

PACKAGE LEAFLET: INFORMATION FOR THE USER

hameln pharmaceuticals ltd · Gloucester · UK

Calcium Gluconate 10 % w/v Injection BP

Calcium gluconate

Read all of this leaflet carefully because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- If any of the side effects become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Calcium Gluconate 10 % w/v Injection BP is and what it is used for
2. 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. Further information

1. WHAT CALCIUM GLUCONATE 10 % W/V INJECTION BP IS AND WHAT IT IS USED FOR

Calcium gluconate 10 % w/v Injection BP solution for injection is a solution for the intake of calcium.

It is used for the intake of calcium in patients with extremely depleted blood calcium levels (hypocalcaemia) and presenting with acute symptoms such as impaired skin sensations (numbness, itching, burning), convulsive muscular rigidity (tetany), cramp in the hands and feet, colic, muscular weakness, speech difficulties and confusion, possibly culminating in convulsions.

2. BEFORE YOU USE CALCIUM GLUCONATE 10 % W/V INJECTION BP

DO NOT USE CALCIUM GLUCONATE 10 % W/V INJECTION BP

- If you are hypersensitive to calcium gluconate or any of the other ingredients of Calcium Gluconate 10% w/v Injection BP (see section 6)
- If you have elevated blood calcium levels (e.g. in patients with over-active parathyroid glands, elevated vitamin D levels in the blood, tumour diseases with bone decomposition, impaired kidney function, osteoporosis due to a lack of mobility, sarcoidosis and so-called milk-alkali syndrome)
- In the case of excessive excretion of calcium in the urine
- In the case of poisoning with **digitalis** medicines (a kind of heart medicine)
- During treatment with **digitalis** medicines unless you have an extremely low blood calcium level with life-threatening symptoms, which can only be treated by an immediate injection of calcium.

TAKE SPECIAL CARE WITH CALCIUM GLUCONATE 10 % W/V INJECTION BP

If you are taking digitalis preparations on a regular basis and, as an exception, you urgently require a calcium injection (see above), your doctor will, in any case, monitor your heart function extremely carefully so that any deterioration in heart function, e.g. severe arrhythmias (irregular heartbeat), can be treated immediately.

If you suffer from:

- deposition of calcium in the kidneys (nephrocalcinosis)
- heart diseases
- sarcoidosis,

you should only be given calcium injections if these are absolutely essential. This also applies if you are taking adrenaline or are elderly.

Impaired kidney function (kidney failure) can be accompanied by increased blood calcium levels and over-active parathyroid glands. If you are suffering from kidney failure, you should only receive calcium injections if these are absolutely essential. Your calcium and phosphate balance must, however, be monitored.

Calcium should be injected slowly in order to prevent, where possible, widening of the blood vessels or impaired cardiac output as a result of a slower or irregular heartbeat.

Heart function should be monitored when injecting into a vein (intravenous injection).

In children, Calcium Gluconate 10 % w/v Injection BP should only be injected into veins, not into a muscle (intramuscular).

During calcium salt treatment, you will be carefully monitored to ensure a normal calcium balance (calcium intake versus calcium excretion) and to prevent any chalky deposits in the tissue. Blood calcium levels and the quantities of calcium excreted in the urine will be monitored especially during high-dose calcium injections.

Calcium is insoluble in fatty tissue and may lead to inflammatory reactions followed by abscess formation, hardening of the tissue and tissue destruction (necroses) in these areas.

If the solution is inadvertently injected beside a blood vessel or not deep enough into a muscle, this could lead to local tissue irritation, possibly followed by peeling of the skin or even necroses, see also section 4. Your doctor will ensure that no solution drains into tissue around the blood vessel and will carefully observe the site of injection.

High doses of vitamin D should be avoided.

TAKING OR USING OTHER MEDICINES

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines obtained without a prescription.

The effect of heart medicines like **Digoxin** and other **digitalis** medicines can be made stronger by calcium up to the point of digitalis poisoning. Therefore, if you are receiving treatment with **digitalis** medicines, you will only receive an intravenous calcium injection for the treatment of severe, immediately life-threatening symptoms of a very low blood calcium level.

Administration of calcium together with **adrenaline** may lead to cardiac arrhythmias (irregular heartbeat).

