

**APPROVED**  
**Order of the Ministry of**  
**Health of Ukraine**  
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**VARIATIONS APPLIED**  
**Order of the Ministry of**  
**Health of Ukraine**  
**21.03.2019 № 629**

**PACKAGE LEAFLET**  
**for medical use of a medicinal product**

**CALCIUM CHLORIDE – DARNITSA**

***Qualitative and quantitative composition:***

*active substance* calcium chloride;

1 ml of solution contains calcium chloride hexahydrate 100 mg equivalent to calcium chloride 50.7 mg.

*excipients:* hydrochloric acid dilute, water for injections.

**Pharmaceutical form.** Solution for injection.

*Basic physical and chemical properties:* clear colorless liquid.

**Pharmacotherapeutic group.** Blood substitutes and perfusion solutions. Electrolyte solutions.  
ATC code B05X A07.

***Pharmacological properties.***

*Pharmacodynamic properties.*

Calcium chloride - Darnitsa eliminates the deficiency of calcium ions. Calcium ions also plays a part in the transmission of nerve impulses, contraction of smooth and skeletal muscles, in the functional activity of the myocardium, blood clotting; necessary for the formation of bone tissue, the 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 chloride, in addition to eliminating hypocalcemia, reduces vascular permeability, has a hemostatic effect.

Intravenous administration of calcium leads to excitation of the sympathetic nervous system, which leads to increased secretion of norepinephrine.

*Pharmacokinetics properties.*

In the blood, calcium is in compounds and in an ionized state. Physiological activity is inherent in ionized calcium. Deposited in bone tissue. Eliminated by the kidneys (20 %) and intestines (80 %). 95 % of calcium eliminated by glomerular filtration is reabsorbed.

**Clinical particulars.**

***Therapeutic indications.***

Cases of hypocalcemia requiring a rapid increase in the concentration of calcium ions in blood plasma (tetany in functional insufficiency of the parathyroid gland, tetany in vitamin D deficiency, hypocalcemia in metabolic transfusion and infusion of citrated blood, alkalosis).

As a part of complex therapy at an acute lead colic.

Cases of magnesium intoxication that occur with magnesium overdose.

Hyperkalemia recorded on the ECG as a violation of cardiac function.

***Contraindications.***

Hypersensitivity to the components of the medicinal product, hypercalcemia, severe hypercalciuria, nephrourolithiasis (calcium), severe renal failure, sarcoidosis, hypercoagulation, propensity to thrombosis.

Expressed atherosclerosis with the phenomena of arterial occlusion. Ventricular fibrillation. Asystole and electromechanical dissociations. Administration of foxglove medicinal products.

Concomitant use with ceftriaxone.

***Interaction with other medicinal products and other forms of interaction***

To date, there are no reliable scientific data on the occurrence of intravascular precipitates in patients (except newborns) with the concomitant use of ceftriaxone and calcium-containing medicinal products. However, calcium-containing solvents should not be used, ceftriaxone and calcium-containing medicines should not be mixed or co-administered to all categories of patients. Calcium-containing solutions should not be administered for 48 hours after the last administration of ceftriaxone.

Calcium-containing products may reduce the effectiveness of calcium channel blockers, reduce the effect of calcitonin in hypercalcemia, bioavailability of phenytoin.

Calcium salts reduce the absorption of a number of medicinal products, such as bisphosphonates, fluorides, some fluoroquinolones and tetracyclines; administration of medicinal products should be spread over at least 3 hours.

Calcium chloride reduces the cardiotonic effects of dobutamine.

Concomitant use with quinidine may cause slow intraventricular conduction and increase the toxicity of quinidine.

Concomitant use medicinal product with cardiac glycosides may cause cardiotoxic effects of the last amplify.

Calcium salts should not be mixed with carbonates, phosphates, sulfates or tartrates in parenteral mixtures.

Thiazide diuretics reduce urinary calcium excretion, which increases the risk of hypercalcaemia.

Concomitant use with vitamin D or its derivatives increases calcium absorption.

Concomitant use with other calcium- or magnesium-containing medicinal products increases the risk of hyperkalaemia or hypermagnesaemia, respectively, especially in patients with chronic renal failure.

Reduces the effectiveness of non-depolarizing muscle relaxants. May increase the duration of action of tubocurarine chloride.

***Special warnings and precautions for use.***

With prolonged use in high doses, hypercalcemia with deposition of calcium salts in the body is possible.

The injection should be given through a fine needle into a large vein to minimize the damaging effect of the medicine on the vessel wall. The solution should be warmed to body temperature.

When a medicinal product administered intravenously, the usual reaction to it is a feeling of heat in the mouth and then all over the body.

Calcium chloride-Darnitsa should not be injected under the skin or into the muscles due to its irritating and necrotizing effect. If the medicinal product solution gets under the skin or into the muscle, it is necessary, if possible, to suck the calcium chloride with a syringe, and inject 10 ml of sodium sulfate into the injection site, 25 % solution for injection, or 5–10 ml of magnesium sulfate, solution for injection 25 %. Diphenhydramine is prescribed to eliminate the resorptive effect, and EDTA is prescribed for hypercalcemia.

