Patient information leaflet

Cerotex®

Trade name: Cerotex®

International non-proprietary name: choline alfoscerate

Pharmaceutical form: capsules

Composition

Composition per capsule
Active substance: choline alfoscerate (as 100% substance) - 400 mg;
excipients: glycerol, purified water;
soft gelatin capsule: gelatin, sorbitol, glycerol, methyl parahydroxybenzoate, titanium dioxide (E 171), iron dye yellow oxide (E 172), propyl parahydroxybenzoate, purified water.

Description

Oval-shaped, yellow or yellow with a light brown tint.
The contents of the capsules are an oily, clear, colorless or slightly colored liquid.

Pharmacotherapeutic group: parasympathomimetics, choline alfoscerate.

ATC code: N07AX02

Pharmacological properties

Pharmacodynamic properties

Nootropic agent. Central cholinostimulator, which contains 40.5% of metabolically protected choline. Metabolic protection promotes the release of choline in the brain. Provides the synthesis of acetylcholine and phosphatidylcholine in neuronal membranes, improves 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 the traumatic brain injury, contributes to the normalization of spatiotemporal characteristic characteristics of spontaneous bioelectrical activity of the brain, regression of focal neurological symptoms and restoration of consciousness; has a positive effect on the cognitive and behavioral reactions of patients with vascular diseases of the brain (dyscirculatory encephalopathy and

residual effects of cerebrovascular accident). It has 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 phosphatidylcholine (membrane phospholipid), improves the plasticity of neuronal membranes. Stimulates dose-dependent release of acetylcholine under physiological conditions, improves synaptic transmission, receptor function. It does not affect the reproductive cycle and does not have a teratogenic, mutagenic effect.

Pharmacokinetic properties

When administered parenterally (10 mg/kg), Cerotex® predominantly accumulates in the brain, lungs and liver. Absorption is 88%, easily penetrates the blood-brain barrier (when taken orally, the concentration in the brain is 45% of that in plasma). The lungs excrete 85% of the medicinal product in the form of carbon dioxide, the rest (15%) is excreted in urine and faeces.

Therapeutic indications

- recovery period of severe traumatic brain injury and ischemic stroke, the recovery period of hemorrhagic stroke, occurring with focal hemispheric symptoms or symptoms of brainstem damage;
- psychoorganic syndrome against the background of degenerative and involutional changes in the brain;
- cognitive disorders (impaired mental function, memory, confusion, disorientation, decreased motivation, initiative and ability to concentrate), including dementia and encephalopathy;
- senile pseudomelancholia.

Contraindications

- hypersensitivity to the medicinal product;
- acute stage of hemorrhagic stroke;
- pregnancy;
- breastfeeding;
- children and adolescents under 18 years of age (due to lack of data).

Posology and method of administration

In the recovery period of traumatic brain injury, ischemic or hemorrhagic stroke, Cerotex® is prescribed 800 mg in the morning and 400 mg in the afternoon for 6 months.

In chronic cerebrovascular insufficiency and dementia syndromes, Cerotex® is prescribed 400 mg (1 capsule) 3 times daily, preferably after meals, for 3-6 months.

Undesirable effects
Gastrointestinal disorders: nausea (which is mainly the result of secondary dopaminergic activation), abdominal pain.
Nervous system disorders: short-term confusion (in this case, it is necessary to reduce the dose). The medicinal product is well tolerated even when used for a long time.

Overdose
Nausea may be observed. Treatment: symptomatic therapy.

Interaction with other medicinal products
Significant interactions with other medicinal products have not been established.

Special warnings
Cerotex® does not affect the speed of psychomotor reactions.
Cerotex® contains sorbitol in the composition of the capsule shell, as a result, the use of the medicinal product in the recommended dose may cause a laxative effect.
The medicinal product should be administered with caution to patients with diabetes mellitus.
Cerotex® is not recommended for persons with congenital fructose intolerance due to the content of sorbitol.
The composition of the capsule shell includes parabens, which can cause allergic reactions (possibly delayed).

Pharmaceutical form and presentation
Capsules 400 mg.
14 capsules in a blister pack made of aluminum foil and polyvinyl chloride film.
1, 2, 3 or 4 blister packs together with patient information leaflet in a carton.

Storage conditions
Store in a dry, dark place at a temperature below 25 ° C.
Keep out of the reach of children.

Shelf life
3 years. Do not use after the expiration date.

Prescription status
On prescription.