MINISTRY OF HEALTH AND HEALTH OF THE RUSSIAN FEDERATION

INSTRUCTION

FOR MEDICAL USE OF MEDICINAL PREPARATIONS

Cerebrin

Registration number:

Trade name: Cerebrin

International unpatented or group name: absent

Pharmaceutical form: solution for injection

Ingredients for 1 ml:

Active substance: a complex of peptides obtained from the brain of a pig 215.2 mg;

Auxiliary substances: sodium hydroxide 2.1 mg, water for injection

1 ml.

Description: Transparent solution from yellowish to yellowish-brown color.

Pharmacotherapeutic group: nootropic agent.

Code ATX: N06BX

Pharmacological properties

Pharmacodynamics

The drug Cerebrin contains low-molecular biologically active neuropeptides that penetrate the blood-brain barrier and directly reach nerve cells. The drug has an organospecific multimodal effect on the brain, i.e. provides metabolic regulation, neuroprotection, functional neuromodulation and neurotrophic activity.

Metabolic regulation: the drug Cerebrin increases the efficiency of aerobic energy metabolism of the brain, improves intracellular protein synthesis in the developing and aging brain.

Neuroprotection: Cerebrin protects neurons from the damaging effects of lactic acidosis, prevents the formation of free radicals, increases survival and prevents neuronal death under conditions of hypoxia and ischemia, reduces the damaging neurotoxic effect of excitatory amino acids (glutamate).

Neurotrophic Activity: Cerebrin is a nootropic peptidergic drug with proven

neurotrophic activity similar to that of natural neuronal growth factors (NGF), but manifested under conditions of peripheral administration.

Functional neuromodulation: Cerebrin has a positive effect on cognitive impairment and memory processes.

Pharmacokinetics

The complex composition of the drug Cerebrin, the active fraction of which consists of a balanced and stable mixture of biologically active oligopeptides with a total polyfunctional effect, does not allow for the usual pharmacokinetic analysis of individual components.

Indications for use

Alzheimer's disease, dementia syndrome of various origins; chronic cerebrovascular insufficiency; ischemic stroke; traumatic injuries of the brain and spinal cord; mental retardation in children; hyperactivity and attention deficit in children; in complex therapy for endogenous depression resistant to antidepressants.

Contraindications

- hypersensitivity to the active or any of the excipients that make up the drug;
- severe renal failure;
- status epilepticus.

Carefully

With caution, the drug is used for allergic diathesis; epileptic diseases, including generalized epilepsy, due to a possible increase in the frequency of seizures; during pregnancy and during breastfeeding.

Use during pregnancy and during breastfeeding

Pregnancy

During pregnancy, Cerebrin should only be used after careful consideration of the benefit-to-risk ratio of treatment. The results of experimental studies do not suggest that it has any teratogenic effect or has a toxic effect on the fetus. However, similar clinical studies have not been conducted.

Breastfeeding period

During breastfeeding, Cerebrin should be used with caution, only after a careful

analysis of the ratio of the positive effect of treatment and the risk associated with its implementation.

Dosage and administration

It is applied parenterally. Doses and duration of treatment depend on the nature and severity of the disease, as well as on the age of the patient. It is possible to prescribe single doses, the value of which can reach 50 ml, but it is more preferable to conduct 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 neurosurgical operations):	from 10 ml to 50 ml
In the residual period of cerebral stroke and traumatic injury to the brain and spinal cord:	from 5 ml to 50 ml
With psychoorganic syndrome and depression	5 to 30 ml
In Alzheimer's disease, dementia of vascular and combined Alzheimer's-vascular genesis:	5 to 30 ml
In neuropediatric practice:	0.1 - 0.2 mg/kg body weight

To increase the effectiveness of treatment, repeated courses can be carried out as long as there is an improvement in the patient's condition due to treatment. After the first course, the frequency of administration of the drug can be reduced to 2 or 3 times a week.

The drug Cerebrin is used as an injection: intramuscularly (up to 5 ml) and intravenously (up to 10 ml). Doses from 10 ml to 50 ml are recommended to be administered only by slow intravenous infusions after dilution with the proposed standard solutions for infusion. The duration of the infusion is from 15 to 60 minutes.

