Package Leaflet: Information for the patient

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Calcium Gluconate 10% solution for injection/infusion BP
Calcium gluconate

Read all of this leaflet carefully before you start receiving this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Calcium Gluconate 10% solution for injection/infusion BP, which will be referred to as Calcium Gluconate 10% injection/infusion throughout this leaflet.

What is in this leaflet

1. What Calcium Gluconate 10% injection/infusion is and what it is used for
2. What you need to know before you are given Calcium Gluconate 10% injection/infusion
3. How Calcium Gluconate 10% injection/infusion is given
4. Possible side effects
5. How to store Calcium Gluconate 10% injection/infusion
6. Contents of the pack and other information

1. What Calcium Gluconate 10% injection/infusion is and what it is used for

Calcium is found naturally in the body and is necessary for the normal function of muscles and nerves. It is needed to make the heart work properly and for blood to clot. Calcium Gluconate 10% injection/infusion is used:
- to replace low levels of calcium in the body (acute symptomatic hypocalcaemia)
- to prevent abnormal heartbeat (arrhythmia) due to high potassium levels in the blood (severe hyperkalaemia)
- to help restore normal heart function in an emergency (cardiac arrest) if potassium levels in the blood are too high
- in the treatment of lead and fluoride poisoning

2. What you need to know before you are given Calcium Gluconate 10% injection/infusion

You should not be given Calcium Gluconate 10% injection/infusion:
- if you are allergic to Calcium Gluconate or any of the other ingredients of this injection (listed in section 6)
- if you have high levels of calcium in your urine (hypercalciuria)
- if you have high levels of calcium in your blood, for example as a result of hyperparathyroidism (overactive parathyroid glands), excessive levels of vitamin D, a tumour, impaired kidney function, osteoporosis due to a lack of mobility, sarcoidosis or so-called milk-alkali syndrome)
- if you have kidney disease and require repeated or prolonged treatment, due to the risk of exposure to aluminium
- if you have been treated with cardiac glycosides (heart medicines) unless you have an extremely low blood calcium level or extremely high blood potassium level with life-threatening symptoms, which can only be treated by an immediate injection of calcium
- if you are a child less than 18 years of age and require repeated or prolonged treatment, due to the risk of exposure to aluminium, which can be leached from ampoule glass
- for Total Parenteral Nutrition (TPN) (feeding by passing stomach via administration into a vein) due to the risk of exposure to aluminium.

Premature and newborn babies (aged up to 4 weeks old) should not be given Calcium Gluconate 10% injection/infusion with the antibiotic ceftriaxone.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before being given Calcium Gluconate 10% injection/infusion if you:
- suffer from chronic kidney disease or you are at risk of stone formation in your urinary tract
- suffer from deposition of calcium in the kidneys (nephrocalcinosis)
- have sarcoidosis (swollen or inflamed patches of tissue, usually affecting the lungs and skin)
- have heart disease
- have impaired kidney function. This condition can be associated with increased blood calcium levels and overactive parathyroid glands so your doctor will carefully monitor chemicals in your blood and you will receive this medicine only if it is absolutely essential.
- are receiving adrenaline (epinephrine)
- are elderly

Children and Adolescents

Calcium Gluconate 10% injection/infusion should not be used for repeated or prolonged treatment, in children (less than 18 years of age) and those with impaired kidney function, due to the risk of exposure to aluminium. Aluminium oxide can be leached from ampoule glass by Calcium Gluconate. In order to limit the exposure of patients to aluminium, especially those with impaired kidney function and children (less than 18 years of age), hameln pharma ltd Calcium Gluconate 10% solution for injection/infusion BP should not be used in the preparation of Total Parenteral Nutrition (TPN), due to the risk of exposure to aluminium.

