Patient information leaflet

Cerotex®

Trade name: Cerotex®

International non-proprietary name: choline alfoscerate

Pharmaceutical form: solution for intravenous and intramuscular administration

Composition per ampoule
Active substance: choline alfoscerate polyhydrate (as anhydrous choline alfoscerate) - 1000 mg;
excipients: water for injections.

Description: clear colorless liquid

Pharmacotherapeutic group: nootropic agent

ATC code: N07AX02

Pharmacological properties
Pharmacodynamic properties
Cerotex® contains choline alfoscerate, which is a centrally acting cholinomimetic with a predominant effect on the central nervous system.
The composition of the medicinal product includes 40.5% choline, released from the compound in the brain; choline is involved in the biosynthesis of acetylcholine (one of the main mediators of nervous excitation). Alfoscerate is biotransformed to glycerophosphate, which is a precursor of phospholipids.
Acetylcholine has a positive effect on the transmission of nerve impulses, and glycerophosphate is involved in the synthesis of phosphatidylcholine (membrane phospholipid), resulting in improved membrane elasticity and receptor function.
Cerotex® enhances metabolic processes and activates the structures of the reticular formation of the brain.
It has a preventive and corrective effect on the factors of the involutional psychoorganic syndrome, such as changes in the phospholipid composition of neuronal membranes and a decrease in cholinergic activity.
Pharmacodynamic studies have shown that choline alfoscerate acts on synaptic, including cholinergic transmission of nerve impulses (neurotransmission), neuronal membrane plasticity and receptor function.
Pharmacokinetic properties
Absorption when taken orally is 88%; it easily penetrates the blood-brain barrier, accumulates mainly in the brain (the concentration in the brain reaches 45% of the blood level), lungs and liver; 85% is excreted by the lungs as carbon dioxide, the rest (15%) is excreted in urine and faeces.
Does not affect the reproductive cycle, does not have a teratogenic and mutagenic effect.

Therapeutic indications
Psychoorganic brain syndromes of the degenerative-involutional type or resulting from cerebrovascular insufficiency, namely, primary or secondary cognitive disorders in the elderly, characterized by memory deficits, confusion and disorientation, lack of motivation and initiative, and impaired attention. Changes in the emotional sphere and senile behavior: emotional lability, irritability, indifference to the environment.
Pseudo-depression in the elderly.

Contraindications

- hypersensitivity to the active substance;
- pregnancy;
- breastfeeding;
- children and adolescents under 18 years of age.

Pregnancy and lactation
The use of Cerotex® during pregnancy and breastfeeding is contraindicated. During treatment with Cerotex®, breastfeeding should be discontinued.

Posology and method of administration
Intravenously (drop infusion) or intramuscularly (slowly) at a dose of 1000 mg/day.
For intravenous administration, the contents of one ampoule (4 ml) are diluted in 50 ml of 0.9% sodium chloride, the infusion rate is 60-80 drops per minute.
The duration of treatment is usually 10 days. If necessary, treatment can be continued according to the doctor's prescription, depending on the clinical picture and the characteristics of the course of the disease, age and tolerability of the medicinal product.
After stabilization of the patient's condition, it is possible to continue treatment with oral dosage forms of the medicinal product.
Doses may be increased at the discretion of the doctor.

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
Symptoms: nausea.
The severity of dose-dependent side effects may be increased.
Treatment: symptomatic therapy. The efficacy of dialysis has not been established.

Interaction with other medicinal products
Clinically significant interaction of the medicinal product with other medicinal products has not been established.

Special warnings
Nausea may be due to dopaminergic activation. Efficacy and safety in children under 18 years of age have not been established.

Effects on ability to drive and use machines
During the period of treatment, care must be taken when driving vehicles and when engaging in other potentially hazardous activities that require increased concentration of attention and speed of psychomotor reactions.

Pharmaceutical form and presentation
Solution for intravenous and intramuscular administration 250 mg/ml.

4 ml in ampoules of colorless neutral glass type I with a colored break ring or with a colored dot and a notch. One, two or three colored rings and/or two-dimensional barcode and/or alphanumeric coding or without additional color rings, two-dimensional barcode, alphanumeric coding are additionally applied to the ampoules.
3 or 5 ampoules in a blister pack made of PVC film and polymer film or without film.
1 or 2 blister packs together with patient information leaflet in a carton.

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

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

Prescription status
On prescription.