Patient information leaflet

Neyrotex

Trade name: Neyrotex

International non-proprietary name: ethylmethylhydroxypyridine succinate

Pharmaceutical form: solution for intravenous and intramuscular injection

Composition for one ampoule	*2 ml*	*5 ml*
Active substance:		
ethylmethylhydroxypyridine succinate	100 mg	250 mg

Excipients: sodium metabisulphite, water for injections.

Description: colorless or yellowish transparent liquid.

Pharmacotherapeutic group: antioxidant agents

ATC code: absent

Pharmacological properties

Pharmacodynamic properties

Mechanism of action, pharmacodynamic effects

It has antihypoxic, membrane-protective, nootropic, anticonvulsant, anxiolytic effects, increases the body's resistance to stress. The medicinal product increases the body's resistance to the effects of major damaging factors, to oxygen-dependent pathological conditions (shock, hypoxia and ischemia, cerebrovascular accident, intoxication with alcohol and antipsychotic medicinal products (neuroleptics)).

Neyrotex improves cerebral metabolism and blood supply to the brain, improves microcirculation and rheological properties of blood, reduces platelet aggregation.

It stabilizes membrane structures of blood cells (erythrocytes and platelets) with hemolysis. It has a hypolipidemic effect, reduces the level of total cholesterol and low-density lipoproteins (LDL).

Reduces enzymatic toxemia and endogenous intoxication in acute pancreatitis.

The mechanism of action of Neyrotex is due to its antihypoxant, antioxidant and membrane-protective action. It inhibits the processes of lipid peroxidation, increases the activity of superoxide dismutase, increases the lipid-protein ratio, reduces the viscosity of the membrane, increases its fluidity. Modulates the activity of membrane-bound enzymes (calcium-independent phosphodiesterase, adenylate cyclase, acetylcholinesterase), receptor complexes (benzodiazepine, gamma-aminobutyric acid (GABA), acetylcholine), which enhances their ability to

bind to ligands, helps to preserve the structural and functional organization of biomembranes, transport neurotransmitters and improve synaptic transmission.
Neyrotex increases the content of dopamine in the brain. It causes an increase in the compensatory activity of aerobic glycolysis and a decrease in the degree of inhibition of oxidative processes in the Krebs cycle under hypoxic conditions with an increase in the content of adenosine triphosphate (ATP), creatine phosphate and activation of the energy-synthesizing functions of mitochondria, stabilization of cell membranes. Neyrotex normalizes metabolic processes in the ischemic myocardium, reduces the necrosis zone, restores and improves the electrical activity and contractility of the myocardium, and also increases coronary blood flow in the ischemic zone, reduces the consequences of reperfusion syndrome in acute coronary insufficiency. Increases antianginal activity of nitropreparations. Neyrotex contributes to the preservation of retinal ganglion cells and optic nerve fibers in progressive neuropathy, the causes of which are chronic ischemia and hypoxia. Improves the functional activity of the retina and optic nerve, increasing visual acuity.

Pharmacokinetic properties

Distribution

When administered intramuscularly, it is determined in plasma for 4 hours after administration. The time to maximum concentration (T_{max}) is 0.45-0.5 hours. The maximum concentration (C_{max}) with a dose of 400-500 mg is 3.5-4.0 μg/ml. Neyrotex quickly passes from the bloodstream to organs and tissues and is quickly eliminated from the body. The retention time (MRT) is 0.7-1.3 hours.

Biotransformation, elimination

The medicinal product is excreted mainly in the urine, mainly in the glucuron-conjugated form and in small amounts unchanged.

Therapeutic indications

Neyrotex is indicated for use in adults:

- acute disorders of cerebral circulation (as part of complex therapy);
- traumatic brain injury, consequences of traumatic brain injury;
- encephalopathy;
- syndrome of vegetative (neurocirculatory) dystonia;
- mild cognitive disorders of atherosclerotic genesis;
- anxiety disorders in neurotic and neurosis-like states;
- acute myocardial infarction (from the first day) as part of complex therapy;
- primary open-angle glaucoma of various stages, as part of complex therapy;

- relief of withdrawal symptoms in alcoholism with a predominance of neurosis-like and vegetative-vascular disorders;
- acute intoxication with antipsychotic drugs;
- acute purulent-inflammatory processes of the abdominal cavity (acute necrotizing pancreatitis, peritonitis) as part of complex therapy.