Calcium and **magnesium** mutually inhibit their effects.

Calcium can reduce the effects of certain medicines used to regulate heart function (**calcium antagonists**).

Administration of certain **medicines increasing the urine flow (thiazide diuretics)** together with calcium can lead to excessively high blood calcium levels (hypercalcaemia), as these medicinal products reduce the excretion of calcium via the kidneys.

PREGNANCY AND BREAST-FEEDING**Pregnancy**

Calcium passes through the placenta into the circulation of the foetus. Pregnant women should, therefore, only receive calcium injections if absolutely essential. The dose must then be carefully calculated and calcium levels in the blood regularly monitored in order to avoid the presence of excessive calcium levels in the blood, which could have an adverse effect on the foetus.

Breast-feeding

Calcium diffuses into breast milk. This should be taken into account when giving calcium to nursing mothers.

DRIVING AND USING MACHINES

Calcium gluconate 10 % w/v Injection BP has no influence on the ability to drive and use machines.

3. HOW TO USE CALCIUM GLUCONATE 10 % W/V INJECTION BP

DOSAGE

Your doctor will select the dose required to raise your blood calcium level / your child's blood calcium level to normal values.

The following recommendations are given for adults and adolescents over 12 years old:

The usual starting dose is 10 ml, i.e. one ampoule of Calcium Gluconate 10 % w/v Injection BP. If required, other doses can be administered until the blood-calcium level increases to normal values or symptoms disappear.

For children and adolescents up to 12 years of age:

The doctor will decide on the dosage and method of administration depending on the blood calcium level and the severity of the symptoms. In the case of mild

Approval for Printing**B. BRAUN** Melsungen AGApproved for Printing Approved for Printing when corrected New draft required

Date _____ Signature _____

schwarz (20%, 45%, 100%)

Dokument = 210 x 297mm
2 Seiten

Lätus 7138



hameln pharmaceuticals ltd
570/12609364/0111
GIF
MS: B

symptoms affecting the nerves and muscles, preference will be given to oral calcium preparations.

Approximate starting doses are as follows:

- For children up to 3 years: 0.4 – 1 ml per kg of body weight
- For children between 4 and 12 years: 0.2 – 0.5 ml per kg of body weight

In the case of exceptionally low blood calcium levels with, for instance, impaired cardiac function, higher starting doses may be required in order to raise the blood calcium level more quickly (up to 2 ml per kg of body weight).

Calcium administration can be repeated, if required. The extent of the subsequent doses will depend on the existing blood calcium level. Continuing the treatment with oral calcium preparations may prove necessary after intravenous therapy, e.g. in cases of vitamin D deficiency.

Elderly patients:

Certain disorders that are sometimes associated with advanced age, such as impaired kidney function and undernourishment (malnutrition) may affect the tolerance of calcium gluconate such that a lower dose must be selected.

METHOD OF ADMINISTRATION

Adults:

For intravenous or intramuscular use. The medicinal product is injected slowly into a vein or deep into a large muscle.

Children and adolescents:

Solely for intravenous administration as a slow injection or slow, i.v. infusion (venous drip) after dilution.

The rate of intake with intravenous infusion or injection should be sufficiently slow. The patient should lie down and heart function in particular should be carefully monitored during the injection.

Due to the risk of local tissue inflammation, injections into muscles should only be made if intravenous injection is not feasible. Your doctor will carefully ensure that the intramuscular injections are administered sufficiently deep, preferably into the large buttock muscle.

IF YOU RECEIVE MORE CALCIUM GLUCONATE 10 % W/V INJECTION BP THAN YOU SHOULD:

Symptoms:

Symptoms of an excessively high blood calcium level (hypercalcaemia) include: loss of appetite, feeling sick, sickness (vomiting), constipation, stomach-ache, passing large quantities of urine, unquenchable thirst, fluid loss, muscle weakness, bone pain, deposition of calcium in the kidneys, dizziness, drowsiness, confusion, high blood pressure (hypertension) and, in severe cases, irregular heartbeat, possibly up to the point of heart attack, and loss of consciousness.

Symptoms of hypercalcaemia and chalky taste, hot flushes and a drop in blood pressure can occur if the intravenous injection is made **too rapidly**.

