

PACKAGE LEAFLET: Information for the user

GLUKONAT KALCIUMI

Solution for injection – 1000 mg / 10 ml

(Calcium gluconate)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Glukonat kalciumi is and what it is used for
2. Before you take Glukonat kalciumi
3. How to take Glukonat kalciumi
4. Possible side effects
5. How to store Glukonat kalciumi
6. Further information

1. WHAT GLUKONAT KALCIUMI IS AND WHAT IT IS USED FOR

Calcium is a mineral element necessary to maintain electrolytic balance and proper functioning of many regulatory mechanisms. Calcium insufficiency is associated with neuromuscular disorders and bone demineralisation. Calcium increases the effectiveness of leukocytes, increases phagocytosis and has an exudative effect on the capillaries during cold weather. Taking calcium increases its concentration in serum and in the whole body. 99% of calcium in the body is bound with phosphates in bones, mainly as hydroxyapatite.

Glukonat kalciumi is indicated in the treatment of hypocalcaemic states and as additional treatment in allergic conditions.

Your doctor may have given you Glukonat kalciumi for another reason. Ask your doctor if you want to know why you were given Glukonat kalciumi.

2. BEFORE YOU TAKE GLUKONAT KALCIUMI

Do not take Glukonat kalciumi if you:

- are hypersensitive to calcium gluconate or to any of the excipients of the solution for injection;
- have hypercalcemia (eg. in hyperparathyroidism, overdosing of vitamin D, tumors causing decalcification, eg. plasmocytoma, bone metastases);
- suffer from severe hypercalciuria;
- suffer from severe renal failure;
- have kidney disease and require repeated or prolonged treatment with Glukonat kalciumi;
- suffer from Zollinger-Ellison syndrome;
- suffer from ventricular fibrillation;
- are less than 18 years of age and require repeated or prolonged treatment with Glukonat kalciumi.

Co-administration of calcium gluconate with ceftriaxone is contraindicated in newborns (up to 28 days of age), even in cases where separated infusions are used.

If you think you have any of the conditions mentioned above, do not use the solution for injection, talk to your doctor first and follow the given advice.

Take special care with Glukonat kalciumi

Tell your doctor if you:

- are being treated with cardiac glycosides because in this case calcium serum levels should be monitored regularly;
- have mild hypercalciuria (not exceeding 300 mg or 7.5 mmol in 24 hours);
- have moderate impairment of renal function or history of nephrolithiasis (renal calculi), because the calcium quantity eliminated via urine should be monitored (where it is necessary

the dose of calcium should be reduced or discontinued. Patients who have predisposition for nephrolithiasis should consume considerable amounts of liquid);

- have heart disease;
- are taking vitamin D during treatment with calcium, the dose of calcium should be reduced, except the cases where it is specifically indicated;
- are elderly;
- are receiving adrenaline (epinephrine).

Co-administration of calcium gluconate with ceftriaxone should be avoided because of the risk of ceftriaxone-calcium precipitation.

Solutions of calcium salts are irritant, and care should be taken to prevent extravasation during intravenous injection. Calcium salts should be given cautiously to patients with sarcoidosis and some malignancies.

This drug should be used with caution in patients on a controlled sodium diet.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those without a prescription such as:

- verapamil (when used in high doses together with vitamin D, calcium can reduce the response of verapamil and maybe the response of other calcium blockers);
- cardiac glycosides (use of high doses of calcium may increase the risk of cardiac arrhythmias);
- citrate (in patients on blood transfusions, citrate may cause a higher calcemia than the norm; in such patients, most of calcium associated with citrate is not active);
- thiazide diuretics (concomitant use with thiazide diuretics may increase renal absorption of calcium);
- ceftriaxone (see section 2);
- adrenaline (epinephrine) (epinephrine's effects are attenuated in postoperative heart surgery);
- magnesium (calcium and magnesium mutually antagonise their effects).

These drugs can be affected by Glukonat kalciumi or may affect the way it acts. For this reason, during their concomitant use, may be needed to reduce or increase the dose of Glukonat kalciumi. Your doctor or pharmacist will advise you.

Pregnancy and breastfeeding

Inform your doctor or pharmacist if you are pregnant, planning to get pregnant or breastfeeding.

Driving and using machines

There is no evidence that calcium gluconate affects the ability to drive or use machines.

3. HOW TO TAKE GLUKONAT KALCIUMI

Always take this drug exactly as your doctor has told you. If you feel that the effect of Glukonat kalciumi is too strong or too weak, talk to your doctor or pharmacist.

Solution for injection Glukonat kalciumi is used as described below:

Intravenous use

Adults: 1 – 2 g (10 – 20 ml solution for injection 1000 mg / 10 ml) per day.

Children up to 1 year: 100 – 200 mg (1 – 2 ml solution for injection 1000 mg / 10 ml) per day;

1 – 6 years: 200 – 250 mg per day;

6 – 15 years: 250 – 500 mg per day.

Your doctor may ask you to take Glukonat kalciumi for a longer time. Ask your doctor for advice if you are not sure for how long you should take it.

If you take more Glukonat kalciumi than you should

If you take more Glukonat kalciumi than you should, or if the children have been taking this medicine by accident, please contact your doctor, the hospital, or call the emergency to get an opinion of the risk and advice on the action to be taken.

If you forget to take Glukonat kalciumi

If you forget a dose, take the next dose when it is the normal time to take it.

Do not take a double dose to make up for the forgotten dose.

If you have any further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

All medicines can cause side effects. Sometimes they may be serious, sometimes not. Do not panic from this list of possible side effects. You may not get any of them.

Inform your doctor if any of the following side effects bothers you.

Soft-tissue calcification has followed the use of calcium salts parenterally.

Too rapid intravenous injection of calcium salts may also lead to symptoms of hypercalcaemia, as well as a chalky taste, hot flushes, and peripheral vasodilatation.

Other side effects that may appear are: sweating, feeling sick or being sick (vomiting), hypotension, circulatory collapse, irregular heartbeat (arrhythmia).

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

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to the Pharmacovigilance Department of the National Agency of Drugs and Medical Devices at the email address farmakovigilanca@akbpm.gov.al or via the website www.akbpm.gov.al/formulari-raportimi. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE GLUKONAT KALCIUMI

Keep out of the reach and sight of children.

Do not use Glukonat kalciumi after the expiry date which is stated on the package.

Do not store above 25°C.

6. FURTHER INFORMATION

What Glukonat kalciumi solution for injection contains

The **active substance** is calcium gluconate.

Each ampoule (10 ml) contains 1000 mg calcium gluconate (10%).

The **excipients** are: boric acid, sodium hydroxide, water for injection.

Content of the pack

Box with 10 ampoules

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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