Contraindications

- hypersensitivity to ethylmethylhydroxypyridine succinate or to any of the excipients;
- acute renal impairment;
- acute hepatic impairment;
- pregnancy, breastfeeding (due to insufficient study of the action of the medicinal product);
- children's age (due to insufficient knowledge of the action of the medicinal product).

With caution
In some cases, especially in predisposed patients with bronchial asthma with increased sensitivity to sulfites, severe hypersensitivity reactions and bronchospasm may develop.
This medicinal product contains less than 1 mmol (23 mg) sodium per 2 ml, which means it is essentially sodium-free.
This medicinal product contains less than 1 mmol (23 mg) sodium per 5 ml, which means it is essentially sodium-free.

Pregnancy and lactation
The use of Neyrotex during pregnancy and breastfeeding is contraindicated.

Posology and method of administration
Intramuscularly (i.m.) or intravenously (i.v.) (bolus or drop infusion). With the infusion method of administration, the medicinal product should be diluted in a 0.9% sodium chloride.
Neyrotex is injected by slow bolus over 5-7 minutes, drop infusion - dripping speed 40-60 drops per minute. The maximum daily dose should not exceed 1200 mg.
In acute cerebrovascular disorder, Neyrotex is used in complex therapy in the first 10-14 days - intravenously, 200-500 mg 2-4 times daily, then 200-250 mg 2-3 times daily, intramuscularly within 2 weeks.
In traumatic brain injury and the consequences of traumatic brain injury, Neyrotex is used for 10-15 days i.v. by drop infusion 200-500 mg 2-4 times daily.
In dyscirculatory encephalopathy in the decompensation phase, Neyrotex should be administered intravenously by bolus or drop infusion at a dose of 200-500 mg 1-2 times daily for 14 days following i.m. 100-250 mg/day injection for the next 2 weeks.
For prevention of dyscirculatory encephalopathy, Neyrotex is administered intramuscularly at a dose of 200-250 mg 2 times daily for 10-14 days.
In neurocirculatory dystonia, neurotic and neurosis-like conditions, the medicinal product is administered intramuscularly at 50-400 mg daily for 14 days.
For mild cognitive impairment in elderly patients and for anxiety disorders, the medicinal product is used intramuscularly at a dose of 100-300 mg daily for 14-30 days.
In acute myocardial infarction, as part of complex therapy, Neyrotex is administered intravenously or intramuscularly for 14 days, against the background of traditional therapy for myocardial infarction (including nitrates, beta-blockers, angiotensin-converting enzyme (ACE) inhibitors, thrombolytics, anticoagulant and antiplatelet drugs, as well as symptomatic agents according to indications).
To achieve the maximum effect in the first 5 days, Neyrotex is administered intravenously, in the next 9 days the medicinal product can be administered intramuscularly.
Intravenous administration of the medicinal product is carried out by drop infusion, slowly (to avoid side effects) for 30-90 minutes (in 100-150 ml of 0.9% sodium

chloride or 5% dextrose (glucose)), if necessary, a slow bolus i.v. administration at least 5 minutes is possible.
Administration (i.v. or i.m.) is carried out 3 times daily, every 8 hours. The daily dose is 6-9 mg/kg of body weight, a single dose is 2-3 mg/kg of body weight. The maximum daily dose should not exceed 800 mg, single - 250 mg.
In open-angle glaucoma of various stages, as part of complex therapy, Neyrotex is administered intramuscularly at 100-300 mg/day, 1-3 times daily for 14 days.
In alcohol withdrawal syndrome, Neyrotex is administered intramuscularly or intravenously at a dose of 200-500 mg 2-3 times daily for 5-7 days.

