CALCIUM GLUCONATE - calcium gluconate 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.

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CALCIUM GLUCONATE INJECTION, USP 10%

Rx Only

STERILE, NONPYROGENIC

0.68 mOsmol/mL 680 mOsmol/L
Ca++ 0.465 mEq/mL pH (6.0-8.2)

100 mL PHARMACY BULK PACKAGENOT FOR DIRECT INFUSION

CAUTION: For Intravenous Use. Not recommended for Intramuscular or Subcutaneous use.

DESCRIPTION

Calcium Gluconate is the calcium salt of gluconic acid, an oxidation product of glucose, and contains 9.3% calcium, which is about one-third of the calcium in strength of calcium chloride USP. Since it is soluble to the extent of only one part in 30 parts of cold water, the 10% solution is supersaturated and is stabilized by the addition of calcium saccharate tetrahydrate 0.46% w/v (which supplies calcium 6.2%). Each mL contains 98 mg of calcium gluconate monohydrate, 4.6 mg of calcium saccharate tetrahydrate, and Water for Injection USP, q.s. Each mL provides 9.3 mg (0.465 milliequivalents) of calcium.

The 100 mL Pharmacy Bulk Package contains many single doses for use in a pharmacy admixture program in the preparation of parenteral fluids. See directions for dispensing from the 100 mL Pharmacy Bulk Package.

pH is adjusted with sodium hydroxide and/or hydrochloric acid.

The structural formula is:

![Structural formula of Calcium Gluconate]

CLINICAL PHARMACOLOGY

Calcium is the fifth most abundant element in the body and is essential for maintenance of the functional integrity of nervous, muscular and skeletal systems and cell membrane and capillary permeability. It is also an important activator in many enzymatic reactions and is essential to a number of physiologic processes including transmission of nerve impulses; contraction of cardiac, smooth and skeletal muscles; renal function; respiration and blood coagulation. Calcium also plays regulatory roles in the
release and storage of neurotransmitters and hormones, in the uptake and binding of amino acids, and in cyanocobalamin (vitamin B<sub>12</sub>) absorption and gastrin secretion.

**INDICATIONS AND USAGE**

Calcium gluconate is used to treat conditions arising from calcium deficiencies such as hypocalcemic tetany, hypocalcemia related to hypoparathyroidism and hypocalcemia due to rapid growth or pregnancy. It is also used in the treatment of black widow spider bites to relieve muscle cramping and as an adjunct in the treatment of rickets, osteomalacia, lead colic and magnesium sulfate overdosage. Calcium gluconate has also been employed to decrease capillary permeability in allergic conditions, nonthrombocytopenic purpura and exudative dermatoses such as dermatitis herpetiformis and for pruritus of eruptions caused by certain drugs. In hyperkalemia, calcium gluconate may aid in antagonizing the cardiac toxicity provided the patient is not receiving digitalis therapy.

**CONTRAINDICATIONS**

Calcium salts are contraindicated in patients with ventricular fibrillation or hypercalcemia. Intravenous administration of calcium is contraindicated when serum calcium levels are above normal.

*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**

For intravenous use only. Subcutaneous or intramuscular injection may cause severe necrosis and sloughing.

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**

*General*

To avoid undesirable reactions that may follow rapid intravenous administration of calcium gluconate, the drug should be given slowly, e.g., approximately 1.5 mL over a period of one minute. When injected intravenously, calcium gluconate should be injected through a small needle into a large vein in order to avoid too rapid increase in serum calcium and extravasation of calcium solution into the surrounding tissue with resultant necrosis.
Rapid injection of calcium gluconate may cause vasodilation, decreased blood pressure, bradycardia, cardiac arrhythmias, syncope and cardiac arrest.

Because of the danger involved in 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 indications are clearly defined.

**Drug Interactions**

The inotropic and toxic effects of cardiac glycosides and calcium are synergistic and arrhythmias may occur if these drugs are given together (particularly when calcium is given intravenously). Intravenous administration of calcium should be avoided in patients receiving cardiac glycosides; if necessary, calcium should be given slowly in small amounts.

Calcium complexes tetracycline antibiotics rendering them inactive. The two drugs should not be given at the same time orally nor should they be mixed for parenteral administration.

Calcium Gluconate Injection has been reported to be incompatible with intravenous solutions containing various drugs. Published data are too varied and/or limited to permit generalizations, and specialized references should be consulted for specific information.

*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.

**Drug & or Laboratory Test Interactions**

Transient elevations of plasma 11-hydroxy-corticosteroid levels (Glenn-Nelson technique) may occur when intravenous calcium is administered, but levels return to control values after one hour. In addition, intravenous calcium gluconate can produce false-negative values for serum and urinary magnesium.

**Pregnancy**

*Pregnancy Category C:* Animal reproduction studies have not been conducted with calcium gluconate. It is also not known whether calcium gluconate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Calcium gluconate should be given to a pregnant woman only if clearly needed.

**Nursing Mothers**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when calcium gluconate is administered to a nursing woman.

**ADVERSE REACTIONS**

Patients may complain of tingling sensations, a sense of oppression or heat waves and a calcium or chalky taste following the intravenous administration of calcium gluconate.
Rapid intravenous injection of calcium salts may cause vasodilation, decreased blood pressure, bradycardia, cardiac arrhythmias, syncope and cardiac arrest. Use in digitalized patients may precipitate arrhythmias.

Local necrosis and abscess formation may occur with intramuscular injection.