Use with caution in patients with chronic renal failure of mild and moderate severity, dehydration, electrolyte imbalance (risk of hypercalcemia), heart disease (risk of arrhythmia), kidney disease, nephrolithiasis or diseases accompanied by hypercalcemia (in particular with malignant neoplasms and sarcoidosis), “pulmonary” heart, respiratory acidosis, respiratory failure (risk of toxic reactions due to calcium chloride oxidation). During using of medicinal product is necessary to carry out careful monitoring of level of calcium in blood.

With rapid intravenous administration, a moderate decrease in blood pressure due to vasodilation is possible.

Calcium chloride for injection should not be given to children orally due to severe gastrointestinal irritation.

Children should not be injected through the scalp.

#### *Fertility, pregnancy and lactation.*

Adequate and strictly controlled studies in pregnant women on the safety and efficacy of the medicinal product have not been performed. Medicinal product should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

The medicinal product may be used during breastfeeding.

#### *Effects on ability to drive and use machines*

Driving and working with other mechanisms is contraindicated during treatment with the medicinal products.

#### ***Posology and method of administration.***

Calcium chloride is administered intravenously by stream infusion (very slowly) and intravenously by drop infusion (slowly).

##### *Adults.*

Injection by stream infusion: inject 5 ml of 10 % solution at a rate of 1 ml/min.

Injection by drop infusion: dilute 5–10 ml of a 10 % solution of the medicinal product in 100–200 ml of 0.9 % sodium chloride solution or 5 % glucose solution at a rate of 6–8 drops/min.

Exchange blood transfusion and citrate blood transfusion: adults and children 30 mg (0.3 ml) for every 100 ml of blood.

Tetany: 10 ml of 10 % solution (1 g) for 10–30 minutes, if necessary, repeat after 6 hours.

Hypocalcemia: from 500 mg to 1 g (5–10 ml) with an interval of 1 to 3 days, depending on the patient's response or plasma calcium levels. If necessary, you can enter a repeated dose of the medicinal product.

Magnesium intoxication: Inject 500 mg (5 ml) rapidly. The administration is carried out under medical supervision and monitoring of the patient's condition, before the introduction of subsequent doses.

Hyperkalemia recorded on the ECG as a violation of cardiac function: the dose should be selected individually, depending on the patient's condition, which should be constantly monitored by cardiogram.

Doses for the elderly are the same as for adults.

##### *For children.*

Hypocalcemia: administered slowly, at a rate of up to 0.5 ml/min, at a dose of 10–20 mg/kg body weight (0.1–0.2 ml / kg body weight), if necessary, repeat every 4–6 hours.

Tetany: 10 mg/kg body weight (0.1 ml/kg body weight) for 5 to 10 minutes, repeated after 6 hours if necessary or continued as infusions. The maximum daily dose for children (regardless of age) is 10 ml (1 000 mg).

##### *Children.*

Use for children is possible from the 1st year of life.

#### ***Overdose.***

*Symptoms of hypercalcemia:* weakness, anorexia, abdominal pain, vomiting, nausea, constipation, polydipsia, polyuria, fatigue, irritability, malaise, depression, dehydration, possible cardiac arrhythmias, tachycardia, possible sharp decrease in blood pressure and hypertension, myalgia, arthralgia, coma.

*Treatment:* at insignificant overdose (concentration of calcium in blood serum - 2,6–2,9 mmol/l) treatment should be withdrawn and cancel administration of other calcium-containing medicines. In severe overdose (serum calcium concentration greater than 2.9 mmol/l) parenterally administered

calcitonin at a dose of 5–10 IU/kg body weight per day (diluted in 500 ml of 0.9 % sodium chloride solution), intravenously for 6 hours. Intravenous injection by stream infusion 2–4 times a day is possible. Use thiazide diuretics; carry out control of concentration of potassium and magnesium in serum, if necessary - administrated medicinal products of potassium and magnesium; to control the function of the cardiovascular system, to introduce beta - blockers for the prevention of arrhythmias. If necessary, perform hemodialysis.

***Undesirable effects.***

*Eye disorders:* taste of chalk in the mouth.

Metabolic and nutritional disorders: hypercalcaemia.

*Psychiatric disorders* depression.

*Cardiac disorders:* moderate and short-term decrease in blood pressure, bradycardia, arrhythmia, hypertension, venous thrombosis. With excessively rapid administration - ventricular fibrillation.

*Immune system disorders:* feeling hot, tingling first in the mouth and then all over the body, redness of the skin, allergic reactions, urticaria.

*General disorders and administration site conditions:* pain and redness along the vein. At extravasation it is possible: heartburn, tissue necrosis and scab formation, cellulite and soft tissue calcification.

***Shelf life.*** 5 years.

**Special precautions for storage**

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

Keep out of the reach of children.

***Incompatibilities.***

Pharmaceutically incompatible with tetracyclines, magnesium sulfate, ceftriaxone, drugs containing phosphates, carbonates or tartrates.

Calcium chloride should not be mixed with ceftriaxone in the same injection as a precipitate may form.

**Nature and contents of container.**

5 ml or 10 ml in an ampoule; 5 ampoules in a contour honeycomb package; 2 contour honeycomb packages in a pack.

**Category of release.** Prescription only medicine.

**Manufacturer** PrJSC "Pharmaceutical firm "Darnitsa".

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

13, Boryspilska Street, Kyiv, 02093, Ukraine.

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