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.

Why is this medicine used? Calcium gluconate 10 % w/v Injection BP is used for:

1. Calcium gluconate 10 % w/v Injection BP is used if:

• you are suffering from excessively low blood calcium levels (hypocalcaemia) and present with acute symptoms such as cramping pain in the limbs, muscle weakness, convulsions, difficulty in breathing, heart noises, and convulsions due to an excessively low blood calcium level.

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 glucose or any of the other substances listed in section 6.1 Ingredients.

• you have elevated blood calcium levels (e.g. in patients with chronic obstructive pulmonary disease, chronic renal failure, elevated vitamin D levels in the blood, tumour diseases with bone deposits, impaired kidney function, increased parathyroid hormone levels or a list of similar conditions).

• you are taking digitalis medicines unless you have an exceptionally low blood calcium level with life-threatening symptoms, which can only be treated by an immediate injection of calcium.

• you are taking corticosteroids or if you have an excessive calcium excretion in the urine.

• you are pregnant or breast-feeding, think you may be pregnant or if you plan to have a baby, ask your doctor for advice before using this medicine.

How is this medicine used? 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 present with acute symptoms such as cramping pain in the limbs, muscle weakness, convulsions, difficulty in breathing, heart noises, and convulsions due to an excessively low blood calcium level. Calcium administration can be repeated, if required. The concentration of the calcium gluconate solution is 10 % w/v. Calcium should be injected slowly in order to prevent, where possible, the appearance of symptoms of an excessively high blood calcium level after injection. If you receive more Calcium Gluconate 10 % w/v Injection BP than you should

• If you receive too much Calcium Gluconate 10 % w/v Injection BP you should:

• Seek medical advice immediately. Tell your doctor or pharmacist the amount of medicine you have taken, the time when you received it and your symptoms.

• Keep this leaflet. You may need to read it again.

• If you get side effects talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.3.

• Do not speculate about possible side effects, ask your doctor or pharmacist if you are not sure.

• You should not use the antibiotic ceftriaxone in premature neonates.

• During treatment with digitalis medicines unless you have an exceptionally low blood calcium level with life-threatening symptoms, which can only be treated by an immediate injection of calcium.

• In the case of exceptionally low blood calcium levels in neonates and children, during calcium injections you should only be given in an intensive care unit.

• If you receive more Calcium Gluconate 10 % w/v Injection BP than you should tell your doctor immediately. Tell your doctor the amount of medicine you have taken, the time when you received it and your symptoms.

• You should not use the antibiotic ceftriaxone in premature neonates.

3. What is Calcium Gluconate 10 % w/v Injection BP and what does it contain? 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 present with acute symptoms such as cramping pain in the limbs, muscle weakness, convulsions, difficulty in breathing, heart noises, and convulsions due to an excessively low blood calcium level.
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 puncturing of the injection into the muscle and not into the adipose tissues.

Place the needle at right angles to the skin and insert it slowly, tapping the plunger of the syringe with the thumb. After a few minutes, if the injection is given into muscle, the plunger should move freely in the syringe. Under no circumstances should the plunger be allowed to move freely in the syringe and later to stop, which would suggest that the needle is not in the muscle and is in a blood vessel, which could result in the destruction of the tissue.

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

**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, redness, swelling, pain or necrosis of the tissue. If injection is given into a blood vessel, which could result in the destruction of the tissue and post-mortem.

Severe, and in some cases, fatal, adverse reactions have been reported in pre-term and full-term neonates (aged <28 days) who had been administered a calcium-phosphate mixture with a calcium-oxalate precipitate. The patient may experience any or all of the following symptoms:

- Shortness of breath
- Inability to breathe
- Cyanosis
- Inability to cry
- Tongue swelling
- Increased breathing rate
- Drowsiness
- Excessive salivation
- Posture changes
- Convulsions

In patients of any age ceftriaxone must not be mixed or administered simultaneously with any calcium-containing intravenous solutions even if the solutions are administered in a syringe. It is a clear, colourless to light brown aqueous solution.

**Incompatibilities**

Calcium salts are incompatible with sodium bicarbonate, citrates, succinic acid, ascorbic acid, sodium thiosulfate, potassium and sodium hydroxide. Incompatible with metabolically active substances such as potassium, magnesium and sodium ions.

**Dilution**

For intravenous infusion, Calcium Gluconate 10% w/v Injection BP may be diluted 1:10 to a concentration of 0.10 mg/ml with sodium chloride 0.9% solution 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 intubation and, if severe hypocalcaemia, it may be necessary to administer isotonic sodium chloride solution by intravenous infusion to expand the extracellular fluid. Calcium salts may be given to reverse the serum calcium concentration. A further dose of calcium gluconate may be given to raise the serum calcium concentration. Serum electrolytes should be carefully monitored throughout treatment of overdose.