Cereton®

International Non-Proprietary Name (INN): Choline alfoscerate

Dosage Form: capsules

Structure: 1 capsule contains:

Active ingredient: Choline alphoscerate (calculation for 100% substance) 400mg.

Excipients: glycerol; purified water.

Capsules composition: gelatine; sorbitol; glycerol; methylparahydroxybenzoate; propyl parahydroxybenzoate; titanium dioxide; iron oxide yellow; purified water.

Description: soft, gelatine, oval capsules of yellow or yellow with a light brown colour. Capsule composition: oily, clear, colourless or slightly coloured liquid.

Pharmacological Classification: nootropics

ATX Code: N07AX02

Pharmacological Action: nootropic

Pharmacodynamics:

Nootropic medicine. Central cholinostimulator, which contains 40.5% of metabolically protected choline. Metabolic protection facilitates the release of choline in the brain. Provides the synthesis of acetylcholine and phosphatidylcholine in neuronal membranes, improves the blood flow and enhances metabolic processes in the central nervous system, activates the reticular formation. Increases the linear velocity of blood flow on the side of a traumatic brain injury, promotes normalization of spatiotemporal characteristics of spontaneous bioelectric activity of the brain, regression of local neurological symptoms and restoration of

consciousness; has a positive effect on the cognitive and behavioural responses of patients with cerebrovascular diseases (discirculatory encephalopathy and residual effects of cerebral circulation disorders). Provides a preventive and corrective effect on the pathogenetic factors of the involutional psychoorganic syndrome, changes the phospholipid composition of neuronal membranes; participates in the synthesis of phosphotidylcholine (membrane phospholipid); improves the plasticity of neuronal membranes. Stimulates dose-dependent ejection of acetylcholine under physiological conditions, improves the synaptic transmission and receptors function. Does not affect the reproductive cycle and does not have a teratogenic, mutagenic effect.

Pharmacokinetics:

In parenteral administration (10 mg/kg), Cereton mainly accumulates in the brain, lungs and liver. Absorption is 88%. Easily penetrates through the blood-brain barrier (in oral intake, the concentration in the brain is 45% of that in the plasma), 85% of the medicine is excreted by the lungs in the form of carbon dioxide, the rest (15%) is excreted by the kidneys and through the intestine.

Intended Uses:

- the recovery period after a severe craniocerebral injury and an ischemic stroke, the recovery period after a hemorrhagic stroke, with local hemispheric symptoms or symptoms of brainstem lesion;
- psychoorganic syndrome against the degenerative and involuntary changes in the brain;
- cognitive disorders (impaired mental and memory function, confusion, disorientation, decreased motivation, initiative and ability to concentrate), including cases of dementia and encephalopathy;
- senile pseudo melancholia.

Contraindications:

- hypersensitivity to the medicine;
- acute stage of hemorrhagic stroke;
- pregnancy;
- breastfeeding;
- age under 18 years old (due to the lack of data).

Dosage and Administration:

Per os. In the recovery period of craniocerebral injury, an ischemic or hemorrhagic stroke Cereton is prescribed at a dose of 800 mg in the morning and 400 mg in the afternoon for 6 months. For treating the chronic cerebrovascular insufficiency and

dementia syndromes, the dose is 400 mg (1 caps.) 3 times a day, preferably after meals, for 3-6 months.

Side Effects:

Nausea is possible (mainly because of dopaminergic activation). Cancellation of the treatment is not required; the dosage should be reduced. Allergic reactions are possible.

Overdose:

Symptoms: nausea. Treatment: symptomatic therapy.

Interaction with Other Drugs:

No significant interaction with other medicines has been identified.

Pregnancy and Lactation:

The drug is contraindicated during pregnancy and lactation.

Influence on the Ability to Drive Vehicles and Mechanisms:

Cereton does not affect the speed of psychomotor reactions.

Terms of Release from Pharmacy: on prescription

<u>Storage Conditions</u>: Store in a dry, dark place at a temperature no higher than 25°C. Keep out of reach of children.

Shelf Life: 3 years. Do not use beyond the expiration date.

Country of Manufacture: Russia