

PACKAGE LEAFLET
for medical use of a medicinal product

CALCIUM GLUCONATE-DARNITSA

Qualitative and quantitative composition:

active substance: calcium gluconate;

1 tablet contains calcium gluconate 500 mg;

List of excipients: potato starch, anhydrous colloidal silicon dioxide, calcium stearate.

Pharmaceutical form. Tablets.

Main physical and chemical properties: tablets of white or white with a slightly yellowish pink tint in color, flat-cylindrical in shape, with a bevel and a dash.

Pharmacotherapeutic group. Mineral supplements. Calcium.

Calcium gluconate. ATC code A12A A03.

Pharmacological properties.

Pharmacodynamic properties.

Calcium gluconate is a calcium salt of gluconic acid containing 9 % calcium. Calcium ions are involved in the transmission of nerve impulses, contraction of smooth and skeletal muscles, the functioning of the myocardium, blood coagulation processes, they are necessary for the formation of bone tissue, the normal functioning of other systems and organs. The concentration of calcium ions in the blood decreases due to many pathological processes; severe hypocalcemia contributes to tetany. Calcium gluconate, in addition to eliminating hypocalcemia, reduces vascular permeability, has antiallergic, anti-inflammatory, hemostatic effect, and also reduces exudation. Calcium ions are a plastic material for the skeleton and teeth, participate in various enzymatic processes, regulate the speed of nerve impulses and the permeability of cell membranes. Calcium ions are necessary for the process of neuromuscular transmission, to maintain the contractile function of the myocardium. Unlike calcium chloride, calcium gluconate has a mild local irritant effect.

Pharmacokinetic properties.

After oral administration, calcium gluconate is partially absorbed, mainly in the small intestine. The maximum concentration in blood plasma is reached in 1.2-1.3 hours. The half-life of ionized calcium from blood plasma is 6.8-7.2 hours. Penetrates through the placental barrier and into breast milk. It is excreted from the body in urine and feces.

Clinical particulars.

Therapeutic indications.

Diseases accompanied by hypocalcemia, increased permeability of cell membranes, impaired conduction of nerve impulses in muscle tissue.

Hypoparathyroidism (latent tetany, osteoporosis), disorders of vitamin D metabolism (rickets, spasmophilia, osteomalacia), hyperphosphatemia in patients with chronic renal failure.

Increased need for calcium (period of intensive growth of children and adolescents; pregnancy, lactation), insufficient calcium in food, impaired metabolism in the postmenopausal period, bone fracture.

Enhanced excretion of calcium (prolonged bed rest, chronic diarrhea, hypocalcemia with prolonged use of diuretics, antiepileptic medicinal products, glucocorticosteroids).

In complex therapy: bleeding of various etiologies; allergic diseases (serum sickness, urticaria, febrile syndrome, itchy dermatoses, angioedema); bronchial asthma, dystrophic alimentary edema, pulmonary tuberculosis, eclampsia, parenchymal hepatitis, liver toxicity, nephritis.

As an antidote for poisoning with magnesium salts, oxalic acid, soluble salts of fluoric acid (when interacting with calcium gluconate, insoluble and non-toxic calcium oxalate and calcium fluoride are formed).

Contraindications.

Hypersensitivity to the components of the medicinal product, hypercalcemia, severe hypercalciuria, hypercoagulation, a tendency to thrombus formation, severe atherosclerosis, increased blood clotting, nephrourolithiasis (calcium), severe renal failure, sarcoidosis, administration of digitalis medicinal products.

Interaction with other medicinal products and other forms of interaction.

The medicinal product slows down the absorption of estramustine, etidronate and other bisphosphonates, quinolones, tetracycline antibiotics, oral iron preparations and fluoride preparations (the interval between their doses should be at least 3 hours). Calcium gluconate reduces the bioavailability of phenytoin. Concomitant use with vitamin D or its derivatives increases calcium absorption. Cholestyramine reduces the absorption of calcium in the digestive tract. Concomitant use of medicinal product with cardiac glycosides may cause cardiotoxic effects of the last amplify. Concomitant use of medicinal product with thiazide diuretics may cause the risk of hypercalcemia development. Calcium gluconate can reduce the effect of calcitonin in hypercalcemia, the bioavailability of phenytoin, the effect of calcium channel blockers. Concomitant use with quinidine may caused slow intraventricular conduction I increase the toxicity of quinidine. Forms insoluble or slightly soluble calcium salts with carbonates, salicylates, sulfates.

