Calcium Gluconate 10% w/v Injection BP

Calcium gluconate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

• Keep this leaflet. You may need it again.

If you have any further questions, ask your doctor or pharmacist.

If you get any side effects talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Calcium Gluconate 10% w/v Injection BP is and what it is used for
2. What needs to be known before you use Calcium Gluconate 10% w/v Injection BP
3. How to use Calcium Gluconate 10% w/v Injection BP
4. Possible side effects
5. How to store Calcium Gluconate 10% w/v Injection BP
6. Content of the pack and other information

1. What Calcium Gluconate 10% w/v Injection BP is and what it is used for
Calcium Gluconate 10% w/v Injection BP is a solution for the intravenous administration of calcium. It is used to:
• reinforce the heart function
• correct low blood calcium levels
• increase calcium levels in the blood stream
• protect the kidneys from damage
• treat cardiac arrest

2. What you need to know before you use Calcium Gluconate 10% w/v Injection BP
Do not use this medicine if:
• you are allergic to calcium gluconate or any of the other ingredients in this medicine (listed in section 6)
• you have elevated blood calcium levels (e.g. in patients with cancer, diabetes or alcohol or drug abuse)
• you have low blood magnesium levels
• you are pregnant or breast-feeding
• you are receiving calcium gluconate even via different infusion line or different infusion site.

Side effects with the use of Calcium Gluconate 10% w/v Injection BP include:
• In the case of poisoning with digitalis medicines (a kind of heart medicine) the effect of heart medicines like digitalis are increased by calcium up to the point of digitalis poisoning.
• The following table gives usual dosis values.

In children (< 18 years) Calcium Gluconate 10 % w/v Injection BP will be given to you as an injection directly into a vein or directly into a muscle. It may be given to you in a lying position and in particular your heart function should be carefully monitored after the injection.

In the case of exceptionally low blood calcium levels in neonates and infants (< 18 years), the usual starting dose is 10 ml, i.e. one ampoule of Calcium Gluconate 10% w/v Injection BP. If required, the dose may be repeated. Following doses will be adjusted according to the respective blood calcium level and the severity of the symptoms. In the case of poisoning with digitalis medicines affecting the nerves and muscles, preference will be given to intravenous calcium preparations. The following table gives usual initial dosage for guidance:

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Possible side effects
Side effects with the use of Calcium Gluconate 10% w/v Injection BP include:

Common: fever, headache, muscle cramps, symptoms such as impaired skin sensations (numbness, itching, burning), continued muscle rigidity, tingling, the hands and feet cold, muscle weakness, confusion, possibly deterioration of your vision (e.g. blurred vision and near vision)

In the case of poisoning with digitalis medicines (a kind of heart medicine) may affect the tolerance of calcium gluconate. Therefore, a treatment is aimed at lowering the elevated high blood calcium levels. If you receive more Calcium Gluconate 10% w/v Injection BP than you should:

Symptoms of high blood calcium level (hypercalcemia) include:
• insufficiency or loss of appetite, feeling sick, being sick (vomiting), constipation, belly ache
• loss of appetite, feeling sick, being sick (vomiting), constipation, belly ache

Calcium administration can be repeated, if required. The concentration of the following doses will depend on the blood calcium level and the severity of the symptoms. In the case of poisoning with digitalis medicines affecting the nerves and muscles, preference will be given to intravenous calcium preparations. The following table gives usual initial dosage for guidance:

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The following information is intended for healthcare professionals only:

**Method of administration:**
In the case of adult patients a longer needle will have to be chosen for safe positioning of the injection into the muscle and not into the adipose tissue.

**Special warnings and precautions for use:**
In patients of any age vaccinations or intravenous perfusions of calcium containing solutions must be performed under careful observation.

**Incompatibilities:**
Calcium salts can form complexes with many drugs and this may result in a precipitate. Calcium salts are incompatible with: halogenated hydrocarbons, sarcosine, some sugars, phosphate, tartrates and sulfates.

**Physical Incompatibility:**
It has been reported with amphotericin, cephalosporins, sobenadine, cephalothin (‘some penicillins’), cephaloxin (‘some tetracyclines’).

**Dilution:**
For intravenous infusion, Calcium Gluconate 10% w/v injection BP may be diluted 1:10 to a concentration of 1.0 mg/ml with the following two infusion fluids: solution in glucose 5% w/v or solution in ringer’s lactate 0.9% w/v. When diluted these recommended infusion fluids, the resulting solutions are intended for immediate single use. Dilution should be performed under controlled and validated aseptic conditions. After mixing, the container should be gently agitated to ensure homogeneity.

**Treatment of overdose:**
Initial management should include notification and, in severe hypercalcaemia, it may be necessary to administer isotonic sodium chloride solution BP in a concentration of 0.9% w/v. However, in patients older than 28 days of age ceftriaxone and calcium-containing solutions may be administered sequentially one after the other if infusion lines at different sites are used or if the infusion lines are replaced or thoroughly flushed between infusions with physiological saline solution to avoid precipitation.

**Sequential infusions of ceftriaxone and calcium-containing products must be avoided in case of hypovolaemia.**

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**Treatment of overdose:**
Initial management should include notification and, in severe hypercalcaemia, it may be necessary to administer isotonic sodium chloride solution by intravenous infusion to expand the extracellular fluid. Calcium salts are given to increase intravenous calcium excretion but should be avoided as they may increase renal absorption of calcium.

**Sodium electrolytes should be carefully monitored throughout treatment of overdose.**

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**Calcium Gluconate 10% w/v injection BP contains:****
- The active substance is calcium gluconate.
- A solution containing 10 mg of calcium gluconate, equivalent to 0.21 mmol calcium.
- 3 ml contains 64 mg of calcium gluconate, equivalent to 2.10 mmol calcium.
- The other ingredient is water for injections.

**Calcium Gluconate 10% w/v injection BP looks like and contents of the pack:**
Calcium Gluconate 10% w/v injection BP is a solution for injection in a solution that is administered in a syringe. It is a clear, colourless to light-yellow aqueous solution.

**Marketing Authorisation Holder and Manufacturer:**
B. Braun Melsungen AG
Carl-Braun-Straße 1
34223 Melsungen
Germany
Post address:
34209 Melsungen
Germany
Phone: +49 5641 70-3107
Fax: +49 5641 70-3102

This medicinal product is authorised in the Member States of the EEA under the following names:

**Belgium:**
Calcium Gluconate 10% B. Braun spuiten over injectie

**Denmark:**
Calciumkortison B. Braun 100 ml

**France:**
Gluconate de Calcium 10 % B. Braun, solution pour perfusion

**Italy:**
Calcio gluconato 10% B. Braun soluzione iniettabile

**Netherlands:**
Calcium Gluconicum 10% B. Braun, spuitvloeistof voor injectie

**Austria:**
Calcium gluconat B. Braun 10 % B. Braun

**Slovak Republic:**
Calcium Gluconicum 10 % B. Braun

**United Kingdom:**
Calcium Gluconate 10 % w/v Injection BP

This leaflet was last revised in 10/2015.