FRESENIUS KABI

CALCIUM GLUCONATE INJECTION, USP 10%

Electrolyte Replenisher

0.68 mOsmol/mL	**680 mOsmol/L**
Ca^{++} 0.465 mEq/mL	**pH 6.0 – 8.2**

DESCRIPTION

Calcium Gluconate Injection, USP is a sterile, nonpyrogenic supersaturated solution of calcium gluconate in Water for Injection, for intravenous use.

Each mL contains:

Calcium Gluconate, USP ..... 94 mg

Calcium Saccharate (tetrahydrate), USP ..... 4.5 mg

Calcium Saccharate provides 6% of the total calcium and stabilizes the supersaturated solution of calcium gluconate. Sodium hydroxide and/or hydrochloric acid may be added for pH adjustment.

Each 10 mL of the injection provides 93 mg calcium equivalent to 1 g 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_{12}) 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 overdose. 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.

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 µg per kg per day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration of TPN products and of the lock-flush solutions used in their 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 an increase in serum calcium and extravasation of calcium solution into the surrounding tissue with the 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 ionotropic 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, USP has been reported to be incompatible with intravenous solutions containing various drugs. Published data are too varied and/or limited to permit generalization, and specialized reference should be consulted for specific information.

Drug/Laboratory Test Interactions

Transient elevations of plasma 11-hydroxycorticosteroid 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 for serum and urinary magnesium.

Pregnancy

Teratogenic Effects: 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 wave and 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

The dose is dependent on the requirements of the individual patient. Intravenous Calcium Gluconate Injection, USP must be administered slowly.

Usual Dosage

Adults..... 500 mg - 2 g (5 - 20 mL)

Children ..... 200 mg - 500 mg (2 - 5 mL)

Infants ..... not more than 200 mg (not more than 2 mL)

As with all parenteral drug products, intravenous admixtures should be inspected for clarity of solutions, particulate matter, precipitate, discolouration and leakage prior to administration, whenever solution and container permit. Solutions showing haziness, particulate matter, precipitate, discolouration or leakage should not be used.

AVAILABILITY OF DOSAGE FORMS

Calcium Gluconate Injection, USP is supplied in flip-top single-dose plastic vials and pharmacy bulk packages.

Single-dose vials:

Product No.	Fill Volume	Vial Size
C360019	10 mL	10 mL
C360059	50 mL	50 mL

Packaged in 25 vials per tray.

Pharmacy bulk packages:

Product No.	Fill Volume	Vial Size
C360161	100 mL	100 mL

Packaged in 20 per tray.

Vial stoppers do not contain natural rubber latex.

Directions for Dispensing from Pharmacy Bulk Package - Not for Direct Infusion:

The pharmacy bulk package is a **single-use** vial for pharmacy use only. The pharmacy bulk package should be suspended as a unit in a laminar flow hood. Entry into the vial must be made with a sterile transfer set or other sterile dispensing device and contents dispensed in aliquots using aseptic technique (see **DOSAGE AND ADMINISTRATION**). Use of syringe/needle is not recommended as it may cause leakage. **Any unused portion should be discarded within 24 hours after initial entry.**

NOTE: Supersaturated solutions are prone to precipitation. The precipitate, if present, may be dissolved by warming the vial to 60 °C – 80 °C, with occasional agitation, until the solution becomes clear. Shake vigorously. Allow to cool to room temperature before dispensing. Use injection only if clear immediately prior to use.

No preservative added. Discard unused portion. Use only if solution is clear and seal is intact and undamaged.

Store at controlled room temperature between 15 °C − 30 °C (59 °F – 86 °F). Do not permit to freeze.

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