

PACKAGE LEAFLET: INFORMATION FOR THE USER

KALCIJUM KARBONAT ALKALOID

1 g Tablets

CALCIUM CARBONATE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• 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 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 pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What Calcium carbonate Alkaloid are and what it is used for
2. Before you use Calcium carbonate Alkaloid
3. How to use Calcium carbonate Alkaloid
4. Possible side effects
5. How to store Calcium carbonate Alkaloid
6. Further information

1. WHAT CALCIUM CARBONATE ALKALOID IS AND WHAT IS IT USED FOR

Calcium carbonate alkaloid medicine contains for the active substance the calcium carbonate, which belongs to the group of minerals.

Calcium carbonate is indicated in hyperphosphatemia, chronic renal insufficiency, whether the patient is on dialysis or not.

Calcium carbonate is used as a supplement to diet when there is insufficient intake of calcium.

2. BEFORE YOU USE CALCIUM CARBONATE ALKALOID

Warn your doctor if you are taking other medicines, have a chronic disease, metabolism disorder, if you are hypersensitive to medicines or you have had an allergic reaction to some of them ...

Do not use Calcium carbonate Alkaloid

- if you have had an allergic reaction to calcium carbonate or any of the excipients in the medicinal product Calcium carbonate Alkaloid (see section 6. What medicine Calcium carbonate Alkaloid contains);
- You have a condition that causes high levels of calcium in the blood and urine (or hypercalcemia hypercalciuria), for example:
- In severe renal failure in patients who are not on dialysis;

- In osteoporosis (bone fragility) due to immobility;
- In hyperparathyroidism;
- In an overdose of vitamin D;
- In tumors caused by deposition of calcium such as plasmacytoma or cancer that has spread to your bones;
- You have kidney stones.

Take special care with Calcium carbonate Alkaloid

If any of the conditions specified below applies to you, tell your doctor:

- the formation of kidney stones history
- Taking medications for heart or diuretics
- at renal insufficiency the tablets should be given only under controlled conditions
- Cancer or any other conditions that may have affected your bones

During treatment with high doses, and particularly during simultaneous administration of vitamin D and / or medicines or nutrients (such as milk), that contain calcium, there is a risk of subsequent hypercalcaemia with renal impairment or lactic-alkaline syndrome. In these patients the level of serum calcium and renal function should be monitored.

Serum calcium or phosphate level, or urinary excretion of calcium should be monitored if you have any of the following conditions:

- The problem with the kidneys
- If you are on calcium carbonate long-term treatment
- Are already taking extra amounts of calcium

If you have high levels of calcium in the blood or developed signs of kidney problems, the dose of calcium carbonate should be reduced or treatment stopped.

Using other medicines

Bear in mind that this information may also apply to medicines that you do not drink, as well as to medicines you intend to take in the future. Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is very important if you are treated to some of these medicines:

- diuretics (the tablet leading to the elimination of water from the body); your level of serum calcium should be regularly monitored.
- heart medicines (cardiac glycosides), electrocardiogram and level of your serum calcium should be monitored.
- Vitamin D increases the possibility of occurrence of hypercalcemia.
- fenitoinom (for the treatment of epilepsy) and a calcium antagonist, they prevent the absorption of calcium.
- Preparations of iron, the concomitant use of calcium carbonate with these medicines can reduce their resorption.
- corticosteroids (e.g., prednisolone, dexamethasone); Your dose of calcium carbonate Alkaloid may need to be increased.
- antibiotics-tetracyclines; they should be taken at least two hours before or four to six hours later.
- hormones (levothyroxine); should be taken at least four hours before or later.
- Anti-infective medicines (quinolones, ciprofloxacin, lomefloxacin, norfloxacin, sparfloxacin): please talk to your doctor.
- fluoride, or bisphosphonate; Calcium Carbonate Alkaloid should be taken at least three hours after taking a fluoride or a biphosphonate.

Using Calcium carbonate Alkaloid with food and drink

Tablets of the calcium carbonate should be taken with a meal with a full glass of water.

Drinking more than 8 cups of coffee during the day reduces the absorption of calcium.

Oxalic acid (in spinach and rhubarb) and phytic acid (in whole grains) create an insoluble calcium salt and reduce the absorption of calcium. Between the application of calcium carbonate and foods containing these substances, it takes at least two hours.