Treatment:

Treatment is aimed at lowering excessively high blood calcium levels.

Fluid is administered at the start of treatment; the infusion of normal saline solution may be required in more severe cases of hypercalcaemia in order to increase the blood volume. Appropriate medicines can be administered in order to lower excessively high blood calcium levels or to increase the elimination of calcium. Treatment with artificial kidney (haemodialysis) or dialysis via the peritoneum can be used if other measures prove unfeasible and the acute symptoms persist. Serum electrolytes must be carefully monitored throughout the overdose treatment period.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Calcium Gluconate 10 % w/v Injection BP solution for injection can cause side effects, although not everybody gets them.

The frequency of side effects is expressed as follows:

- Very common: more than 1 in 10 patients
- Common: 1 to 10 patients out of 100
- Uncommon: 1 to 10 patients out of 1,000
- Rare: 1 to 10 patients out of 10,000
- Very rare: less than 1 in 10,000 patients
- Unknown: frequency cannot be estimated based on the available data.

Side effects on the heart, circulation or other body functions may appear as symptoms of an excessively high blood calcium level after overdosing or too rapid intravenous injection. The presence and frequency of such symptoms depend directly on the speed of injection and the dose administered. Such side effects **rarely** occur when the medicinal product is used as directed.

SIDE EFFECTS

Heart and circulation disorders

Drop in blood pressure (hypotension), slow or irregular heartbeat, circulatory collapse and hot flushes, mainly after the injection has been administered too rapidly.

Stomach and gut disorders

Feeling sick and sickness (vomiting)

General disorders

Hot flushes and sweating

Effects at the site of administration

Common: Intramuscular injections may be accompanied by pain and redness.

Side effects when the medicinal product is used incorrectly:

- If the injection is not administered deep enough into a muscle, the solution may penetrate the fatty tissue, possibly leading to inflammation, hardening and destruction (necrosis) of the tissue.
- Calcium deposits in the soft tissue after the penetration of the solution into the surrounding tissue, possibly followed by peeling of the skin and necrosis, have been reported.
- Redness of the skin and a feeling of burn or pain during intravenous injection may indicate an inadvertent injection beside the blood vessel, which could lead to necrosis of the tissue.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE CALCIUM GLUCONATE 10 % W/V INJECTION BP

Keep out of the reach and sight of children.

Do not use Calcium Gluconate 10% w/v Injection BP solution for injection after the expiry date, which is stated on the container and carton.

Do not store above 25°C.

The solution must be used immediately once the ampoule has been opened.

After diluting (see "Method of administration"), the ready-to-use solutions must be administered as soon as possible but should not, under any circumstances, be stored for longer than 24 hours at 2 – 8° C.

Calcium Gluconate 10 % w/v Injection BP must not be used if you notice the following changes:

- damage to the container or closure,
- discolouration or cloudiness (turbidity) of the solution
- visible particles in the solution.

6. FURTHER INFORMATION

What Calcium Gluconate 10 % w/v Injection BP contains

- The active substance is calcium gluconate.
 - 1 ml of solution for injection contains:
 - 94 mg of calcium gluconate for parenteral use, equivalent to 0.23 mmol calcium
 - 1 ampoule of 10 ml solution for injection contains
 - 940 mg of calcium gluconate for parenteral use, equivalent to 2.26 mmol of calcium
 - The other ingredients are:
 - Calcium saccharate, water for injection

What 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 (a solution, that is administered in a syringe). It is a clear, colourless, aqueous solution.

Calcium Gluconate 10 % w/v Injection BP is contained in 10-ml plastic ampoules made from colourless polyethylene, in packs of 20 ampoules.

MARKETING AUTHORISATION HOLDER AND MANUFACTURER:

B. Braun Melsungen AG,
 Carl-Braun-Straße 1
 34212 Melsungen, Germany
 Tel.: 05661-71-0
 Fax: 05661-71-4567

Postal address:
 34209 Melsungen, Germany

Distributor

hameln pharmaceuticals ltd
 Gloucester
 UK

This information was last approved in: 02/2011

 **hameln**
 pharmaceuticals

hameln pharmaceuticals ltd
 Gloucester
 UK