Side effect

The frequency of adverse reactions was determined in accordance with the recommendations of the World Health Organization:

Very common: (≥1/10)

Common: (≥1/100 to <l/10)

Uncommon: (≥1/1000 to <1/100)

Rare: (≥1/10,000 to <1/1,000)

Very rare, including isolated reports: <1/10,000)

Classification of lesions of systems and organs	Frequency	Side effect
Immune System Disorders	Very rarely	Hypersensitivity reactions, allergic reactions (headache, pain in the neck, limbs, lower back; shortness of breath, chills, collaptoid state)
Mental disorders	Rarely	Arousal manifested by aggressive behavior, confusion, insomnia
Nervous System Disorders	Rarely	Dizziness (if the drug is administered too quickly)
	Very rarely	Grand mal seizures and convulsions (isolated cases)
Heart disorders	Very rarely	Increased heart rate, arrhythmia (with too rapid administration of the drug)
Gastrointestinal disorders	Very rarely	Loss of appetite, dyspepsia, diarrhea, constipation, nausea, vomiting
Skin and subcutaneous tissue disorders	Rarely	Feeling of heat, increased sweating (if the drug is administered too quickly)
General disorders and disorders at the injection site	Very rarely	Skin hyperemia, itching, burning at the injection site

Extremely rare cases of hyperventilation, arterial hypertension, arterial hypotension, fatigue, tremor, depression, apathy, flu-like symptoms (cough, runny nose, respiratory infections) have been reported.

It should be noted that some adverse reactions (excitation, arterial hypertension, arterial hypotension, lethargy, tremor, depression, apathy, dizziness, headache, shortness of breath, diarrhea, nausea) were identified during clinical studies and occurred equally as in patients treated with the drug, and in patients of the placebo group.

If any of the side effects indicated in the instructions are aggravated, or you notice any other side effects not listed in the instructions, tell your doctor about it.

Overdose

Not found.

Interaction with other drugs

Given the pharmacological profile of the drug Cerebrin, special attention should be paid to possible additive effects when used together with antidepressants or monoamine oxidase inhibitors (MAOIs). In such cases, it is recommended to reduce the dose of the antidepressant.

The use of high doses of Cerebrin (30-40 ml) in combination with high doses of MAO inhibitors can cause an increase in blood pressure.

Compatibility

Cerebrin and Balanced Amino Acid Solutions should not be mixed in the same infusion solution.

The drug Cerebrin is incompatible with solutions containing lipids, and with solutions that change the pH of the medium (5.0-8.0).

Special instructions

With excessively rapid injections, a feeling of heat, increased sweating, dizziness may occur. Therefore, the drug should be administered slowly.

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

• 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% dextrose (glucose) solution.

Simultaneous administration of Cerebrin with vitamins and drugs that improve cardiac circulation is allowed, however, these drugs should not be mixed in the same syringe with Cerebrin.

It is necessary to use only a clear solution and only once.

Influence on the ability to drive vehicles and mechanisms

The drug Cerebrin does not affect the ability to drive vehicles and mechanisms.

Release form

During production at the site of the Federal State Budgetary Scientific Institution "FNTSIRIP them. M.P. Chumakov RAS, Russia:

5 ml of the drug in neutral glass ampoules of hydrolytic class I.

During production at the site of the Federal State Enterprise "Kursk Biofactory", Russia:

1 ml, 2 ml or 5 ml of the drug in neutral glass ampoules of hydrolytic class I.

10 ml or 20 ml of the drug in neutral glass vials of hydrolytic class I, sealed with rubber stoppers and crimped with aluminum caps or combined “flip-offs”.

Each ampoule/vial is labeled with label or writing paper or a label with self-adhesive paper.

5 ampoules are placed in a PVC blister pack.

2 blister packs with 1 ml and 2 ml ampoules or 1 blister pack with 5 ml ampoules with a knife for opening ampoules or an ampoule scarifier, together with instructions for medical use, are placed in a cardboard pack.

When packing ampoules with a ring or a break point, a knife for opening ampoules or an ampoule scarifier is not included.

5 bottles are placed in a PVC blister pack.

1 blister pack with vials, together with instructions for medical use, is placed in a cardboard box.

Storage conditions

Store in a place protected from light at a temperature not exceeding 25 ºC.

After opening the ampoule / vial, the solution should be used immediately.

Keep out of the reach of children.

Terms of release of the product

Released by prescription.

Expiration date

3 years.