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PACKAGE LEAFLET: INFORMATION FOR THE USER

hameln pharma ltd · Gloucester · UK

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 to read it again.
- If you have any further questions, ask your doctor.
- 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

Calcium Gluconate 10 % w/v Injection BP is a solution for the supplementation of calcium.

It is used for the supply of calcium in patients with abnormally low blood calcium levels (hypocalcaemia) and presenting with acute symptoms such as impaired skin sensations (numbness, itching, burning), convulsive muscular rigidity (tetany), cramps in the hands and feet, colic, muscle weakness, confusion, possibly culminating in convulsions and cardiac symptoms (e.g. irregular heartbeat and even acute heart failure).

It is also used:
– 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

2. What you need to know before you use Calcium Gluconate 10 % w/v Injection BP

Do not use Calcium Gluconate 10 % w/v Injection BP

- if you are allergic to calcium gluconate or any of the other ingredients of this medicine (listed in section 6)
- if you have elevated blood calcium levels (e.g. in patients with overactive 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.
- the antibiotic ceftriaxone should not be used in premature neonates and neonates (≤ 28 days of age) if they are receiving (or are expected to receive) calcium-containing products which are administered into a vein.

Warnings and precautions

Talk to your doctor before using 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 monitor your heart function extremely carefully. The monitoring will ensure, that any worsening of your heart function, e.g. severe arrhythmias (irregular heartbeat), can be treated immediately.

Your doctor will consider very carefully whether this medicine is suitable for you if you suffer from:
- deposition of calcium in the kidneys (nephrocalcinosis)
- heart diseases
- sarcoidosis,

In these cases you should only be given calcium injections if these are absolutely essential. This also applies if you receive adrenaline (see "Other medicines and Calcium Gluconate 10 % w/v Injection BP") or are elderly.

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

Your doctor will take special care if you are receiving the antibiotic ceftriaxone. He will not administer it to you simultaneously with calcium gluconate even via different infusion line or different infusion sites.

Calcium should be injected slowly in order to prevent, where possible, widening of the blood vessels or impaired cardiac function.

Your heart rate or ECG should be monitored when this medicine is injected into a vein (intravenous injection).

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 when calcium is injected at high doses.

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

If the solution is inadvertently injected beside a blood vessel or not deep enough into a muscle, this can result in local tissue irritation, possibly followed by peeling of the skin or even necrosis (see 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.

Children and adolescents

In children (< 18 years) Calcium Gluconate 10 % w/v Injection BP should only be injected into veins, not into a muscle (intramuscular).

Other medicines and Calcium Gluconate 10 % w/v Injection BP

Tell your doctor if you are taking or have recently taken any other medicines. The effect of heart medicines like **digoxin** and other **digitalis** medicines can be increased by calcium up to the point of digitalis poisoning. Therefore, if you are receiving treatment with digitalis medicines, you will only be given 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** after heart surgery weakens the effects of adrenaline on the heart and circulation.

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 formation and output (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.

Administration of calcium simultaneously with ceftriaxone will lead to agglomeration.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you maybe pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Pregnancy
Calcium passes through the placenta into the circulation of the foetus and reaches higher levels in the foetal blood than in the mother's blood.

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 excessive calcium levels in the blood, which could be harmful to the foetus.

Breast-feeding
Calcium is excreted into breast milk. Your doctor will keep this in mind when administering calcium to you when you are breast-feeding your infant.

Driving and using machines

This medicine has no influence on the ability to drive and use machines.

3. How to use Calcium Gluconate 10 % w/v Injection BP

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.
The recommended dose will selected by your doctor in order to raise your blood calcium level / your child's blood calcium level to normal values.

Replacement of low levels of calcium in the body (acute symptomatic hypocalcaemia)

Adults
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 your actual blood calcium level.

Use in infants, toddlers, children and adolescents
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 symptoms affecting the nerves and muscles, preference will be given to oral calcium preparations.

The following table gives usual **initial** dosage values for guidance:

Age	ml/kg
3 months	0.4 – 0.9
6 months	0.3 – 0.7
1 year	0.2 – 0.5
3 years	0.4 – 0.7
7.5 years	0.2 – 0.4
12 years	0.1 – 0.3
> 12 years	as for adults

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

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

Prevention of abnormal heartbeat (arrhythmia) due to high potassium levels in the blood (severe hyperkalaemia) and for cardiac arrest due to too high potassium levels in the blood

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.

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. Therefore, a lower dose must be selected.

Method of administration

Calcium Gluconate 10 % w/v Injection BP will be given to you as an injection slowly into a vein or deep into a large muscle. It should be given to you in a lying position and in particular your heart function should be carefully monitored during the injection.

Due to the risk of local tissue irritation, injections into a muscle (intramuscular injection) 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.

The rate of intravenous infusion or injection should be sufficiently slow.

Infants, toddlers, children and adolescents
For intravenous (into a vein) administration as a slow injection or slow intravenous infusion (venous drip), both after dilution. In children, this medicine should not be injected into a muscle or under the skin.

If you receive more Calcium Gluconate 10 % w/v Injection BP than you should

Symptoms of a high blood calcium level (hypercalcaemia) include: loss of appetite, feeling sick, being sick (vomiting), constipation, belly ache, passing large quantities of urine, increased thirst, fluid loss, muscle weakness, deposition of calcium in the kidneys, drowsiness, confusion, high blood pressure (hypertension) and, in severe cases, irregular heartbeat, up to the point of cardiac arrest and loss of consciousness.

