

CALCIUM CHLORIDE- calcium chloride injection, solution
Civica, Inc.

10% Calcium Chloride Injection, USP

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1 Gram (100 mg/mL)

Represents 27 mg (1.4 mEq) Ca⁺⁺/mL

A HYPERTONIC SOLUTION IN A 10 ML SINGLE-DOSE VIAL FOR PROMPT INTRAVENOUS INJECTION.

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

Administer only by slow injection (not to exceed 1 mL/minute)

Rx only

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 bacteriostat, 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 osmolar concentration is 2.04 mOsmol/mL (calc.). 10% calcium chloride injection is oxygen sensitive.

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

CLINICAL PHARMACOLOGY

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 asystole and electromechanical dissociation.

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 perivascular 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 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.

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 for an elderly patient should be cautious, usually 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 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.

DRUG ABUSE AND DEPENDENCE

None known.

OVERDOSAGE

Too rapid injection may produce lowering of blood pressure and cardiac syncope. 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 0.136 to 0.252 mEq 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 mEq 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:

| NDC No. | Container | Size | Carton |
|--------------|------------|-------|----------|
| 72572-052-10 | Glass Vial | 10 mL | 10 Vials |

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 1-800-734-9236 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Mfd for: Civica, Inc.
Lehi, Utah 84043

Mfd by: American Regent, Inc.
New Albany, OH 43054

Revised: March 2021

RQ1098-A



PRINCIPAL DISPLAY PANEL Container Label

NDC 72572-052-01 Rx Only

10% Calcium Chloride Injection, USP

1 Gram/10 mL (100 mg/mL)

For Intravenous Use Only

Sterile, nonpyrogenic

10 mL Single-dose vial

NDC 72572-052-01 Rx Only Usual dosage:
See package insert.
10% Calcium Chloride Caution: Do not inject
intramuscularly
Injection, USP or subcutaneously.
2.04 mOsmol/mL (calc.),
pH 6.3 (5.5 to 7.5).
Contains no more than
1,000 mcg/L of aluminum.
1 Gram/10 mL Mfd for: Civica, Inc.
Lehi, UT 84043
(100 mg/mL) Mfd by: American Regent, Inc.
New Albany, OH 43054
For Intravenous Use Only RN1138-A Rev. 03/2021
Sterile, nonpyrogenic.
10 mL Single-Dose Vial

(01)10372572052013

PRINCIPAL DISPLAY PANEL Carton Labeling

NDC 72572-052-10 Rx Only

10% Calcium Chloride Injection, USP

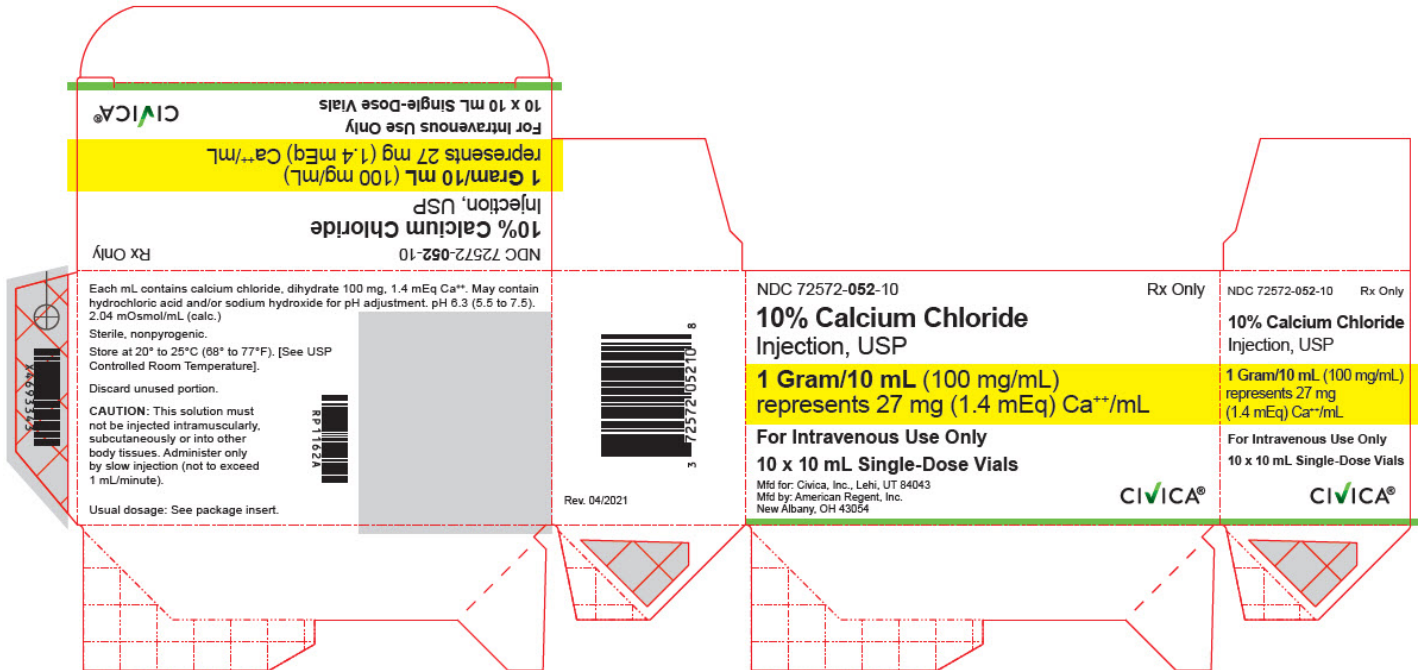
1 Gram/10 mL (100 mg/mL)
represents 27 mg (1.4 mEq) Ca⁺⁺/mL

For Intravenous Use Only

10 x 10 mL Single-dose vials

Mfg for: Civica, Inc., Lehi, Utah 84043

Mfd by: American Regent, Inc., New Albany, OH 43054



Serialization Label



LOT: TEST

EXP: 11 2020

GTIN: 30372572052109

SN: 0

CALCIUM CHLORIDE

calcium chloride injection, solution

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:72572-052

Route of Administration INTRAVENOUS

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32Z N48698) | CALCIUM CHLORIDE | 100 mg in 1 mL |

Inactive Ingredients

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:72572-052-10 | 10 in 1 BOX | 04/02/2021 | |
| 1 | NDC:72572-052-01 | 10 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA209088 | 04/02/2021 | |

Labeler - Civica, Inc. (081373942)

Registrant - American Regent, Inc. (002033710)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|------------------------|
| American Regent, Inc. | | 027223179 | manufacture(72572-052) |

Revised: 8/2020

Civica, Inc.