Patient information leaflet

Kardiotex

Trade name: Kardiotex

International non-proprietary name: meldonium

Pharmaceutical form: solution for intravenous and parabulbar administration

Composition

One ampoule contains:

active substance: meldonium dihydrate without adsorbed moisture - 500 mg (as anhydrous meldonium - 401.05 mg);

excipient: water for injections - up to 5 ml.

Description: clear colorless liquid

Pharmacotherapeutic group: metabolic agent.

ATC Code: C01EB22

Pharmacological properties

Pharmacodynamic properties

Meldonium is a structural analogue of gamma-butyrobetaine, a substance that is present in every cell of the human body. Meldonium inhibits gamma-butyrobetaine hydroxygenase, reduces the synthesis of carnitine and the transport of long-chain fatty acids through cell membranes, prevents the accumulation in cells of activated forms of unoxidized fatty acids - derivatives of acylcarnicin and acylcoenzyme A. In ischemic conditions, restores the balance of oxygen delivery and consumption in cells, prevents violation transport of adenosine triphosphate (ATP). At the same time, it activates glycolysis, which proceeds without additional oxygen consumption. As a result of a decrease in the concentration of carnitine, gamma-butyrobetaine, which has vasodilating properties, is intensively synthesized.

The mechanism of action determines the variety of its pharmacological effects: increased efficiency, reduced symptoms of mental and physical overstrain, activation of tissue and humoral immunity, cardioprotective effect. In case of acute ischemic myocardial damage, it slows down the formation of a necrosis zone and shortens the rehabilitation period. With heart failure it improves myocardial contractility, increases exercise tolerance, reduces the frequency of angina attacks. In acute and chronic ischemic disorders of cerebral circulation, it improves blood circulation in the focus of ischemia. Effective in case of vascular pathology of the fundus. The medicinal product eliminates functional disorders of the nervous system in patients with chronic alcoholism during withdrawal.

Pharmacokinetic properties
The maximum plasma concentration is reached immediately after administration. It is metabolized in the body with the formation of two main metabolites, which are excreted by the kidneys. The half-life is 3-6 hours.

Therapeutic indications

- as part of the complex therapy of coronary heart disease (angina pectoris, myocardial infarction), chronic heart failure, dyshormonal cardiomyopathy;
- as part of complex therapy for acute cerebrovascular disorders (ischemic stroke, cerebrovascular insufficiency);
- decreased performance, physical overload (including athletes);
- withdrawal syndrome in chronic alcoholism (in combination with specific therapy);
- hemophthalmos and retinal hemorrhages of various etiologies, thrombosis of the central retinal vein and its branches, retinopathy of various etiologies (diabetic, hypertensive).

Contraindications

- hypersensitivity to the components of the medicinal product;
- increased intracranial pressure (in violation of venous outflow and intracranial tumors);
- age up to 18 years of age (efficacy and safety have not been established)

With caution: hepatic and/or renal impairment

Pregnancy and lactation
The safety of the medicinal product during pregnancy has not been established. In order to avoid possible adverse effects on the fetus, the medicinal product should not be prescribed during pregnancy.
It is not known whether the medicinal product is excreted in breast milk. If necessary, the use of Kardiotex during lactation, breastfeeding should be discontinued.

Posology and method of administration
Taking into account the possibility of developing an exciting effect, the medicinal product is recommended to be used in the morning.
Cardiovascular diseases
As part of complex therapy - 500 mg intravenously - 1.0 g (5-10 ml of a solution for intravenous and parabulbar administration of 100 mg/ml), using the entire dose at once or dividing it into 2 injections. The duration of treatment is 10-14 days.
The course of treatment can be repeated (usually 2-3 times a year) - on the recommendation of a doctor.
Cerebral circulation disorders
In the acute phase of cerebrovascular accident, 500 mg (5 ml of a solution for intravenous and parabulbar administration 100 mg/ml) are administered intravenously once daily for 10 days.
Decreased performance, physical overload (including athletes)
In mental and physical exertion (including athletes), 500 mg intravenously (5 ml of a solution for intravenous and parabulbar administration of 100 mg/ml) once daily. The duration of treatment is 10-14 days.
Withdrawal syndrome in chronic alcoholism (in combination with specific therapy)

In withdrawal syndrome, 500 mg (5 ml of a solution for intravenous and parabulbar administration 100 mg/ml) are used intravenously twice daily. The duration of treatment is 10-14 days.
Ophthalmopathology (hemophthalmos and retinal hemorrhages of various etiologies, thrombosis of the central retinal vein and its branches, retinopathy of various etiologies (diabetic, hypertensive).
50 mg of the medicinal product is administered parabulbarly (0.5 ml of a solution for intravenous and parabulbar administration of 100 mg/ml) for 10 days, including as part of combination therapy.

Undesirable effects
Cardiovascular disorders: rare - tachycardia, blood pressure increased/decreased.
Nervous system disorders: rare - psychomotor agitation.
Gastrointestinal disorders: rare - dyspeptic disorders.
Allergic reactions: rare - pruritus, rash, hyperemia of the skin, angioedema; very rare - eosinophilia.
Others: very rare – fatigue.

Overdose
Symptoms: blood pressure decreased, accompanied by headache, tachycardia, dizziness and fatigue.
Treatment: symptomatic.

Interaction with other medicinal products
May be used concurrently with antianginal agents, anticoagulants, antiplatelet agents, antiarrhythmic agents, diuretics, bronchodilators.
May intensify the action of cardiac glycosides.
In view of the possible development of moderate tachycardia and arterial hypotension, this medicinal product should be used with caution when combined with nitroglycerin, nifedipine, alpha-blockers, antihypertensive agents and peripheral vasodilators.

Special warnings
Kardiotex is not a first-line medicine for acute coronary syndrome.

Effects on ability to drive and use machines
Data on the adverse effects of the drug Kardiotex on the speed of psychomotor reactions are not available.

Pharmaceutical form and presentation
Solution for intravenous and parabulbar administration 100 mg/ml.
5 ml in colorless glass ampoules.
5 ampoules in a blister pack. 1 or 2 blister packs together with patient information leaflet in a carton.

Storage conditions
Store below 25 °C. Do not freeze.
Keep out of the reach of children.

Shelf life
5 years.
Do not use after the expiry date stated on the package.

Prescription status
On prescription.