**DOSAGE AND ADMINISTRATION**

Calcium Gluconate should be administered intravenously either directly or by infusion. The dose is dependent upon the individual requirements of the patient. Calcium Gluconate may also be administered by intermittent infusion at a rate not exceeding 200 mg/min, or by continuous infusion.

**DIRECTIONS FOR DISPENSING FROM 100 mL PHARMACY BULK PACKAGE - NOT FOR DIRECT INFUSION.**

The 100 mL Pharmacy Bulk Package is for use in a Pharmacy Admixture Service only. The 100 mL Pharmacy Bulk Package should be suspended (inverted) by its IV hang label in a laminar flow hood or biological safety cabinet. Prior to entering a Pharmacy Bulk Package remove the flip-off seal and cleanse the rubber closure with a suitable antiseptic agent. Entry into the Pharmacy Bulk Package must be made with a sterile transfer set or other sterile dispensing device and the contents dispensed in aliquots using aseptic technique. Use of a syringe needle is not recommended as it may cause leakage. ANY UNUSED PORTION MUST BE DISCARDED WITHIN 4 HOURS AFTER INITIAL ENTRY. The date and the time initially opened should be recorded in the space provided on the Pharmacy Bulk Package label.

**USUAL DOSAGE:**

- **Adults:** 500 mg - 2 grams (5-20 mL)
- **Children:** 200-500 mg (2-5 mL)
- **Infants:** not more than 200 mg (not more than 2 mL)

**HOW SUPPLIED**

Calcium Gluconate Injection, USP 10%

NDC 0517-3910-25  10%  10 mL Single Dose Vials packed in boxes of 25
NDC 0517-3950-25  10%  50 mL Single Dose Vials packed in boxes of 25
NDC 0517-3900-25  10%  100 mL Pharmacy Bulk Package packed in boxes of 25

**Supersaturated solutions are prone to precipitation.**

**NOTE:** If crystallization has occurred, warming in a 60°C water bath for 15-30 minutes with occasional shaking, may dissolve the precipitate. Cool to body temperature before use. The injection must be clear at the time of use. Parenteral drug products should be inspected visually for particulate matter and discoloration, whenever solution and container permit.

**No preservative added.** Unused portion of vial should be discarded. Use only if solution is clear and seal intact.

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

**AMERICAN REGENT, INC.**

**SHIRLEY, NY 11967**

IN3910

Rev. 7/11
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

PRINCIPAL DISPLAY PANEL – 50 mL Container

NDC 0517-3950-25

CALCIUM GLUCONATE
INJECTION, USP

10%

23.25 mEq/50 mL Calcium

(0.465 mEq/mL)

50 mL SINGLE DOSE VIAL

FOR SLOW INTRAVENOUS USE

Rx Only

AMERICAN
REGENCY, INC.
SHIRLEY, NY 11967

Rev. 2/08

NDC 0517-3900-25

CALCIUM GLUCONATE
INJECTION, USP

10%

23.25 mEq/50 mL Calcium

(0.465 mEq/mL)

Each mL contains: Calcium Gluconate
(Monohydrate) 98 mg, Calcium Saccharate
(Tetrahydrate) 4.6 mg, Water for Injection
q.s., pH adjusted with Sodium Hydroxide
and/or Hydrochloric Acid. Calcium
Saccharate provides 6.2% of the total
Calcium content. 0.68 mOsmol/mL
Contains no more than 12,500 mcg/L
of aluminum.

WARNING: DISCARD UNUSED
PORTION. IF CRYSTALLIZATION
OCCURS, WARMING MAY DISSOLVE
THE PRECIPITATE (See Package Insert).
THE INJECTION MUST BE CLEAR
AT THE TIME OF USE. 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.
Rev. 2/08

NDC 0517-3900-25

CALCIUM GLUCONATE
INJECTION, USP

10%

46.5 mEq/100 mL Calcium

(0.465 mEq/mL)

0.68 mOsmol/mL

pH (6.0-8.2)
CALCIUM GLUCONATE

calcium gluconate injection, solution

Product Information

Product Type: HUMAN PRESCRIPTION DRUG
Item Code (Source): NDC:0517-3950
Route of Administration: INTRAVENOUS

Active Ingredient/Active Moiety

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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tr>
<td>CALCIUM GLUCONATE MONOHYDRATE (UNII: CZN0MI5R31) (CALCIUM - UNIESY7Q814VUP)</td>
<td>CALCIUM GLUCONATE MONOHYDRATE</td>
<td>98 mg in 1 mL</td>
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Inactive Ingredients

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<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tr>
<td>CALCIUM SACCHARATE (UNII: 6AP9J91K4V)</td>
<td>4.6 mg in 1 mL</td>
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<td>SODIUM HYDROXIDE (UNII: 55X04QC32I)</td>
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<tr>
<td>HYDROCHLORIC ACID (UNII: QTT17582CB)</td>
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<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
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Packaging

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<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
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<tbody>
<tr>
<td>1</td>
<td>NDC:0517-3950-25</td>
<td>25 in 1 TRAY</td>
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<td>1</td>
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<td>50 mL in 1 VIAL, SINGLE-DOSE</td>
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### Marketing Information

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### CALCIUM GLUCONATE

**calcium gluconate injection, solution**

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<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
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<td>25 in 1 TRAY</td>
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<tr>
<td>1</td>
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<td>100 mL in 1 VIAL, PHARMACY BULK PACKAGE</td>
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### Labeler

- American Regent, Inc. (622781813)

Revised: 9/2011