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

Treatment is aimed at lowering the elevated high blood calcium levels. Your doctor will decide on the treatment to be given. It may include administration of fluids or specific medication to lower the blood calcium level. In severe cases dialysis may become necessary.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

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

The frequency of side effects is expressed as follows:
Very common: affects more than 1 user in 10
Common: affects 1 to 10 users in 100
Uncommon: affects 1 to 10 users in 1,000
Rare: affects 1 to 10 users in 10,000
Very rare: affects less than 1 user in 10,000
Not known: 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 injection into a vein.

The presence and frequency of such symptoms depend directly on the speed of injection and the dose administered.

The following side effects may be serious. If any of the following side effects occur tell your doctor immediately, he will stop giving you this medicine:

Not known (Frequency cannot be estimated from the available data):
- slow or irregular heartbeat
- drop in blood pressure (hypotension)
- circulatory collapse (possibly fatal)

Rarely (affects 1 to 10 users in 10, 000):
Severe, and in some cases, fatal, adverse reactions have been reported in pre-term and full-term neonates (aged <28 days) who had been treated

with intravenous ceftriaxone and calcium. Precipitations of ceftriaxone-calcium salt have been observed in lung and kidneys post-mortem.

Other side effects include:

Not known (Frequency cannot be estimated from the available data):
- widening of blood vessels,
- hot flushes, mainly after the injection has been administered too rapidly.
- feeling sick or being sick (vomiting)
- sensation of heat
- sweating
- injections into muscles may be accompanied by pain and redness

Side effects when the medicinal product is used incorrectly

- If the injection is not given deep enough into a muscle, the solution may penetrate the fatty tissue, possibly resulting in inflammation, hardening and destruction (necrosis) of the tissue.
- It is been reported that following leaking of the solution from a vein into the surrounding tissue calcium deposition in the soft tissue may occur. It may be followed by peeling and destruction of the skin .
- 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 result in the destruction of the tissue.

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Calcium Gluconate 10 % w/v Injection BP

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 container and carton.

The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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

After diluting the ready-to-use solution must be administered as soon as possible but should not be stored for longer than 24 hours at 2 – 8° C.

Do not use this medicine if you notice the following changes:
- damage to the ampoule, discolouration or cloudiness (turbidity) of the solution, visible particles in the solution.

Do not throw away any medicines via household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Content of the pack and other information

What Calcium Gluconate 10 % w/v Injection BP contains

- The active substance is calcium gluconate.
- 1 ml of solution contains 94 mg of calcium gluconate, equivalent to 0.21 mmol calcium
  10 ml contains 940 mg of calcium gluconate, equivalent to 2.10 mmol calcium
- Excipients: The product also contains an amount of the excipient calcium D-saccharate tetrahydrate equivalent to 0.02 mmol calcium per ml (or 0.15 mmol calcium per 10ml).
- The other ingredient is water for injections.

Total calcium content: 0.23 mmol per ml (2.25 mmol per 10ml).

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 to light brown aqueous solution.

It comes in:
Polyethylene ampoules, content: 10 ml
available in packs of 20 x 10 ml

Marketing Authorisation Holder and Manufacturer:

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The following information is intended for healthcare professionals only:

Method of administration

In the case of adipose patients a longer needle will have to be chosen for safe positioning of the injection into the muscle and not into the adipose tissues.

If repeated injections are necessary, the injection site should be changed every time.

Paediatric patients (< 18 years)
Only slow intravenous injection or intravenous infusion (both after dilution), in order to achieve sufficiently low administration rates and to avoid irritation/necrosis in case of accidental extravasation. The intravenous administration rate should not exceed 5 ml of a 1:10 dilution per minute of Calcium Gluconate 10% w/v Injection BP in children and adolescents.

Special warnings and precautions for use

In patients of any age ceftriaxone must not be mixed or administered simultaneously with any calcium-containing intravenous solutions even via different infusion lines or different infusion sites.

Cases of fatal reactions with calcium-ceftriaxone precipitates in lungs and kidneys in premature and full-term newborns aged less than 1 month have been described.

However, in patients older than 28 days of age ceftriaxone and calcium-containing solutions may be administered sequentially one after another if infusion lines at different sites are used or if the infusion lines are replaced or thoroughly flushed between infusions with physiological salt-solution to avoid precipitation. Sequential infusions of ceftriaxone and calcium-containing products must be avoided in case of hypovolaemia.

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 % w/v Injection 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.

Calcium salts are incompatible with oxidising agents, citrates, soluble carbonates, bicarbonates, oxalates, phosphates, tartrates and sulphates.

Physical incompatibility has also been reported with amphotericin, cephalothin sodium, ceftriaxone (see "Warnings and precautions"), cephazolin sodium, cephamandole nafate, novobiocin sodium, dobutamine hydrochloride, prochlorperazine and tetracyclines.

This medicinal product must not be mixed with other medicinal products except those mentioned in section "Dilution" or unless compatibility has been satisfactorily demonstrated.

Dilution

For intravenous infusion, Calcium Gluconate 10% w/v Injection BP may be diluted 1:10 to a concentration of 10 mg/ml with the following two infusion fluids: sodium chloride 9 mg/ml (0.9%) solution for injection or glucose 50 mg/ml (5%) solution for injection. When diluted with 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 rehydration and, in severe hypercalcaemia, it may be necessary to administer isotonic sodium chloride solution by intravenous infusion to expand the extracellular fluid. Calcitonin may be given to lower the elevated serum calcium concentration. Furosemide may be administered to increase calcium excretion but thiazide diuretics should be avoided as they may increase renal absorption of calcium. Serum electrolytes should be carefully monitored throughout treatment of overdose.

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