

PACKAGE LEAFLET: Information for the user

KALCIUM GLUKONAT

Tablets – 500 mg

(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 Kalcium glukonat is and what it is used for
2. Before you take Kalcium glukonat
3. How to take Kalcium glukonat
4. Possible side effects
5. How to store Kalcium glukonat
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1. WHAT KALCIUM GLUKONAT 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.

Kalcium glukonat is indicated as additional treatment to the osteoporosis of different etiology (postmenopausal osteoporosis, senile osteoporosis, osteoporosis induced by corticosteroids, gastrectomy or immobilization); prophylaxis of bone demineralisation before, during or after menopause; additional medication in rickets or osteomalacia; latent tetany (in acute cases calcium gluconate is used parenterally); in case of increased needs for calcium during pregnancy and breast feeding, as well as in the period of growth (childhood, adolescence); allergic condition (as additional treatment).

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

2. BEFORE YOU TAKE KALCIUM GLUKONAT

Do not take Kalcium glukonat if you:

- are hypersensitive to calcium gluconate or to any of the other ingredients of the tablet;
- 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;
- suffer from Zollinger-Ellison syndrome;
- suffer from ventricular fibrillation.

If you think you have any of the conditions mentioned above, do not take the tablets, talk to your doctor first and follow the given advice.

Take special care with Kalcium glukonat

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);

- during treatment with calcium you are taking vitamin D, the dose of the latter should be reduced, except the cases where it is specifically indicated.

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:

- tetracyclines and medicines containing fluoride (oral calcium can reduce their absorption. In cases where they should be taken together, the administration should be separated by at least 3 hours);
- vitamin D (concomitant use with vitamin D increases the absorption of calcium);
- corticosteroids (concomitant use with corticosteroids may interfere in the absorption of calcium);
- 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 (oral use of high doses of calcium may increase the risk of cardiac arrhythmias);
- thiazide diuretics (concomitant use with thiazide diuretics may increase renal reabsorption of calcium).

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

Taking Kalcium glukonat with food or drinks

Some foods (eg. spinach, whole grains, milk and dairy products) decrease the absorption of calcium from the digestive system.

Pregnancy

Inform your doctor or pharmacist if you are pregnant or planning to get pregnant to determine the optimal dose of calcium gluconate because it is indicated in pregnancy.

Breastfeeding

Inform your doctor or pharmacist if you are breastfeeding.

Calcium gluconate may be used during breastfeeding.

Driving and using machines

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

3. HOW TO TAKE KALCIUM GLUKONAT

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

Tablets Kalcium glukonat are used as described below:

Oral use.

Adults: 1-1.5 g, 3 times daily.

Children: 0.5-1 g, twice daily.

You should take the tablets at the same time every day.

The tablets Kalcium glukonat should be swallowed whole with a glass of water.

Your doctor may ask you to take Kalcium glukonat 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 Kalcium glukonat than you should

If you take more Kalcium glukonat than you should, or if 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 Kalcium glukonat

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:

- gastrointestinal disorders (flatulence, constipation, diarrhoea);
- exanthema or allergic reactions (urticaria, angioedema, pruritus).

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.

5. HOW TO STORE KALCIUM GLUKONAT

Keep out of the reach and sight of children.

Do not use Kalcium glukonat after the expiry date which is stated on the package.

Do not store above 25°C.

6. FURTHER INFORMATION**What Kalcium glukonat tablets contain**

The active substance is calcium gluconate.

Each tablet contains 500 mg calcium gluconate.

The excipients are: microcrystalline cellulose, sodium starch glycolate, magnesium stearate, talc.

Contents of the pack

Box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in August 2023.