פורמט עלון זה נקבע ע"י משרד הבריאות ותוכנו נבדק ואושר בתאריך: 08/2012

Physician's Package Insert

Calcium Gluconate-Fresenius Injection

For administration I.V or I.M

COMPOSITION

Each 10 ml ampoule contains 902.5 mg Calcium gluconate.

Stabilized with 47.5 mg Calcium saccharate.

PHARMACOLOGICAL ACTION

Calcium is essential to body metabolism and must be supplemented when deficient owing to disease states or other conditions.

INDICATIONS

All conditions where injectable calcium supplement is indicated.

Calcium gluconate is the preferred form for injection.

CONTRA-INDICATIONS

Calcium salts are contra-indicated in patients with ventricular fibrillation, hypercalcaemia, or hypercalciuria (hypertiroidism, vitamin D overdosage, decalcifying tumours such as plasmacytoma and skeletal metastases), nephrocalcinosis, sarcoidosis, milk- alkali syndrome, hyper-coagulability of blood. Intravenous administration of calcium is contraindicated when serum calcium levels are above normal.

Should not be given concurrently with digitalis therapy.

Contra- Indicated in severe renal disease; calcium loss due to immobilization, osteoporosis.

PRECAUSIONS:

Supersaturated solutions are prone to precipitation. If precipitation is evident in syringes, do not use syringe. Precipitation if present in vials and ampoules may be dissolved by heating to 80ºC in a dry heat oven for a minimum of one hour. Shake vigorously. Allow to cool to room temperature before dispensing. The solution should not be used if precipitate remains in vials and ampoules after following the above procedure. 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 1 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 resulting necrosis.

Injection of calcium salts intramuscularly or subcutaneously can cause local reactions including sloughing or severe necrosis of the skin, especially in infants and small children. Intramuscular injection in infants has been reported to cause abscess formation. The oral or intravenous route should be used.

Rapid injection of calcium gluconate may cause vasodilation, decreased blood pressure, bardycardia, cardiac arrhythmias, syncope and cardiac arrest. Administer cautiously to patients with impaired renal function or a history of renal stone formation.

If injected into the ventricular cavity in cardiac resuscitation, it must not be injected in the myocardial tissue.

Pregnancy: Animal reproduction studies have not been conducted with calcium gluconate. It also is not known if 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.

Lactation: 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.

High dose calcium therapy by any of the parenteral routes should always be accompanied by very careful monitoring of blood concentration and urinay calcium excretion, particularly in children. Treatment should be stopped at once if blood calcium exceeds 2.62 to 2.74 mmol/L (105 to 119 mg/L) or if more than 0.12 mmol/kg (5 mg/kg) is excreted in the urine in a period of 24 hours. Heart rhythm should also be monitored.

DRUG INTERACTIONS:

The ionotropic and toxic effects of cardiac glycosides and calcium are synergistic and arrhythmias may occur if these drug are given together (particularly when calcium is given I.V.). I.V. administration of calcium should be avoided in patients receiving cardiac glycosides; if necessary, calcium should be given slowly in small amounts. Calcium can weaken the effects of calcium antagonists. Calcium and magnesium inhibit each other reciprocally in their effect.

Calcium complexes tetracycline antibiotics rendering them inactive. The 2 drugs should not be given at the same time orally, nor should they be mixed for a parenteral administration.

Calcium gluconate injection has been reported to be incompatible with I.V. solutions containing various drugs. Published data are too varied and/or limited to permit generalization, and specialized reference should be consulted for specific information.

High vitamin D intake should be avoided during calcium therapy unless especially indicated.

Drugs/Laboratory Test interactions:

Transient elevations of plasma 11-hydroxycorticosteroid levels (Glen-Nelson technique) may occur when I.V. calcium is administered, but levels return to control values after 1 hour. In addition, I.V. calcium gluconate can produce false-negative for serum and urinary magnesium.

Admixture incompatibilities: Calcium salts should not generally be mixed with carbonates, phosphates, sulfates or tartrates in parenteral admixtures; they are conditionally compatible with potassium phosphates, depending on concentration.

SIDE EFFECTS:

Symptoms of hypercalcaemia, nausea, vomiting, hot flushes, sweating, chalk-like taste, tingling of the skin, hypertension, disturbances of cardiac rhythm, syncope and even vasomotor collapse may ensue if intravenous injection is too rapid.

DOSAGE AND DIRECTIONS FOR USE

1 to 2 g by intramuscular or intravenous injection. Children up to 1 year, up to 300 mg; 1 to 5 years, 300 - 600 mg; 6 to 12 years, 600 to 1000 mg, by slow intravenous injection.

KNOWN SYMPTOMS OF OVERDOSAGE AND ITS TREATMENT

Overdosage with calcium salts results in hypercalcaemia.

Symptoms include anorexia, lassitude, muscle and joint pains, nausea and vomiting, thirst and polyuria. The deposition of calcium in the kidneys leads to loss of renal concentrating capacity and renal damage. Elevated serum calcium concentrations can produce bradycardia and cardiac arrhythmias. Treatment consists of withdrawal of all calcium supplements and administration of large volumes of fluids. In mild cases sodium phosphate, sulphate, chloride or citrate may be given intravenously. Frusemide and ethacrynic acid may be useful adjuncts but the thiazide diuretics are not

effective. Disodium edetate has been used but renal damage may occur with high dosage.

IDENTIFICATION

Clear solution in glass ampoules.

PRESENTATION

10 ml ampoules in packs of 10.

STORAGE INSTRUCTIONS

Store below 25°C. Keep out of reach of children.

Registration No:

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Manufactured by:

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Marketing Authorization Holder:

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