

PACKAGE LEAFLET

Package leaflet: Information for the user

Kalciumklorid Abboxia 0,46 mmol/ml solution for injection

calcium

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

(Note: This medicinal product is used at hospitals and the doctor has decided that you need it. It might therefore be that you have not read this leaflet before the product is given to you.)

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What "Invented name" is and what it is used for
2. What you need to know before you use "Invented name"
3. How to use "Invented name"
4. Possible side effects
5. How to store "Invented name"
6. Contents of the pack and other information

1. What "Invented name" is and what it is used for

"Invented name" is a solution for injection containing the active substance calcium. "Invented name" is used for the treatment of adults and children who have low levels of calcium, too high levels of magnesium or potassium in the blood as well as having too high dose of calcium channel blocker (medicine to treat high blood pressure).

2. What you need to know before you use "Invented name"

Do not use "Invented name"

- if you are allergic to calcium chloride or any of the other ingredients of this medicine (listed in section 6).
- if you have an excess of calcium in the blood, in the urine or have a severe kidney disease
- if you have heart fibrillation
- if you have kidney stones since this condition may be worsened
- if you are also using ceftriaxone
- if you are using digitalis glycosides or adrenaline

Warnings and precautions

Talk to your doctor or nurse before using "Invented name".

Inform your doctor if you have an impaired kidney function, heart problems or if you are treated with vitamin D.

"Invented name" should not be given if you have an inflammation in one or several organs (sarcoidosis), a condition which may lead to additional increased levels of calcium in the blood.

If you have low levels of calcium in the blood (hypocalcemia), overtreatment of this condition should be avoided.

You should not be treated with added calcium if you have blood poisoning (sepsis).

Other medicines and "Invented name"

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

This includes:

- ceftriaxone (treatment of infections)
- cardiac glycosides/digitalis (treatment of heart failure)
- adrenaline (used in emergency care in connection with asthma, cardiopulmonary resuscitation (heart arrest) and allergic reactions (hypersensitivity and anaphylactic shock)).
- calcium channel blocker (treatment of high blood pressure)
- medicinal products containing calcium and magnesium
- muscle relaxation medicines
- thiazide diuretics (treatment of high blood pressure)

Pregnancy, breast-feeding and fertility

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

Pregnancy

There is insufficient data to assess the effects on pregnancy. Your doctor will decide if you may use "Invented name" during the pregnancy.

Breast-feeding

There is insufficient data to assess the effects on breast-feeding. Your doctor will decide if you may use "Invented name" during breast-feeding.

Fertility

No known risks.

Driving and using machines

"Invented name" does not affect your ability to drive or use machines.

3. How to use "Invented name"

This medicine will be given by health care professionals with relevant training and experience. Your doctor will decide the appropriate dose for you.

If you use more "Invented name" than you should

It is unlikely that you or your child will be given too much medicine as this medicine will be administered by health care professionals. A too high dose of "Invented name" may give symptoms such as thirst, nausea, vomiting, constipation, large urine volumes, stomach pain, muscle weakness, psychiatric disorders and in severe cases heart arrhythmia and coma.

Contact health care professionals if these symptoms occur.

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

4. Possible side effects

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

Not known (frequency cannot be estimated from the available data)

- slow heart beats, arrhythmia, fainting
- blood pressure fall, blood vessel dilation
- constipation, stomach pain, nausea, vomiting
- skin redness, skin rash, pain at the injection site
- heat sensation, accumulation of calcium in the skin

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store "Invented name"

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

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

6. Contents of the pack and other information

What "Invented name" contains

- The active substance is calcium. 1 ml contains calcium chloride dihydrate corresponding to 18,3 mg calcium. Contains 0,46 mmol/ml calcium and 0,91 mmol/ml chloride.
- The other ingredient is water for injections.

What "Invented name" looks like and contents of the pack

Clear, colourless to slightly coloured solution in clear glass ampoules.

Pack sizes: 10 x 10 ml, 20 x 10 ml, 50 x 10 ml, 100 x 10 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

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The following information is intended for healthcare professionals only:

Handling before use

For single use only, unused product should be discarded.

The solution for injection should be visually inspected before use. Only clear, colourless solutions without visible particles or precipitation may be used.

Handling during use

Be precautious to avoid extravasation at intravenous injection. Calcium chloride may cause severe necrotizing tissue damages.

Calcium should not be given solely but together with an ongoing glucose drip (without calcium phosphorus or magnesium) when administration is performed via peripheral infusion lines. There is a risk of precipitation at concurrent intravenous administration of calcium chloride and phosphate or magnesium. The precipitation can get stuck in small blood vessels and give rise to emboli.

”Invented name” solution for injection must not be given in the same infusion line as other calcium containing solutions such as nutrition solutions. Calcium chloride is irritating and should not be given intramuscularly, subcutaneously or in perivascular tissue since severe necrosis may occur. Direct injection into the heart tissue should be avoided.

Intravenous administration of calcium chloride may cause vasodilation, which may result in a moderate drop in blood pressure.

Continuous ECG monitoring should be performed when using calcium salts, to prohibit cardiac toxicity in connection with hyperkalemia.

Caution should be taken at administration of intravenous calcium solutions since there is an increased risk of hypercalcemia in conditions such as chronic renal impairment, dehydration or electrolyte imbalance.

Caution should be taken at administration of intravenous calcium products in patients with cardiac disease since calcium salts may increase the risk of cardiac arrhythmia.

Calcium chloride acidifies and caution should be taken at administration in conditions when acidification may cause issues such as renal disease, cor pulmonale, respiratory acidosis and respiratory failure.

The serum concentrations of calcium should be closely monitored in patients with renal impairment, especially at concurrent treatment with high doses of vitamin D. Frequent monitoring of S-calcium levels is recommended during the treatment to assure that normal levels are not exceeded.

It may be necessary to also monitor the calcium concentrations in the urine to avoid hypercalciuria which may occur in presence of hypocalcemia.

Incompatibilities

Since there are no compatibility studies available, this medicinal product must not be mixed with other medicinal products.

Tetracyclines

Calcium salts may form complex with tetracyclines and therefore tetracyclines and calcium salts should not be mixed for parenteral administration.

Magnesium sulphate

Mixing calcium salts with magnesium sulfate may cause precipitation of calcium sulfate. Magnesium sulfate and calcium chloride should therefore not be mixed for parenteral administration.

Phosphate containing medicines

Mixing calcium salts with carbonates may cause precipitation of calcium carbonates. Carbonate-containing medicines and calcium salts should not be mixed for parenteral administration.

Tartrate containing medicines

Mixing calcium salts with tartrates may cause precipitation of calcium tartrate. Tartrate-containing medicines and calcium salts should not be mixed for parenteral administration