Pregnancy and breast-feeding

- Ask your doctor, health care provider or pharmacist for advice before taking any medicine.

Driving and using machines

- Calcium carbonate Alkaloid has no influence on the ability to drive and use machines.

Important information about some of the ingredients of Calcium carbonate Alkaloid

- No important information about the ingredients of the medicine.

3. HOW TO USE CALCIUM CARBONATE ALKALOID

- Always take use Calcium carbonate Alkaloid exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

In hyperphosphatemia:

In patients with hyperphosphatemia, dosage of calcium carbonate is individual. Your doctor will prescribe you therapeutic dose.

Adults: 2.5 - 17 g per day, in divided doses.

Children from 6 to 12 years: ½ tablet, three to four times a day.

Children from 12 to 18 years: 1 - 1½ tablets, three to four times a day; A maximum of 5 g per day.

For lack of calcium in the diet:

Adults: 0,5 - 3 g three times a day

Children from 6 to 12 years: ½ tablet, three to four times a day.

Children from 12 to 18 years: 1 - 1½ tablets, three to four times a day; A maximum of 5 g per day.

Tablets of the calcium carbonate should be taken with a meal with a full glass of water.

If you use more Calcium carbonate Alkaloid than you should

If you take more Calcium carbonate Alkaloid than you should, immediately tell your doctor or pharmacist!

If you accidentally take a larger amount of the medicine Calcium carbonate Alkaloid than it should, perhaps you will experience the increase of the level of calcium in the blood.

Symptoms of this phenomenon are: excessive thirst, nausea, vomiting, constipation, abdominal pain, muscle nausea, fatigue, mental disorders, loss of appetite, bone pain, frequent need to urinate more than usually, the problem with the kidneys and in severe cases, irregular heartbeat.

If you forget to take Calcium carbonate Alkaloid

Do not take a double dose to make up for a forgotten dose!

Continue with the implementation of the medicine as usual

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you notice any side effects, please inform your doctor or pharmacist about it.

The side effects of Calcium carbonate Alkaloid may include:

Uncommon side effects (occurring in less than 1 in 100 people):

- Too much calcium in the blood (hypercalcemia) - symptoms include nausea, vomiting, loss of appetite, constipation, abdominal pain, extreme thirst, frequent need to urinate than usual, muscle, nausea, drowsiness and confusion.
- Too much calcium in the urine (hypercalciuria)

Rare side effects (occurring in less than 1 in 1000 people):

- Nausea
- Stomach pain
- Constipation
- Diarrhea
- Intumescence (flatulention)
- Heartburn
- Rash
- Hives
- Itching

Very rare side effects (occurring in less than 1 in 10,000 people):

- Milk-alkali syndrome (usually only occur in case of overdose, characterized by the emergence of hypercalcemia (increased levels of calcium in the blood), alkalosis (rh blood factor passes 7.45) and kidney dysfunction. Patients with renal impairment, dehydration and electrolyte imbalance are especially prone to this syndrome).

If you are taking Calcium carbonate Alkaloid, because you have a renal dysfunction and are on dialysis, inform your doctor if you notice any white deposits on the skin.

If any of the side effects become serious, or if you notice unwanted effects which are not recorded in this leaflet, please tell your doctor or pharmacists.

5. HOW TO STORE CALCIUM CARBONATE ALKALOID

- Keep out of the reach and sight of children.
- Do not use this medicine after the expiry date which is stated on the label.
- Do not store above 25°C. Store in the original carton
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What Calcium carbonate Alkaloid contains

- Active ingredients: calcium carbonate.
- Other ingredients: microcrystalline cellulose; gelatin; silica, colloidal anhydrous; sodium starch glycolate (type A); magnesium stearate; sodium lauryl sulfate.
- Each tablet contains 1 g of calcium carbonate (which corresponds to 400 mg of calcium).

Packing

- Calcium carbonate 1 g Alkaloid tablets are round, flat, white tablets imprinted with the partition line on one side.

The tablets are packaged in glass, brown jar with a polypropylene closure. Each jar contains 50 tablets. Cardboard box contains one jar and instructions.

Manufacturer

Alkaloid AD
Bul. Alexander the Macedonian 12
1000 Skopje, R. Macedonia

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