Cerebrolysin®

Registration number:
P N013827/01-080707 (П N013827/01-080707)

Trade name:
Cerebrolysin®

International nonproprietary name (INN):
None

Dosage form:
Solution for injection

Composition:
Active ingredient: 1 ml of aqueous solution contains 215.2 mg of Cerebrolysin concentrate (a peptide complex derived from porcine brain).

The active fraction of Cerebrolysin consists of peptides with molecular weight not exceeding 10,000 daltons.

Excipients: sodium hydroxide and water for injection.

Description:
Clear amber-colored solution.

Pharmacotherapeutic group:
Nootropic agent

ATC code:
N06BX

Pharmacological action:

Pharmacodynamics:
Cerebrolysin contains low-molecular biologically active neuropeptides that cross the blood-brain barrier and directly reach nerve cells.

The drug has organ-specific multimodal action on the brain, i.e., provides metabolic regulation, neuroprotection, functional neuromodulation and neurotrophic activity.

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

b) neuroprotection: Cerebrolysin protects neurons from the damaging effects of lactacidosis, prevents free radical formation, increases survival and prevents neuronal death under hypoxic and ischemic conditions, reduces the damaging neurotoxic effect of excitatory amino acids (glutamate).

c) neurotrophic activity: Cerebrolysin is the only nootropic peptidergic drug with proven neurotrophic activity similar to natural neuronal growth factors (NGF), but manifesting under peripheral administration conditions.

d) functional neuromodulation: Cerebrolysin has a positive effect on cognitive function disorders and memory processes

Pharmacokinetics:
The complex composition of Cerebrolysin, whose active fraction consists of a balanced and stable mixture of biologically active oligopeptides with total polyfunctional action, does not allow for conventional pharmacokinetic analysis of individual components.

Indications:
- alzheimer’s disease
- dementia syndrome of various origins
- chronic cerebrovascular insufficiency,

- ischemic stroke
- traumatic brain and spinal cord injuries
- mental development delay in children
- hyperactivity and attention deficit in children
- in complex therapy – for endogenous depression resistant to antidepressants

Contraindications:

- individual intolerance to the drug
- acute renal failure
- status epilepticus

Pregnancy and lactation:

The drug should be used with caution during the first trimester of pregnancy and during lactation.

During pregnancy and breastfeeding, Cerebrolysin should be used only after careful analysis of the risk-benefit ratio of the treatment.

Results of experimental studies do not suggest that Cerebrolysin has any teratogenic effects or toxic effects on the fetus. However, similar clinical studies have not been conducted.

Dosage and administration:

Administered parenterally. Doses and duration of treatment depend on the nature and severity of the disease, as well as the patient's age.

Single doses up to 50 ml may be prescribed, however, a course of treatment is preferred.

The recommended optimal course of treatment consists of daily injections for 10-20 days.

Condition	Dosage
Acute conditions (ischemic stroke, traumatic brain injury, complications of neurosurgical operations)	10 ml to 50 ml
Residual period of cerebral stroke and traumatic injuries of the brain and spinal cord	5 ml to 50 ml
Psychoorganic syndrome and depression	5 ml to 30 ml
Alzheimer's disease, vascular dementia, and mixed Alzheimer-vascular dementia	5 ml to 30 ml
Neuropediatric practice	0.1–0.2 ml/kg of body weight

To increase treatment effectiveness, repeated courses may be conducted as long as improvement in the patient's condition is observed as a result of treatment.

After the first course, the frequency of dose administration may be reduced to 2 or 3 times per week.

Cerebrolysin is administered as injections: intramuscularly (up to 5 ml) and intravenously (up to 10 ml).

Doses from 10 ml to 50 ml should only be administered through slow intravenous infusions after dilution with proposed standard infusion solutions.

Duration of infusions ranges from 15 to 60 minutes.

Side effects:

Common side effects — more than 1/100 — less than 1/10; rare side effects — more than 1/1000 — less than 1/100; very rare side effects — more than 1/10000 — less than 1/1000; extremely rare side effects — less than 1/10000.

With excessively rapid administration, in rare cases, sensations of heat, sweating, dizziness and (in isolated cases) possible increased heart rate or arrhythmias may occur.

Gastrointestinal effects: in rare cases, loss of appetite, dyspepsia, diarrhea, constipation, nausea and vomiting were observed.

CNS and peripheral nervous system effects: in rare cases, the presumed activation effect was accompanied by agitation (manifesting as aggressive behavior, confusion, insomnia).

Immune system effects: in extremely rare cases, hypersensitivity reactions or allergic reactions were noted, manifesting as headache; pain in the neck, extremities, lower back; shortness of breath, chills, and collaptoid state.

Local reactions: in rare cases, skin redness, itching, and burning at the injection site are noted.

Others: studies reported extremely rare cases of hyperventilation, arterial hypertension, arterial hypotension, fatigue, tremor, depression, apathy, dizziness, and flu-like symptoms (cough, rhinitis, respiratory tract infections).

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

Overdose:

Not identified

Drug interactions:

Given the pharmacological profile of Cerebrolysin, special attention should be paid to possible additive effects when co-administered with antidepressants or MAO inhibitors. In such cases, it is recommended to reduce the dose of the antidepressant.

Cerebrolysin and balanced amino acid solutions should not be mixed in the same infusion solution.

Cerebrolysin is incompatible with solutions containing lipids and with solutions that alter the pH (5.0-8.0).

Special instructions:

Rapid injection may cause sensations of heat, sweating, dizziness. Therefore, the drug should be administered slowly.

The drug’s compatibility has been tested and confirmed (for 24 hours at room temperature and in the presence of light) with the following standard infusion solutions:

- 0.9% sodium chloride solution (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

Concurrent administration of Cerebrolysin with vitamins and drugs improving cardiac circulation is permitted, however, these drugs should not be mixed in the same syringe with Cerebrolysin.

Use only clear solution and only once.

Effect on ability to drive:
Clinical trials have shown that Cerebrolysin does not affect the ability to drive vehicles and operate machinery.

Presentation:
Solution for injection 1 ml ampoules

1 ml in brown glass ampoules. 10 ampoules are placed in a PVC blister pack covered with waxed paper. One blister pack with package insert is placed in a cardboard box.

“In bulk” packaging

10 ampoules (1 ml) are placed in a PVC blister covered with waxed paper. 50 or 225 blisters with package insert are placed in a cardboard box.

Solution for injection 5 ml and 10 ml ampoules

5 ml, 10 ml in brown glass ampoules. 5 ampoules are placed in a PVC blister pack covered with waxed paper. One blister pack with package insert is placed in a cardboard box.

30 мл Solution for injection 30 ml vials

30 ml in a brown glass vial, sealed with a rubber stopper under an aluminum safety crimp cap with a needle hole in the center and closed with a protective plastic cap. 1 or 5 vials with package insert are placed in a cardboard box.

Storage conditions:
in a light-protected place at temperature not exceeding 25°C.

Keep out of reach of children.

Note: after opening the ampoule/vial, the solution must be used immediately.

Shelf life:
Shelf life of ampoules – 5 years.

Shelf life of vials – 4 years.

Do not use after the expiry date stated on the package.

Dispensing conditions:
Prescription only

Manufacturer:
Neuro Pharma GmbH A-4866 Unterach, Austria, Europe

These instructions translated from official manufacturer instructions in Russian by Extrapharma online pharmacy