxide for pH adjustment. The osmolality of 10% calcium chloride injection is 2.54 mOsm/mL (calc.). 10% calcium chloride injection is oxygen sensitive.

INSTRUCTIONS FOR ADMINISTRATION

Calcium chloride dihydrate is chemically designated CaCl2·2H2O (dihydrate) and is described as white, odorless fragments or granules freely soluble in water.

CLINICAL PHARMA COLGY
Calcium is the fifth most abundant element in the body and the major fraction is in the bony 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 physiological 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 USAGE
10% calcium chloride injection is indicated for the treatment of hypocalcemia in those conditions requiring a prompt increase in plasma calcium levels.

CONTRAINDICATIONS
Calcium chloride is contraindicated for cardiac resuscitation in the presence of ventricular fibrillation or in patients with the risk of existing digitalis toxicity. Calcium chloride is not recommended in the treatment of anaphylactic and electromagnetic shock.

WARNINGS
10% calcium chloride injection 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 parenchymal tissues. WARNING: 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
Do not administer unless solution is clear and seal is intact. Discard unused portion.

Because of its additive effect, calcium should be administered very cautiously to a patient who is digitalized or who is taking effective doses of digoxin or digoxin-like preparations. It is particularly important to prevent a high concentration of calcium from reaching the heart because of the danger of cardiac syncpe.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies with solutions in polypropylene syringes have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Pediatric Use: Safety and effectiveness are based on similar clinical conditions in children and adults.

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 reproductive capacity. Calcium chloride should be given to a pregnant woman only if clearly needed.

Geriatric Use: An evaluation of current literature revealed no clinical experience identifying differences in response between elderly and younger patients. In general, dose selection in elderly patients should be in the same range as that in younger patients. In general, starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

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 peripheral 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 vasoconstriction and dilute the calcium remaining in the tissues locally. Local application of heat may also be helpful.

DRUG ABUSE AND DEPENDENCE
None known.

OVERDOSAGE
Teo rapid injection may produce lowering of blood pressure and cardiac syncpe. Persistent hypercalcemia from overdosage 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
10% calcium chloride injection is administered only by slow intravenous injection (not to exceed 1 mL/min), preferably in a central or deep vein. 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 200 mg to 1 g (2 to 10 mL) at intervals of 1 to 3 days depending on the response of the patient and/or results of serum ionized calcium determinations. Repeated injections may be required because of rapid excretion of calcium.

The pediatric dosage in hypocalcemic disorders ranges from 2.7 to 5 mg/kg hydrated calcium chloride (or 0.126 to 0.252 mg/kg elemental calcium per kg, or 0.027 to 0.05 mL of 10% calcium chloride injection per kg). No data from clinical trials is available about repeated dosages, though textbook references recommend repeat dosages q 4 to 6 hours.

Caution: 10% calcium chloride injection consists of 1 gram of calcium chloride in a 10 mL vial, or 100 mg/mL. This concentration represents 27 mg or 1.4 mL of elemental calcium per mL. Thus, one 10 mL vial provides 270 mg of elemental calcium. The dosage recommendation in various references is given either as amount of calcium chloride or amount of elemental calcium, and often it is not specified. Ionized calcium concentrations should be measured, to assist in dosage adjustment.

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

HOW SUPPLIED
10% calcium chloride injection, USP is supplied in single-dose containers as follows:

<table>
<thead>
<tr>
<th>NDC No.</th>
<th>Container</th>
<th>Size</th>
<th>Carton</th>
</tr>
</thead>
<tbody>
<tr>
<td>0517-6710-10</td>
<td>Glass Vial 10 mL</td>
<td>10 Vials</td>
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</table>

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

CLINICAL STUDIES
Medical Literature also refers to the administration of calcium chloride in the treatment of magnesium intoxication due to overdosage of magnesium sulfate, and to combat the deleterious effects of hyperkalemia as measured by electrocardiogram (ECG), pending correction of the increased potassium level in the extracellular fluid. However, adequate well-controlled, randomized clinical studies have not been done to support these indications.

To report SUSPECTED ADVERSE REACTIONS, contact American Regent, Inc. at 1-800-734-9230 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

AMERICAN REGENT  
SHIRLEY, NY 11967

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