Other medicines and Calcium Gluconate 10% injection/infusion

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important with the following medicines as they may interact with your Calcium Gluconate 10% injection/infusion:
- digoxin (a heart medicine) and other cardiac glycoside medicines may have their effect increased
- thiazide diuretics (certain water tablets), may reduce your body's ability to eliminate calcium and high levels may occur
- ceftriaxone (an antibiotic), due to the risk of precipitation, must not be given simultaneously, even via separate infusion lines
- adrenaline (epinephrine), a medicine used after heart surgery, may have its effect reduced
- magnesium and calcium may reduce each other's effects
- calcium channel blockers (heart medicines), may have their effects reduced
- vitamin D, a high intake should be avoided.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before receiving this medicine.
Calcium Gluconate 10% injection/infusion should not be used during pregnancy unless absolutely necessary.
As calcium is passed into breast milk, discuss with your doctor if breast feeding should be discontinued.

Driving and using machines

It is unlikely that this medicine has an effect on the ability to drive and use machinery however you should not drive or use machinery if you are affected by the administration of Calcium Gluconate 10% injection/infusion.

3. How Calcium Gluconate 10% injection/infusion is given

Your nurse or doctor will give you the injection. Your doctor will decide the correct dosage for you and how and when the injection will be given. During treatment, your blood and urine calcium levels will be monitored closely.

When this medicine is injected or infused into your vein your heart should be monitored to ensure that any worsening of your heart function like severe arrhythmias (irregular heartbeat) can be treated immediately.

This medicine should be injected or infused slowly in order to prevent, where possible, widening of the blood vessels or impaired heart function. Too rapid injection or infusion may affect the heart and blood circulation due to high levels of calcium.

Calcium Gluconate 10% injection/infusion may cause local tissue irritation. Reddening of the skin, burning sensation and pain during injection or infusion into a vein may indicate that the medicine was inadvertently given outside a blood vessel which can lead to serious tissue damage (skin necrosis). Your doctor will ensure that no solution drains into tissue around the blood vessel and will carefully observe the site of injection or infusion.

You should be lying down when you receive the medicine.

Taking into account the content of aluminium in one ampoule (when measured at the end of shelf life) and considering current scientific knowledge, it cannot be excluded that exposure to aluminium (from administering more than the recommended number of ampoules) could contribute to future total aluminium exposure (from the environment, drinking water and food) and potential toxicity in patients. Due to this risk, repeated or prolonged treatment in children (less than 18 years of age) is not recommended.

If you are given more Calcium Gluconate 10% injection/infusion than you should

Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much. If you think you have been given too much, you feel sick, are sick, are constipated, have stomach pain, suffer muscle weakness, feel thirsty, are passing a lot of urine, feel confused or have bone pain you must tell the person giving you the injection immediately.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may be serious. If any of the following side effects occur tell your doctor immediately:

Frequency: rare (may affect up to 1 in 1,000 people)
- Severe side effects, in some cases leading to death, have been reported in premature and newborn babies (aged up to 28 days) who had been treated with intravenous ceftriaxone (an antibiotic) and calcium.

The following information is intended for healthcare professionals only.
PREPARATION GUIDE FOR:

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Calcium Gluconate 10% solution for injection/infusion BP

Total calcium content in one 10 ml ampoule is 2.23 mmol of calcium (2.12 mmol calcium as calcium gluconate and 0.11 mmol calcium as calcium saccharate).

- Colourless, clear and free from visible particles
- pH 6.0 - 7.0
- Osmolality 270 - 310 mOsmol/kg

Please refer to the Summary of Product Characteristics for full prescribing and other information

Method of administration

For slow intravenous injection and/or infusion.

The intravenous administration rate should not exceed 0.45 mmol of calcium per minute in adults and 0.22 mmol of calcium per minute as a bolus in children. For continuous infusions, the rate should be adjusted based on the serum calcium levels and the severity of the hypocalcaemic symptoms with a maximum administration rate of 0.022 mmol/kg body weight /hour in neonates (0 to 27 days) and 0.045mmol/kg body weight /hour in children (28 days to < 18 years).

For the management of acute severe hyperkalaemia, further doses can be considered and adjusted according to ECG resolution of arrhythmias.

Calcium Gluconate 10% solution for injection/infusion can be diluted with glucose 5% or sodium chloride 0.9%.

The patient should be in the lying position and should be closely observed during injection. Monitoring should include heart rate or ECG.

Appropriate venous access should be ensured as extravascular administration can result in severe skin injuries including tissue necrosis.

