Calcium Gluconate

10 % Solution for Injection
MINERAL

Extravasation must be avoided; the injection site should be monitored carefully. High Vitamin D intake should be avoided.

Pregnancy and Lactation

Pregnancy:
Calcium ions across the placental barrier and its concentration in fetal blood is higher than in maternal blood. Calcium gluconate injections should be used during pregnancy only if considered to be essential by the physician. 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 fetus.

Lactation:
Calcium is excreted in breast milk. This should be borne in mind when administering calcium to women who are breast-feeding their infants.

Interactions
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. The only exception may be that IV calcium administration is imperative for treatment of severe hypercalcemia symptoms putting the patient at immediate vital risk, if safer therapeutic alternatives are not available and calcium administration via the oral route is not possible (see also sections "Contraindications" and "Special Warnings...").

Co-administration of calcium and epinephrine may lead to cardiac arrhythmia.
Calcium and magnesium mutually antagonise their effects. Calcium may antagonise the effect of calcium antagonists (calcium channel blockers). Combination with thiazide diuretics may induce hypercalcaemia as these medicinal products reduce renal calcium excretion.

The medicinal product should not be mixed with any other drug, unless compatibility has been satisfactorily demonstrated.

Calcium salts should only be used with caution and after careful establishment of the indication in patients with hyperparathyroidism, hypertension, D, deactivating malignancies, renal insufficiency, immobilisation osteoporosis, sarcoidosis, milk-alkali syndrome, increased calcium excretion in urine (hypercalciuria), intoxication with cardiac glycosides, therapy with cardiac glyco-

eidoses.

Plasma levels and urinary excretion of calcium should be monitored when high-dose parenteral calcium is administered.

Calcium is insoluble in adipose tissue and may therefore cause infiltration and subsequent abscess formation, tissue induration and necrosis.

After perivascular or superficial IM injection local irritation, possibly followed by skin a blation or tissue necrosis, may occur, see also section "Adverse effects.

Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

Composition
Active substances:
Each 10 mL ampoule contains 940 mg Calcium Gluconate for Injection, equivalent to 2.26 mmol calcium ie 10 mL.
Each 1 mL contains 94 mg Calcium Gluconate for Injection, equivalent to 0.23 mmol calcium in 1 mL.
Excipients:
Calcium saccharate, water for injections.

Pharmaceutical form
Solution for injection.

Pharmacotherapeutic group
Solutions affecting the electrolyte balance: electrolytes.

Indications
Treatment of acute symptomatic hypocalcaemia

Contraindications
Calcium Gluconate 10 % B. Braun must not be administered in the following conditions:
- Hypersensitivity to calcium and to the excipient,
- Elevated calcium level in blood (hypercalcemia), e.g. in patients with hyperparathyroidism, hypertension D, deactivating malignancies, renal insufficiency, immobilisation osteoporosis, sarcoidosis, milk-alkali syndrome,
- Increased calcium excretion in urine (hypercalciuria),
- Intoxication with cardiac glycosides,
- Therapy with cardiac glyco-

eidoses.

Special warnings and precautions for use
In the exceptional case of IV administration of calcium gluconate to patients receiving cardiac glycosides, adequate cardiac monitoring is mandatory and emergency treatment of cardiac complications such as serious arrhythmias must be available.

Calcium salts should only be used with caution and after careful establishment of the indication in patients with hyperparathyroidism, heart diseases, sarcoidosis (Boré’s disease), in patients receiving epinephrine (see section "Interactions”), or in the elderly.

Renal impairment may be associated with hypercalcemia and secondary hyperparathyroidism. Therefore, to patients with renal impairment, parenteral calcium should be administered only after careful assessment of the indication and the calcium-phosphate balance should be monitored.

Solutions containing calcium should be administered slowly to minimise peripheral vasodilation and cardiac depression.

Intravenous injections should be accompanied by heart rate and ECG control because bradycardia with vasodilatation or arrhythmia can occur when calcium is administered too quickly.

In children, Calcium Gluconate 10 % B. Braun should not be injected IM but only slowly IV.

Patients receiving calcium salts should be monitored carefully to ensure maintenance of correct calcium balance without tissue deposition.

Plasma levels and urinary excretion of calcium should be measured when high-dose parenteral calcium is administered.

Calcium is insoluble in adipose tissue and may therefore cause infiltration and subsequent abscess formation, tissue induration and necrosis.

Recommended dosage schedule
Adults:
The usual initial dose in adults is 10 mL of Calcium Gluconate 10 % B. Braun, corresponding to 2.26 mmol or 4.52 mEq of calcium. If necessary, the dose may be repeated, depending on the patient’s clinical condition. Subsequent doses should be adjusted according to the actual serum calcium level.

Children and adolescents (< 18 years):
The dose and the route of administration depend on the degree of hypercalcemia and the nature and severity of the symptoms. In the case of mild neuromuscular symptoms oral calcium administration should be preferred.

The following table gives usual initial dosage values for guidance:

<table>
<thead>
<tr>
<th>Age</th>
<th>Body wt. (kg)</th>
<th>mL</th>
<th>Equivalent to mmol (mEq) calcium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inf.</td>
<td>1.5</td>
<td>0.25</td>
<td>0.45 - 1.13 [0.9 - 2.26]</td>
</tr>
<tr>
<td>3 yr</td>
<td>10</td>
<td>2</td>
<td>0.45 - 1.13 [0.9 - 2.26]</td>
</tr>
<tr>
<td>6 yr</td>
<td>24</td>
<td>5</td>
<td>1.13 - 2.26 (2.26 - 4.52)</td>
</tr>
<tr>
<td>12 yr</td>
<td>38</td>
<td>5</td>
<td>1.13 - 2.26 (2.26 - 4.52)</td>
</tr>
</tbody>
</table>

As for adults.

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