

PACKAGE LEAFLET: Information for the patient

KLORUR KALCIUMI

Solution for injection – 1000 mg / 10 ml

(Calcium chloride)

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

1. WHAT KLORUR 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. 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.

It is indicated in:

- calcium deficiency (spasmophilia, tetany, adjuvant medication in rickets, osteomalacia, osteoporosis, in healing of fractures);
- allergic diseases (serum sickness, anaphylactic shock, urticaria, angioneurotic edema);
- chronic infectious disease;
- exudative eczema;
- adjuvant medication in treating insect bites.

Your doctor may have given you Klorur kalciumi for another purpose. Ask your doctor if you want to know why you were given this medicine.

2. BEFORE YOU TAKE KLORUR KALCIUMI

Do not use Klorur kalciumi if you:

- are hypersensitive to the drug;
- have hypercalcaemia (eg. hyperparathyroidism, overdose of vitamin D, tumors causing decalcification such as plasmacytoma, bone metastases);
- have severe hypercalciuria;
- have severe renal failure;
- have Zollinger-Ellison syndrome;
- are treated with digitalis drugs.

If you think you have any of the above conditions, ask your doctor for advice and follow his instructions.

Take special care with Klorur kalciumi

Solution of calcium chloride is irritating and care should be taken to avoid extravasation during injection.

Calcium salts should be used with caution in patients with renal function impairment (must not be used in severe renal impairment) or in diseases associated with increase of vitamin D concentrations, such as sarcoidosis.

In addition, they should be avoided in patients with renal calculi or data on renal calculi.

Calcium chloride, because of its acidifying nature, is unsuitable for the treatment of hypocalcaemia caused by renal insufficiency or in patients with respiratory acidosis or respiratory failure.

Plasma-calcium concentrations should be monitored closely in patients with renal impairment and during parenteral dosage and if large doses of vitamin D are used concurrently.

Taking other medicines

Concomitant use with other drugs may affect or be affected by Klorur kalciumi.

Please tell your doctor or pharmacist if you are taking or have taken recently other drugs, including those taken without a prescription.

Hypercalcaemia occurs when calcium salts are given with thiazide diuretics or vitamin D. Calcium enhances the effects of digitalis glycosides on the heart and may precipitate digitalis intoxication; parenteral calcium therapy is best avoided in patients receiving cardiac glycosides. Calcium salts reduce the absorption of a number of other drugs such as bisphosphonates, fluoride, some fluoroquinolones, and tetracyclines.

Ask your doctor or pharmacist for advice if you are taking concomitantly with Klorur kalciumi the above mentioned drugs.

Taking Klorur kalciumi with food and drinks

It is not applicable.

Pregnancy

Calcium crosses the placenta.

Tell your doctor or pharmacist if you are pregnant or planning to get pregnant, and ask him for advice before taking this drug during pregnancy.

Breastfeeding

Calcium passes into breast milk.

Tell your doctor or pharmacist if you are breastfeeding, and ask him for advice before taking this drug during this period.

Driving and using machines

There are no data available.

3. HOW TO TAKE KLORUR KALCIUMI

Klorur kalciumi will be administered to you very slowly into the vein (previously diluted) by your doctor or nurse in the hospital. The solution is compatible with glucose 5% and sodium chloride 0.9%.

Your doctor will decide the right dose for you.

If you take more Klorur kalciumi than you should

As this medicine will be given to you whilst you are in hospital, it is unlikely that you will be given too much. However, if you think you have been given too much of this medicine, please tell your doctor or nurse.

If you forget to take Klorur kalciumi

As this medicine will be given to you whilst you are in hospital, the doses are unlikely to be forgotten. However, if you feel that a dose has been missed, please tell your doctor or nurse.

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

4. POSSIBLE SIDE EFFECTS

All drugs can cause side effects. Sometimes they may be serious, sometimes not.

Injection of calcium salts can cause irritation, and intramuscular or subcutaneous injection in particular can cause local reactions including necrosis of the skin.

Solutions of calcium chloride are extremely irritant and should not be injected intramuscularly or subcutaneously.

Soft-tissue calcification follows the use of calcium salts parenterally.

Excessive amounts of calcium salts may lead to hypercalcaemia. This complication is usually associated with parenteral use, but can occur after oral dosage, usually in patients with renal failure or who are also taking vitamin D.

Symptoms of hypercalcaemia include anorexia, nausea, vomiting, constipation, abdominal pain, muscle weakness, mental disturbances, polydipsia, polyuria, nephrocalcinosis, renal calculi, and, in severe cases, cardiac arrhythmias and coma.

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.

Tell your doctor if any of the above side effects bothers you.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE KLORUR KALCIUMI

Keep out of the reach and sight of children.

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

Do not store above 25°C.

Store in the original package.

Attention! The ampoule is for single use only.

6. FURTHER INFORMATION

What Klorur kalciumi contains

The active substance is calcium chloride.

Each 10 ml ampoule contains 1000 mg of calcium chloride.

The other ingredients are: hydrochloric acid or sodium hydroxide may be added for pH adjustment, water for injection.

Contents 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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