Size : 82 x 190mm

82.00 mm

190.00 mm

POM

CALCIUM GLUCONATE INJECTION BP 10% W/V

For Slow IV or IV Additive use only

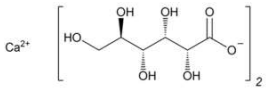
Composition:

Each ml contains:
Calcium Gluconate BP.....9.3% w/v
Calcium D. Saccharate USP.....0.46% w/v
Eq. to Total Calcium.....0.938% w/v
Water for Injection BP.....q.s.

DESCRIPTION

Calcium Gluconate Injection Contain Calcium Gluconate.

Calcium Gluconate is White, crystalline, odorless, tasteless granules or powder. Freely soluble in boiling water; sparingly (and slowly) soluble in water; insoluble in alcohol.



CLINICALPHARMACOLOGY

Calcium is the most abundant mineral in the human organism (approx. 1.5 % of the entire body weight). More than 99% of the body's total calcium is located in bones and teeth, approx. 1% is dissolved in intra- and extracellular fluid. Calcium is necessary for the functional integrity of nerves and muscles. It is essential for muscle contraction, cardiac function and blood coagulation. After injection the administered calcium shows the same distribution behaviour as the endogenous calcium. About 45-50% of the total plasma calcium is in the physiologically active ionised form, about 40-50% is bound to proteins, mainly albumin, and 8-10% is complexed with anions.After injection the administered calcium adds to the intravascular calcium pool and is handled by the organism in the same manner as the endogenous calcium.Excretion of calcium occurs in the urine although a large proportion undergoes renal tubular reabsorption.

INDICATIONS AND USAGE

Properties: Calcium is an essential body electrolyte. It is necessary for the functional integrity of nerve and muscle and is essential for the muscle contraction, cardiac function and coagulation of the blood.
Calcium homeostasis is mainly regulated by three endocrine factors: parathyroid hormone is secreted in response to a fall in plasma calcium concentration and acts by accelerating calcium transfer from bone and by increasing its intestinal absorption and its renal reabsorption; calcitonin lowers plasma calcium by decreasing bone resorption and by increasing renal excretion of the ion; vitamin D stimulates intestinal absorption of calcium and decreases its renal excretion.
Indications: Parenteral administration of calcium is indicated where the pharmacological action of a high calcium ion concentration is required, as for example, in acute hypocalcaemia, cardiac resuscitation and some cases of neonatal tetany.
Intravenous injections of calcium have been used in the treatment of the acute colic of lead poisoning, and as an adjunct in the treatment of acute fluoride poisoning. Also, for the prevention of hypocalcaemia in exchange transfusions.

DOSAGE

The normal concentration of calcium in plasma is within the range of 2.25 - 2.75 mmol or 4.5-5.5 mEq per litre. Treatment should be aimed at restoring or maintaining this level.
During therapy, serum calcium levels should be monitored closely.
Acute hypocalcaemia: 10-20ml (2.2-4.4mmol)
Fluoride or lead poisoning: 0.3ml/kg (0.07mmol/kg)
Neonatal tetany: 0.3ml/kg (0.07mmol/kg)
Cardiac resuscitation: 7-15ml (1.54-3.3mmol). It should be noted that the absolute amount of calcium required for this indication is difficult to determine and may vary widely.In hypocalcaemic tetany, an initial intravenous injection of 10ml of the 10% solution (2.25mmol) should be followed by a continuous infusion of about 40ml (9mmol) daily. Plasma calcium should be monitored.
Paediatric population:
Calcium Gluconate Injection is indicated for the treatment of neonatal tetany – it should not be routinely used in children less than 18 years of age.

CONTRAINDICATION

Hypersensitivity to the active substance or to any of the excipients
Patients with severe renal failure;
Patients with hypercalcaemia
Patients with hypercalciuria;
Patients receiving cardiac glycosides.

WARNINGS

Calcium passes across the placental barrier and its concentration in foetal blood is higher than in maternal blood.
Calcium Gluconate Injection should not be used during pregnancy unless the clinical condition of the woman requires treatment with Calcium Gluconate Injection. The administered dose should be carefully calculated, and the serum calcium level regularly evaluated in order to avoid hypercalcaemia, which may be deleterious for the foetus.
Calcium is excreted in breast milk. This should be borne in mind when administering calcium to women who are breast-feeding their infants. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Calcium Gluconate Injection therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

DRUG INTERACTION

The effects of digoxin and other cardiac glycosides may be potentiated by calcium, which may result in serious toxicity. Therefore, intravenous administration of calcium preparations to patients under therapy with cardiac glycosides is contraindicated.
Co-administration of calcium and epinephrine attenuate epinephrine's β-adrenergic effects in postoperative heart surgery patients
Calcium and magnesium mutually antagonise their effects.

ADVERSE REACTIONS

Bradycardia, cardiac arrhythmia, Hypotension, vasodilatation, circulatory collapse (possibly fatal), flushing, mainly after too rapid injection, Nausea, vomiting, Heat sensations, sweating.

STORAGE

Store below 30°C.
Protect from light.
Keep out of reach of children.

PACKING

Calcium Gluconate Injection BP 10% w/v is available in pack of 10 x 10ml Ampoules.

Manufactured in India by
ANGEL BIOGENICS PVT. LIMITED
Shapar-Veraval, Dist. Rajkot - 360 024
At : 46/4-7, Vill. Zak, Tal.Dehgam,
Gandhinagar - 382 305 (India.)

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