

LAVOISIER CALCIUM GLUCONATE 1 g/10 ml, solution for oral use

QUALITATIVE AND QUANTITATIVE COMPOSITION

CALCIUM GLUCONATE 1.0 g
Water for injectable preparationss.q.10.0ml
Calcium content: 89.4 mg/ampoule
in each 10 ml ampoule of solution for oral use

PHARMACEUTICAL FORM

Solution for oral use.

THERAPEUTIC INDICATIONS

Calcium deficiencies particularly in period of growth.

POSOLOGY AND ADMINISTRATION

ORAL USE RESERVED TO CHILDREN UNDER 6 YEARS

2 to 3 ampoules of 10 ml daily.

CONTRA-INDICATIONS

- Hypersensitivity to one of the components.
- Hypercalcemia, hypercalciuria, calcic lithiasis, tissue calcifications.
- In prolonged immobilization associated with hypercalcemia and/or hypercalciuria: calcium therapy should be administered only when walking is resumed.

WARNINGS AND PRECAUTIONS FOR USE

- Administration of calcium and vitamin D concomitantly requires that calcemia and calciuria be closely monitored.
- In patients with renal insufficiency, calcemia and calciuria measurements must be performed routinely and high dose therapy be avoided.
- In long-term treatment and/or patients with renal failure, calciuria should be monitored and treatment be reduced or interrupted temporarily if calcium levels exceed 0.12 to 0.15 mmol/kg/24 h (5 to 6 mg/kg/24h) in children.
- Inspect for particulate matter of the solution. Discard ampoule in the presence of a precipitate.

INTERACTIONS WITH OTHER DRUGS AND OTHER FORMS OF INTERACTIONS

Especially with association of vitamin D.

ASSOCIATION REQUIRING PRECAUTION FOR USE:

- **Thiazidic diuretics:** risk of hypercalcemia due to decreased calcium excretion in urine.

ASSOCIATIONS TO BE USED WITH PRECAUTION:

- **Cyclizines:** decrease cyclizines digestive absorption. Calcium salts should not be taken at the same time as cyclizines (interval of more than 2 hours, if possible).
- **Digitalis:** risk of arrhythmias. Clinical observation and if needed EKG and calcium monitoring.
- **Diphosphonates:** decrease diphosphonates digestive absorption. Calcium salts should not be taken at the same time as diphosphonates (interval of more than 2 hours, if possible).

ADVERSE REACTION

- Gastrointestinal tract disturbances such as constipation, flatulence, nausea.
- Hypercalciuria, hyperkalcemia (with long term use of this drug and at high doses).

Overdosage

Symptoms: include thirst, polyuria, polydypsia, nausea, vomiting, dehydration, hypertension, vasomotor disorders, constipation

In children, all these signs may anticipate statural-ponderal growth impairment.

Treatment: suspension of any calcium intake and if needed of vitamin D, rehydration and depending on the severity of poisoning: isolated use or combined therapy with diuretics, corticoids, calcitonin, possibly associated with peritoneal dialysis.

CLINICAL PHARMACOLOGY

Pharmacodynamics

CALCIUM / MINERAL ELEMENT (A: Digestive system and metabolism).

Pharmacokinetics

Absorption:

Calcium is primarily absorbed from the upper small intestine following a mechanism of saturable active transfer dependent on vitamin D. Calcium absorption rate in this form accounts for about 30 % of the dose ingested.

Elimination:

Calcium is excreted through sweat glands and digestive secretions. Urinary calcium depends both on glomerular filtration and tubular rate reabsorption of calcium.

PHARMACEUTICAL DATA

Shelf life:

5 years

Nature and contents of container

10 ml ampoule, brown glass (type III), with two self-breakable tips.

Instructions for use, Drug handling instruction

Inspect for limpidity and discoloration of the solution. Discard ampoule if any precipitate.

PACKAGING AND PRODUCT LICENSE NUMBER

MA 305 838-8: 10 ml ampoule (brown glass) - 20 units pack

Not Reimbursed by French Health Care Security - Approved for institutions.

HOW SUPPLIED: Not applicable

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