Posology

Please refer to the Summary of product characterises for full posology.
During therapy, serum calcium levels should be monitored closely.

Treatment of acute symptomatic hypocalcaemia

The normal concentration of calcium in plasma is within the range of 2.25-2.75 mmol or 4.5-5.5 mEq per litre in adults. Treatment should be aimed at restoring or maintaining this level.

Treatment of acute severe hyperkalaemia with or without ECG changes and for cardiac arrest due to hyperkalaemia

Calcium therapy for severe hyperkalaemia (serum potassium concentration above 6.5 mmol/L in adults) is an emergency treatment aiming to reduce cardiac cell excitability (cardioprotective effect) while other measures to lower potassium levels are instituted.
For cardiac arrest Calcium Gluconate 10% solution for injection/infusion should be given only if caused by severe hyperkalaemia.

Frequency: not known (frequency cannot be estimated from the available data)
- slow or irregular heartbeat
- drop in blood pressure (hypotension)
- circulatory collapse (enlarging of blood vessels with a life-threatening drop in blood pressure)
- hot flushes, mainly after the injection has been given too rapidly
- feeling sick (nausea) or being sick (vomiting)
- sensation of heat
- sweating

Side effects when Calcium Gluconate 10% injection/infusion is used incorrectly or in special situations
- Too rapid injection or infusion may cause cardiovascular side effects, due to high levels of calcium. The presence and frequency of such symptoms depend on the speed of injection or infusion and the given dose.
- It has been reported that following leaking of the solution from a vein into the surrounding tissue (extravasation), calcium deposition in the soft tissue may occur. It may be followed by peeling and destruction of the skin.

If Calcium Gluconate 10% injection/infusion is given for repeated or prolonged treatment to children below 18 years of age or to patients with kidney disease, there is a potential risk of aluminium build-up and side effects may occur, like brain development and bone growth disorders and a blood disorder in which body organs and tissues do not get enough oxygen (microcytic anaemia).

If you think this injection is causing you any problems, or you are at all worried, talk to your doctor, nurse or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Calcium Gluconate 10% injection/infusion
Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the label and carton after "EXP". The expiry date refers to the last day of that month.
Your injection will be stored at less than 25°C and protected from light.
Do not use this medicine if you notice the solution shows any discolouration, precipitation or any other visible particles.

6. Contents of the pack and other information
What Calcium Gluconate 10% injection/ infusion contains
The active substance is calcium gluconate. Each 1 ml of solution contains 95 mg calcium gluconate.
The other ingredients are Calcium D Saccharate and Water for Injections.

What Calcium Gluconate 10% injection/ infusion looks like and contents of the pack
Calcium Gluconate 10% injection/infusion is supplied in 10 ml clear glass ampoules. 10 ampoules supplied in each carton.

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For any information about this medicine, please contact the Marketing Authorisation Holder.

This leaflet was last revised in April 2024.

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Treatment should be tailored to the individual patient. The onset of action of intravenous calcium gluconate is within three minutes. With a relatively short duration of action (30 – 60 minutes) further doses may be necessary if hyperkalaemia remains uncontrolled.

Risk of medications errors due to non-equivalence of calcium gluconate and calcium chloride salts
Calcium gluconate and calcium chloride are presented in 10 ml ampoules at 10% (w/v) for injection but are **not equivalent** in calcium content:
- 10 ml of Calcium Gluconate 10% solution for injection/infusion BP contains 2.23 mmol calcium
- 10 ml of calcium chloride 10% solution contains 6.8 mmol of calcium

The difference in calcium content should be accounted for to achieve the correct calcium dose when using either salt to avoid medication errors.

Incompatibilities
Calcium salts can form complexes with many drugs, and this may result in a precipitate (See section 4.4). Calcium salts are incompatible with oxidising agents, citrates, soluble carbonates, bicarbonates, phosphates, tartrates and sulfates. Physical incompatibility has also been reported with amphotericin, cephalothin sodium, cephazolin sodium, cephamandole nafate, ceftriaxone, novobiocin sodium, dobutamine hydrochloride, prochlorperazine, and tetracyclines.