

INSTRUCTIONS (translated from Russian by Extrapharmacy.ru)

for medical use of the drug **Cerebrolysin®**

Registration number: P N013827 / 01-080707

Dosage Form: injection

COMPOSITION

Active ingredient: 1 ml of an aqueous solution containing 215.2 mg of concentrated Cerebrolysin (complex of peptides derived from porcine brain). The active fraction of Cerebrolysin is presented by peptides, the molecular weight does not exceed 10,000 daltons.

Excipients : sodium hydroxide and water for injection.

DESCRIPTION

The clear solution of amber color.

Pharmacotherapeutic group: nootropics

ATX code: N06BX

PHARMACHOLOGIC EFFECT

Cerebrolysin contains low molecular weight biologically active neuropeptides, which penetrate the blood-brain barrier and enter directly to the nerve cells. The drug has multimodal organ-specific action on the brain, i.e. It provides metabolic regulation, neuroprotection, functional neuromodulation and neurotrophic activity.

a) metabolic regulation: Cerebrolysin improves the efficiency of aerobic energy metabolism of the brain, improves intracellular protein synthesis in the developing and aging brain.

b) neuroprotection: Cerebrolysin protects neurons from damaging effects of lactic acidosis, prevents the formation of free radicals, improves survival and prevents death of neurones in conditions of hypoxia and ischemia, reduces the damaging neurotoxic effects of excitatory amino acids (glutamate).

c) the neurotrophic activity: Cerebrolysin is the only peptidergic nootropic drug with proven neurotrophic activity similar to the action of natural factors of neuronal growth (NGF), but manifests itself in a peripheral administration.

g) functional neuromodulation: Cerebrolysin has a positive effect in disorders of cognitive functions, the processes in the memory

INDICATIONS

Alzheimer's disease, dementia syndrome of different genesis, chronic cerebrovascular insufficiency, ischemic stroke, traumatic injuries of the brain and spinal cord; mental retardation in children, hyperactivity and attention deficit disorder in children; in complex therapy - with endogenous depression, resistant to antidepressants

CONTRAINDICATIONS

idiosyncrasy of the drug

acute renal failure

status epilepticus

PREGNANCY AND LACTATION

The drug is carefully prescribed in the I trimester of pregnancy and lactation.

During pregnancy and during breastfeeding Cerebrolysin should be used only after a thorough analysis of the ratio of the positive effect of the treatment and the risks associated with its implementation. The experimental results do not suggest that Cerebrolysin has any teratogenic or has a toxic effect on the fetus. However, similar clinical studies have not been conducted.

DOSAGE AND ADMINISTRATION

It is used parenterally. Dose and duration of treatment depends on the nature and severity of the disease and the patient's age. Possible to assign single doses, which may reach the magnitude of 50 ml, but more preferably, a course of treatment.

The recommended optimal course of treatment is daily injections for 10-20 days :

- Acute conditions (ischemic stroke, traumatic brain injury, complications of brain surgery), from 10 ml to 50 ml
- The residual period of stroke and traumatic injury of the brain and spinal cord from 5 ml to 50 ml
- When psychoorganic syndrome and depression from 5 ml to 30 ml
- In Alzheimer's disease, vascular dementia and Alzheimer's combined-vascular genesis: from 5 ml to 30 ml
- In the neuro-pediatric patients: 0.1-0.2 ml / 1kg body weight

To improve the efficiency of treatment - repeated courses may be applied as long as there is improvement in the patient following treatment. After the first course - dose frequency assignment may be reduced to 2 or 3 times a week.

Cerebrolysin is used in the form of injections: intramuscularly (5 mL), and intravenously (10 mL). Doses between 10 ml up to 50 ml should enter only by slow intravenous infusion after dilution by standard solutions for infusion. The duration of infusion was 15 to 60 minutes.

SIDE EFFECT

When excessively rapid introduction in rare cases a feeling of heat, sweating, dizziness, and (in rare cases) may palpitations or arrhythmia.

From the gastrointestinal tract: rarely observed loss of appetite, indigestion, diarrhea, constipation, nausea and vomiting.

From the central and peripheral nervous system: in rare cases, the alleged effect of activation was accompanied by of the excitation (exhibit aggressive behavior, confusion, insomnia). There are reports of occurrence in rare cases (<0.01%) of large seizures and seizures during treatment with Cerebrolysin.

Immune system: very rarely observed hypersensitivity reactions or allergic reactions, manifesting a headache; by pain in the neck, legs, lower back; shortness of breath, chills and collaptoid state.

Local reactions: In rare cases, there is skin redness, itching and burning at the injection site.

Other: according to the results of studies reported very rarely hyperventilation, hypertension, hypotension, fatigue, tremor, depression, apathy, dizziness and flu-like symptoms (cough, runny nose, respiratory tract infections).

It should be noted that some of the undesirable effects (agitation, hypertension, hypotension, lethargy, tremor, depression, apathy, dizziness, headache, shortness of breath, diarrhea, nausea) were identified during clinical trials and occurred equally in Cerebrolysin treated patients and placebo patients.

OVERDOSE

Not found

INTERACTION WITH OTHER DRUGS

Given the pharmacological profile of Cerebrolysin should pay special attention to possible additive effects when coadministered with antidepressants or MAO inhibitors. In such cases it is recommended to reduce the dose of antidepressant.

Do not mix in the same solution for infusion Cerebrolysin and balanced amino acid solutions.

Cerebrolysin is incompatible with solutions which contain lipids and with solutions which change the pH (5.0-8.0).

SPECIAL INSTRUCTIONS

If the injection too fast perhaps feeling the heat, sweating and dizziness. Therefore, the drug should be administered slowly.

Tested and confirmed the compatibility of the drug (for 24 hours at room temperature and the presence of light) with the following standard solutions for infusion:

0.9% sodium chloride (9 mg NaCl / ml).

Ringer's solution (Na + - 153,98 mmol / l Ca2 + - 2.74 mmol / L, K + - 4.02 mmol / L; Cl -163.48 mmol / l).

5% glucose solution

Cerebrolysin is allowed for simultaneous appointment with vitamins and drugs that improve heart circulation, however, these drugs should not be mixed in the same syringe with Cerebrolysin. Use only clear solution, and only once.

EFFECTS ON ABILITY TO DRIVE VEHICLES

Clinical trials have shown that Cerebrolysin has no influence on the ability to drive vehicles and use machinery.

STORAGE CONDITIONS

Store in a dark place at room temperature (not higher than 25 ° C),

Carefully protected from children.

Note: After the ampoule / vial has been opened the solution should be used immediately.

SHELF LIFE

Shelf life of ampoules - 5 years.

bottles Shelf life - 4 years.

Do not use beyond the expiration date printed on the package.

MANUFACTURER

Ever Neuro Pharma GmbH, A-4866 Unterach, Austria, European Union

RELIABLE SUPPLIER

Extrapharmacy Online Store [<http://extrapharmacy.ru>]

