

LAVOISIER CALCIUM GLUCONATE 10%, injectable solution

QUALITATIVE AND QUANTITATIVE COMPOSITION

Calcium gluconate.....7.00 g
Calcium glucoheptonate3.28 g
in each 100 ml of injectable solution

Each 10 ml single dose ampoule contains: 0.7 g of calcium gluconate
and 0.328 g calcium glucoheptonate.

Calcium content: 2.23 mmol/ 10 ml ampoule (89.4 mg/ 10 ml ampoule)

pH: 5.5 to 7

PHARMACEUTICAL FORM

Injectable solution

Clear, colorless solution.

THERAPEUTIC INDICATIONS

Emergency calcitherapy:

- Hypocalcemia
- Hypocalcemic tetany
- Hypocalcemic rickets: injectable calcium can be used in infusion during initial phase of treatment in combination with specific vitamin D therapy

POSODOLOGY AND ADMINISTRATION

Slow intravenous injection.

Infusion.

Adults:

Depending on the emergency level:

- Initiate treatment either with 100 to 200 mg of calcium element (i.e. 1 to 2 ampoules) in slow IV (10 to 15 minutes):
- Then continue (or initiate directly) with 1 to 2 mg of calcium element/kg/hour in infusion.

Children and neonates:

- Usual dose: 50 mg of calcium element/kg/24 hours (approximately ½ ampoule/kg/24 hours) in infusion.
- Extreme emergency: 5 mg of calcium element/kg/in slow IV (diluting 1 ml in 5 ml of isotonic solution) for 10 to 15 minutes.

CONTRA-INDICATIONS

This drug is contraindicated for use in patients with:

- Hypercalcemia, hypercalciuria,
- In association with digitalis (see section 4.5).

WARNINGS AND PRECAUTIONS FOR USE

- Not to be injected by subcutaneous or intramuscular routes.
- In any case, treatment evaluation and serum calcium concentrations should be monitored (possibly EKG).
- Injection must be performed the patient lying down.
- If calcium gluconate is administered undiluted, injection rate must be very slow (10 ml for 10 to 15 minutes).
- As this solution is supersaturated, a precipitate of the active ingredient may form. Discard ampoule if any precipitate.

INTERACTIONS WITH OTHER DRUGS AND OTHER FORMS OF INTERACTIONS

Contraindicated interactions:

- + **Digitalis:**
Severe, even life-threatening arrhythmias.

Association requiring precaution for use:

- + **Thiazidic Diuretics:**
Risk of hypercalcemia by decreased calcium excretion in urine.
Association with mineral forms of phosphorus is contraindicated, triggering precipitates in the medium. Only associations with binding of phosphorus to an organic anion may be used.

PREGNANCY AND LACTATION

- In clinical trials, no particular malformative or foetotoxic effect have been reported until now.
- However, the follow-up of pregnancies exposed to injectable calcium route is insufficient evidence to exclude any risk.
- Therefore, use in pregnancy of injectable calcium must be considered only if absolutely necessary.
- As calcium passes into the breast milk, lactation should be avoided.

EFFECTS ON ABILITY TO DRIVE VEHICLES AND USE MACHINES.

Not applicable.

ADVERSE REACTION

Vascular diseases

In case of prolonged infusion, subcutaneous or visceral vascular calcifications are feared risks.

Skin and subcutaneous tissue diseases

Risk of tissue necrosis in case of extravasation.

OVERDOSAGE

- Symptoms of hypercalcemia are cardiovascular including (arterial hypertension, vasomotor disorders, arrhythmias with possible heart failure) and systemic (polyuria, polydipsia, vomiting, dehydration).
- Discontinuance of treatment, calcium supplementation and rehydration of the patient. Resuscitation in intensive care unit if severe hypercalcemia.

CLINICAL PHARMACOLOGY

Pharmacodynamics

Pharmacotherapeutic group: CALCIUM/MINERAL ELEMENT
Code ATC: A12AA20 (A: Digestive system and metabolism)

When administered by parenteral route, calcium gluconate rapidly corrects hypocalcemia and neuromuscular induced symptoms.

Pharmacokinetics

Urinary excretion mainly.

Pre-clinical safety data

Not applicable.

PHARMACEUTICAL DATA

List of excipients

Water for injectable preparations.

Incompatibilities

In the absence of compatibility studies, drug admixtures must be avoided.

Shelf life

3 years

Storage special precautions

No storage special precautions required.

Nature and content of outer packaging

10 ml ampoule, (colorless glass type I) 10, 100 units pack.

Safety and handling instructions

- Verify physical integrity of container.
- Inspect for limpidity, discard ampoule in the presence of a precipitate.
- To be used immediately after initial closure puncture.
- Discard unused portions of the liquid.

PACKAGING AND PRODUCT LICENSE NUMBER

Pharmacy Packaging:

Ampoule bottle (glass)

MA 376 003-6: 10 ml - 10 units pack - Reimbursed by French Health Care Security 65% - Public
Price including VAT: 6,74 €

Hospital Packaging:

Ampoule bottle (glass)

MA 569 636-0: 10 ml - 100 units pack - Approved for institutions

HOW SUPPLIED

Not applicable.

DATE OF MA APPROVAL

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