ENCEBRAIN

Instructions
by medical applicationmedicine

Tradename: Encebrain.

International generic name: Pyritinol.

Medicinal form: Suspension for oral administration.

Composition: *5 ml suspension contains:*
Active ingredient: pyritinol 80.5 mg, which corresponds to the content of pyritinol dihydrochloride monohydrate 100 mg.

Pharmacotherapeutic group: Nootropic drug.

ATX code: N06BX02

Pharmacological action:
Pharmacodynamics :
Pyritinol increases pathologically reduced metabolism in the brain by increasing the uptake and utilization of glucose, increases the metabolism of nucleic acids and the release of acetylcholine at the synapses of nerve cells, and improves cholinergic transmission between cells of the nervous tissue. Helps stabilize the structure of the cell membrane of nerve cells and their function by inhibiting lysosome enzymes, thereby preventing the formation of free radicals.

Pyritinol improves the rheological properties of blood, increases the plasticity of red blood cells by increasing the ATP content in their membrane, which leads to a decrease in blood viscosity and improved blood flow. Pyritinol, improving blood circulation in ischemic areas of the brain, increases their oxygen supply; increases glucose metabolism. As a result, memory performance improves and impaired metabolic processes in the nervous tissue are restored, which contributes to the full functioning of its cells.

Pharmacokinetics:
Pyritinol is rapidly absorbed when taken orally. Bioavailability averages 85% (76-93%). Cmax in plasma is achieved 30-60 minutes after oral administration of 100 mg pyritinol dihydrochloride monohydrate.

Pyritinol is rapidly metabolized , 20 - 40% of the substance is reversibly bound to plasma proteins. Conjugated metabolites are excreted primarily through the kidneys. Total urinary excretion within 24 hours is 72.4 - 74.2%. The largest part of the received dose is excreted during the first 4 hours after administration. Only 5% of the dose is excreted in feces. T 1/2 about 2.5 hours.

With repeated oral administration, no accumulation is observed. Toxic concentrations do not develop even with impaired renal function.

Penetrates through the BBB, metabolites accumulate mainly in the gray matter of the brain. Pyritinol penetrates the placental barrier. The studies conducted did not reveal teratogenic or embryotoxic activity.

Indications to application:
- symptomatic treatment of dementia syndrome (including primary degenerative dementia, vascular and mixed forms of dementia), accompanied by impairments of memory, concentration and thinking, fatigue, lack of motivation and motivation, affective disorders;
- rehabilitation period of ischemic stroke;
- cerebral atherosclerosis;
- chronic cerebrovascular accidents;
- encephalopathy: atherosclerotic, post-traumatic, diabetic, toxic;
- consequences of encephalitis;
- asthenodepressive conditions;
- mental retardation, cerebroasthenic syndrome, minimal brain dysfunction in children;
- chronic alcoholism;
- age-related disorders of higher nervous activity, mental performance and memory;
- a state of chronic stress, accompanied by a decrease in higher mental functions;
- disturbances in memory, concentration and thinking;
- lack of motivation and decreased motivation;
- disorders of neuropsychic development in children.

Way applications and doses:
Newborns: from the 3rd day after birth, 1 ml of suspension per day for a month, the dose is taken in the morning. Starting 2 months after birth, this dose is increased by 1 ml every week until the daily dose reaches 5 ml (1 teaspoon).

Children from 1 year: ½ - 1 teaspoon of suspension 1-3 times / day (from 50 to 300 mg of pyritinol dihydrochloride monohydrate per day depending on indications).

Children from 7 years: ½ - 2 teaspoons of suspension 1-3 times / day (from 50 to 600 mg of pyritinol dihydrochloride monohydrate per day depending on indications). The drug should be taken during or after meals. For sleep disorders, the last daily dose should not be taken in the evening or at night.

Adults: 2 teaspoons of suspension 3 times a day (600 mg pyritinol dihydrochloride monohydrate per day).

The duration of therapy depends on the clinical picture of the disease, at least 8 weeks and can be continued if necessary. As a rule, therapeutic success is achieved after 3-4 weeks of treatment. The optimal effect usually occurs after 6-12 weeks. In newborns at high risk of developing perinatal CNS pathology, the average duration of treatment is an average of 6 months. After 3 months, you should check whether there are indications for further treatment.

Contraindications for use:
- hypersensitivity to pyritinol and excipients;

- chronic rheumatoid arthritis;
- severe renal or liver failure;
- severe blood diseases;
- autoimmune diseases: systemic lupus erythematosus, myasthenia gravis, pemphigus (acute phase or history).

Use during pregnancy and breastfeeding:
Data from a limited number of pregnant women using this drug indicate no adverse effects of pyritinol on pregnancy or fetal/newborn health. No other relevant epidemiological data are currently available. Animal studies have not revealed any direct or indirect adverse effects of pyritinol on pregnancy, embryonic development, childbirth or postnatal development.

Pyritinol crosses the placental barrier and small amounts (maximum 0.4%) are excreted into breast milk. There is no threat to the child.

The drug should be used only if the expected benefit to the mother outweighs the possible risk to the fetus and child.

Side effect:
From the digestive system: nausea, vomiting, diarrhea are possible; rarely - loss of appetite, changes in taste sensitivity, liver dysfunction (increased levels of transaminases , cholestasis).
From the side of the central nervous system: sleep disturbances are possible; rarely - increased excitability, headache, dizziness, fatigue.
Other: allergic reactions of varying severity are possible, usually manifested in the form of rashes on the skin or mucous membranes, itching, increased body temperature. When using the drug according to indications in recommended doses, the development of side effects is unlikely.

Special instructions:
It is not recommended to prescribe the last dose of the drug in the evening.

Use for liver dysfunction:
The drug should be prescribed with caution to patients with severe liver failure.

Use for renal impairment:
The drug should be prescribed with caution to patients with severe renal failure.

Use in children:
Prescribed to children from the 3rd day after birth.

Drug interactions:
Pyritinol can potentiate the adverse reactions of penicillamine, gold drugs, sulfasalazine, levamisole.

Storage conditions:
At a temperature not higher than 25 °C.
Keep out of reach of children.

Best before date:
Indicated on the packaging.
Do not use after expiration date.

Vacation conditions:
On prescription.

Produced for:
MAXX PHARM LTD
London, Great Britain