Certain types of foods (spinach, rhubarb, bran, grains) can reduce the absorption of calcium from the gastrointestinal tract.

Special warnings and precautions for use.

When used in patients receiving cardiac glycosides and/or diuretics, as well as with long-term treatment, the concentration of calcium and creatinine in the blood should be monitored. In case of an increase in their concentration, the dose of the medicinal product should be reduced or its use should be temporarily discontinued. Due to the fact that vitamin D₃ increases the absorption of calcium from the digestive tract, in order to avoid an overdose of calcium, the intake of vitamin D₃ and calcium from other sources must be considered.

With caution and with regular monitoring of the level of calcium excretion in the urine, appoint patients with moderate hypercalciuria exceeding 300 mg/day (7.5 mmol/day), not severely impaired renal function, a history of urolithiasis. If necessary, you should reduce the dose of the medicinal product or withdrawal it. Patients with a tendency to form concretion in the urinary tract are advised to increase the amount of fluid consumed during treatment.

When treating with a medicinal product, you should avoid taking high doses of vitamin D or its derivatives, unless there is a specific indication for this.

An interval of at least 3 hours should be observed between taking calcium gluconate tablets and oral preparations of estramustine, etidronate and other bisphosphonates, phenytoin, quinolones, tetracycline antibiotics, oral iron preparations and fluoride preparations.

Fertility, pregnancy and lactation.

The use of the medicinal product is permissible taking into account the ratio of benefit to the woman/risk to the fetus (child), which is determined by the doctor.

When taking calcium supplements during lactation, its penetration into breast milk is possible.

Effects on ability to drive and use machines.

The medicinal product does not affect the reaction rate when driving motor transport or operating other mechanisms.

Posology and method of administration.

The tablet must be chewed or crushed.

Calcium gluconate should be taken orally before meals.

Single doses: adults and children from 14 years old - 1-3 g (2-6 tablets), from 3 to 4 years old - 1 g (2 tablets), from 5 to 6 years old - 1-1.5 g (2-3 tablets), from 7 to 9 years old - 1.5-2 g (3-4 tablets), from 10 to 14 years old - 2-3 g (4-6 tablets). Take 2-3 times a day.

The daily dose for elderly patients should not exceed 2 g (4 tablets).

The duration of treatment is determined by the doctor individually, depending on the patient's condition.

Children.

Medicinal product is used for children starting from 3 years.

Overdose.

With prolonged use in high doses, hypercalcemia with deposition of calcium salts in the body is possible. The likelihood of developing hypercalcemia increases with simultaneous treatment with high doses of vitamin D or its derivatives.

Symptoms of hypercalcemia: drowsiness, weakness, anorexia, abdominal pain, vomiting, nausea, constipation, polydipsia, polyuria, tiredness, irritability, feeling unwell, depression, dehydration, heart rhythm disturbances, myalgia, arthralgia, arterial hypertension.

Treatment: The medicinal product withdrawal; in severe cases - parenteral calcitonin at a dose of 5-10 IU/kg of body weight per day (diluting it in 500 ml of 0.9% sodium chloride solution), intravenously drip for 6 hours. Possible intravenous jet slow administration 2-4 times a day.

Undesirable effects.

The medicinal product is usually well tolerated, but sometimes violations are possible:

Gastrointestinal disorders: nausea, vomiting, constipation, diarrhea, pain in the epigastric region, with prolonged use in high doses - the formation of calcium calculi in the intestine;

Renal and urinary disorders: impaired renal function (frequent urination, swelling of the lower extremities);

Metabolism and nutrition disorders: hypercalcemia, hypercalciuria;

Cardiac disorders: bradycardia;

Immune system disorders: hypersensitivity reactions, including allergic reactions.

These phenomena disappear quickly after dose reduction or medicinal product withdrawal.

Shelf life. 5 years.

Special precautions for storage.

Store in the original package at a temperature not above 25 °C.

Keep out of the reach of children.

Nature and contents of container.

10 tablets in a blister; 3 or 10 blisters in a pack; 10 tablets in blister.

Category of release.

Non-prescription medicine - No. 10, No. 30; Prescription only medicine - No. 100.

Manufacturer. PrJSC "Pharmaceutical firm "Darnitsa".

The manufacturer's location and address of the place of business.

13, Boryspilska Street, Kyiv, 02093, Ukraine.

Date of last revision.

14.07.2017