In acute intoxication with antipsychotic medicinal products, the product is administered intravenously at a dose of 200-500 mg/day for 7-14 days.
In acute purulent-inflammatory processes of the abdominal cavity (acute necrotizing pancreatitis, peritonitis), Neyrotex is prescribed on the first day, both in the preoperative and postoperative periods. The administered doses depend on the form and severity of the disease, the prevalence of the process, and the variants of the clinical course. Cancellation of the drug should be made gradually only after a stable positive clinical and laboratory effect.
In acute edematous (interstitial) pancreatitis, Neyrotex is prescribed 200-500 mg 3 times daily, intravenously (in 0.9% sodium chloride) and intramuscularly. *Mild necrotizing pancreatitis* - 100-200 mg 3 times daily by drop infusion (in 0.9% sodium chloride) and i.m. *Moderate* - 200 mg 3 times daily, intravenously (in 0.9% sodium chloride). *Severe* - 800 mg on the first day, with a double regimen of administration; further 200-500 mg 2 times daily with a gradual decrease in the daily dose. *Extremely severe* - initial dose of 800 mg/day until persistent relief of manifestations of pancreatogenic shock, after stabilization of the condition, 300-500 mg 2 times daily by i.v. drop infusion (in 0.9% sodium chloride) with a gradual decrease in daily dosage.

Undesirable effects
Safety profile summary
In order to avoid the occurrence of side effects, it is recommended to observe the dosing regimen and the rate of administration of the medicinal product.
Summary of adverse reactions
Frequencies are defined in accordance with the classification of the World Health Organization as follows: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1000 to < 1/100); rare (≥ 1/10,000 to <1/1,000); and very rare (< 1/10,000) or not known (cannot be estimated from available data).
Immune system disorders: very rare - anaphylactic shock, angioedema, urticaria.
Mental disorders: very rare - drowsiness.
Nervous system disorders: very rare - headache, dizziness (may be associated with an excessively high rate of administration and is of a short duration).
Vascular disorders: very rare - decrease in blood pressure (BP), increase in blood pressure (may be associated with an excessively high rate of administration and is of a short-term nature).
Respiratory, thoracic and mediastinum-related disorders: very rare - dry cough, sore throat, chest discomfort, shortness of breath (may be associated with an excessively high rate of administration and is short-term).
Gastrointestinal disorders: very rare - dry mouth, nausea, unpleasant odor, metallic taste in the mouth.
Skin and subcutaneous tissue disorders: very rare - itching, rash, hyperemia.
General disorders and administration site conditions: very rare – warm feeling.

Overdose
Symptoms

Drowsiness, insomnia.
Treatment
Due to low toxicity, overdose is unlikely. Treatment, as a rule, is not required, the symptoms disappear within a day. With severe manifestations, supportive symptomatic treatment is carried out.

Interaction with other medicinal products
Enhances the effects of benzodiazepine anxiolytics, anticonvulsants (carbamazepine) and antiparkinsonian agents (levodopa). Reduces the toxic effects of ethyl alcohol.

Effects on ability to drive and use machines
During the use of this medicine, care should be taken when working, requiring the speed of psychophysical reactions (driving vehicles, mechanisms, etc.).

Pharmaceutical form and presentation
Solution for intravenous and intramuscular injection 50 mg/ml.
2 ml in ampoules of light-protective glass with a colored break ring or with a colored dot and a notch. One, two or three colored rings and/or two-dimensional barcode and/or alphanumeric coding or without additional color rings, two-dimensional barcode, alphanumeric coding are additionally applied to the ampoules.
5 ampoules in a blister pack made of PVC film and polymer film or without film.
2 or 10 blister packs together with patient information leaflet in a carton.
5 ml in ampoules of light-protective glass with a colored break ring or with a colored dot and a notch. One, two or three colored rings and/or two-dimensional barcode and/or alphanumeric coding or without additional color rings, two-dimensional barcode, alphanumeric coding are additionally applied to the ampoules.
5 ampoules in a blister pack made of PVC film and polymer film or without film.
1 blister pack together with patient information leaflet in a carton.

Shelf life
5 years.
Do not use after the expiration date.

Storage conditions
Store in a place protected from light at a temperature below 25 ° C.
Keep out of the reach of children.

Prescription status
On prescription.