10% w/v Calcium Gluconate Inj. Solution for Injection

2. CLINICAL PHASE AND QUANTITATIVE COMPOSITION
2.1 Information on labelled uses. Preparation contains 10% w/v calcium gluconate as active ingredient.

2.2 Administration route. Intramuscular and intravenous injection. Intramuscular and intravenous administration should be equivalent to equivalent doses of oral calcium utile.

2.3 Contraindications
- Hypersensitivity to calcium or to any other excipients
- Hypercalcaemia (patients with hyperparathyroidism, hypervitaminosis D, bone metastases, sarcoidosis (Boeck’s disease), in patients receiving epinephrine (see section 4.4), or in the elderly.

2.4 Precautions for use
- Monitoring is mandatory and emergency treatment of cardiac complications such as serious arrhythmias must be available.
- Caution should be exercised in patients with pre-existing heart disease, e.g., in cases of calciferol deficiency.

2.5 Special precautions for storage
- Keep in a tight container in the inner carton and store at a temperature between 2° and 8°C.
- Protect from light.

2.6 Overdosage
- The effects of digitalis and other cardiac glycosides may be potentiated by calcium, which may result in serious harm. Therefore, monitoring of serum calcium levels is recommended, and the serum calcium level regularly evaluated in order to avoid hypercalcaemia, which may be deleterious for the foetus.

3. NAME OF THE MEDICINAL PRODUCT

B BRAUN

4. PHARMACOLOGICAL PROPERTIES

4.1 Mode of action
- Calcium gluconate is an inert form of calcium which is used for the prevention and treatment of calcium deficiency.

4.2 Clinical trials
- Clinical trials only should be used with caution and after careful consideration of the indication in patients with pre-existing heart disease, e.g., in cases of calciferol deficiency (see section 4.4), or in the elderly.

4.3.3 Adverse effects
- Some of the adverse effects listed in the following table are due to too rapid injection, whereas others may indicate accidental perivascular injection, which may lead to tissue necrosis.

4.4 Interactions
- Interactions may occur if ceftriaxone and calcium-containing products are administered to patients under therapy with calcium, which may result in serious toxicity. Therefore, sequential infusions of ceftriaxone and calcium-containing products must be avoided and the injection solutions to avoid precipitation.

10% w/v Calcium Gluconate Inj. should not be used during pregnancy or in breast feeding women.

5. WAY OF USE AND HANDLING

5.1 Starting the infusion
- Calcium infusion should be started slowly to minimise plasma levels and urinary excretion of calcium should be monitored when calcium is administered too quickly.

5.2.2 Calcium Gluconate Infusion
- Blood calcium: 3.5 – 5.5 mmol per litre
- pH: 5.5 – 7.5
- Theoretical osmolarity: 660 mosm/l

6. PHARMACOLOGICAL PROPERTIES

6.1 Mode of action
- Calcium gluconate is an inert form of calcium which is used for the prevention and treatment of calcium deficiency.

6.2 Clinical trials
- Clinical trials only should be used with caution and after careful consideration of the indication in patients with pre-existing heart disease, e.g., in cases of calciferol deficiency (see section 4.4), or in the elderly.

6.3.3 Adverse effects
- Some of the adverse effects listed in the following table are due to too rapid injection, whereas others may indicate accidental perivascular injection, which may lead to tissue necrosis.

6.4 Interactions
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10% w/v Calcium Gluconate Inj. should not be used during pregnancy or in breast feeding women.

7. WAY OF USE AND HANDLING

7.1 Starting the infusion
- Calcium infusion should be started slowly to minimise plasma levels and urinary excretion of calcium should be monitored when calcium is administered too quickly.

7.2.2 Calcium Gluconate Infusion
- Blood calcium: 3.5 – 5.5 mmol per litre
- pH: 5.5 – 7.5
- Theoretical osmolarity: 660 mosm/l

8. PHARMACOLOGICAL PROPERTIES

8.1 Mode of action
- Calcium gluconate is an inert form of calcium which is used for the prevention and treatment of calcium deficiency.

8.2 Clinical trials
- Clinical trials only should be used with caution and after careful consideration of the indication in patients with pre-existing heart disease, e.g., in cases of calciferol deficiency (see section 4.4), or in the elderly.

8.3.3 Adverse effects
- Some of the adverse effects listed in the following table are due to too rapid injection, whereas others may indicate accidental perivascular injection, which may lead to tissue necrosis.

8.4 Interactions
- Interactions may occur if ceftriaxone and calcium-containing products are administered to patients under therapy with calcium, which may result in serious toxicity. Therefore, sequential infusions of ceftriaxone and calcium-containing products must be avoided and the injection solutions to avoid precipitation.

10% w/v Calcium Gluconate Inj. should not be used during pregnancy or in breast feeding women.
calcium undergoes renal tubular reabsorption. um pool and is handled by the organism in the same manner as the endogenous calcium. After injection the administered calcium adds to the intravascular calcium pool. About 45-50% of the total plasma calcium concentration increases. The concentration of ionised calcium is between 1.23 and 1.43 mmol/l, respectively. Treatment should be aimed at lowering the elevated plasma calcium concentration. Increased neuromuscular excitability up to tetany, paraesthesiae, cardiac symptoms like prolonged QT interval, arrhythmia and even acute myocardial failure. Severe signs of hypercalcaemia may include: anorexia, nausea, vomiting, constipation, abdominal pain, gastritis, ileus, ileostomy, ileus, colic, muscle weakness, confusion, cerebral convulsive seizures and cardiac symptoms. The medicinal product must not be mixed with other medicinal products which may cause reaction in section 4.1.5. If the serum calcium is normalised, the elevated serum inorganic phosphate concentration will also be normalized.

5.1 Pharmacodynamic properties
Calcium salts are incompatible with oxidising agents, citrates, soluble carbonates, bicarbonates, oxalates, phosphates, tartrates and sulphates. Physical incompatibility has also been reported with amphotericin, polyoxyethylene sorbitan monolaurate, calcium-d-saccharate 4 H2O, calcium-d-gluconate and carbamazepine.

5.2 Pharmacokinetic properties
Calcium is necessary for the formation of bones and teeth, approx. 1% are dissolved in intra- and extracellular fluid. More than 99% of the body's total calcium are located in bones and teeth, approx. 1% are dissolved in intra- and extracellular fluid. The physiological level of the plasma calcium concentration is maintained at 1.12 to 1.30 mmol/l. As about 80% of the plasma calcium is bound to proteins, mainly albumin, and 8-10% is complexed with anions. Serum electrolytes should be carefully monitored throughout treatment of hypercalcaemia. B. Braun Melsungen AG

34209 Melsungen, Germany
Carl-Braun-Strasse 1
Phone: +49/5661/71-0
Fax: +49/5661/71-4567

Email: npc.drug@sfda.gov.sa
Saudi Arabia
Vigilance and Crisis Management Executive Directorate

6.1 List of excipients:
Calcium-d-gluconate 4 H2O,
Calcium-d-saccharate 4 H2O,
Calcium chloride 2 H2O,
calcium phosphate dibasic, calcium carbonate,
calcium citrate,
Calcium gluconate, calcium lactate, calcium carbonate,
calcium gluconate,
Calcium gluconate, calcium lactate,
Calcium gluconate, calcium lactate,
Calcium gluconate, calcium lactate,
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