Ceraxon®

International Non-Proprietary Name (INN): Citicoline

Dosage Form: oral solution

Structure: 1 sachet (10ml) contains:
Active ingredients: citicoline sodium 1045.0mg (equivalent to 1000mg of citicoline).
Excipients: sorbitol, glycerol, methylpara-hydroxybenzoate, propylpara-hydroxybenzoate, dihydrate of sodium citrate, sodium saccharinate, strawberry flavor (strawberry essence 1487-SLucta), potassium sorbate, citric acid 50% solution to pH 5.9-6.1, purified water.

Description: transparent colorless liquid with a strawberry smell

Pharmacological Classification: nootropics

ATX Code: N06BX06

Pharmacological Action: nootropic

Pharmacodynamics:
Being a predecessor of the key ultrastructural components of the cell membrane (mainly phospholipids), citicoline has a wide spectrum of action - it helps to repair damaged cell membranes, inhibits the effect of phospholipases, prevents excessive formation of free radicals, and prevents cell death by affecting the mechanisms of apoptosis. In the acute period of a stroke, citicoline reduces the amount of damage to the brain tissue, and improves cholinergic transmission. In case of craniocerebral injury, it reduces the duration of post-traumatic coma and the severity of neurologic symptoms; besides, it helps to reduce the duration of the recovery period. In chronic cerebral hypoxia, citicoline is effective in treating cognitive disorders such as memory impairment, lack of initiative, difficulties arising from daily activities and self-care. It increases the level of attention and consciousness, and reduces the manifestation of amnesia. Citicoline is effective in the treatment of sensitive and motor neurological disorders of degenerative and vascular etiology.

Pharmacokinetics:
Absorption: Citicoline is well absorbed when ingested. After an oral administration, the absorption is almost complete, and bioavailability is approximately the same as after intravenous administration.
Metabolism: The medicine is metabolized in the intestine and in the liver with the formation of choline and cytidine. The concentration of choline in the blood plasma is significantly increased after an intake.
Distribution: Citicoline is mainly distributed in the structures of the brain, with the rapid distribution of choline fractions into the structural phospholipids and cytidine fractions - into cytidine nucleotides and nucleic acids. Citicoline penetrates into the brain and is actively embedded in the cellular, cytoplasmic and mitochondrial membranes, forming part of the fraction of structural phospholipids.
Excretion: Only 15% of an administered dose is excreted from the body: less than 3% - by the kidneys and through the intestine and about 12% - with exhaled CO2.
There are two phases in excretion of citicoline with urine: the first phase lasts for about 36 hours, during this phase the rate of excretion rapidly decreases; during the second phase the rate of excretion decreases much more slowly. The same is observed in exhaled CO2 - the excretion rate quickly decreases after about 15 hours, and then starts to decrease much more slowly.

Intended Uses:
- Acute period of an ischemic stroke (as part of the complex therapy);

- The recovery period after an ischemic and hemorrhagic strokes;
- Craniocerebral injury, acute (as part of the complex therapy) and recovery periods;
- Cognitive and behavioral disorders in degenerative and vascular diseases of the brain.

Contraindications:
- Hypersensitivity to any of the ingredients;
- Expressed vagotonia (predominance of the tone of the parasympathetic part of the vegetative nervous system);
- Rare hereditary diseases associated with intolerance to fructose;
- Due to the lack of sufficient clinical data, the medicine is not recommended for children under 18 years old.

Dosage and Administration:
Ceraxon® is administered orally. Before use, the medicine can be diluted in a small amount of water (120 ml or ½ cup). Taken with meals or between meals.
Recommended dosage:
Acute period of an ischemic stroke and craniocerebral injury: 1000 mg (10 ml or 1 sachet) every 12 hours. The treatment lasts for at least 6 weeks.
The recovery period after an ischemic and hemorrhagic strokes, the recovery period after a craniocerebral injury, cognitive and behavioral disorders in degenerative and cerebrovascular diseases of the brain: 500-2000 mg per day (5-10 ml 1-2 times a day or 1 packet (1000 mg) 1- 2 times a day). Dosage and duration of treatment depends on the severity of a disease symptoms.
Elderly patients.
When prescribing Ceraxon® to elderly patients the dose adjustment is not required.
Recommendations for the use of Ceraxon ® in sachets:

1. While holding a sachet vertically, gently tear off its edge at the mark "Open here".

2. The contents of the sachet can be drunk directly after opening or it can be diluted in ½ cup of water (120ml).

Side Effects (very rare):
Allergic reactions (rash, skin itch, anaphylactic shock), headache, dizziness, heat, tremor, nausea, vomiting, diarrhea, hallucinations, swelling, dyspnea, insomnia, agitation, decreased appetite, numbness in paralyzed limbs, changes in hepatic enzymes activity. In some cases, Ceraxon® can stimulate the parasympathetic system, as well as produce a short-term change in blood pressure.
If any of the side effects listed in the instruction are aggravated, or if other side effects not listed in the instruction occur, consult a doctor.

Overdose:
Given the low toxicity of the medicine, overdose cases are not described.

Interaction with Other Drugs:
Citicoline increases the effects of levodopa. Do not prescribe along with medicines containing meclofenoxate.

Pregnancy and Lactation:
There is no sufficient data on the use of citicoline in pregnant women. Although no adverse effects have been identified in animal studies, Ceraxon is prescribed during pregnancy only in cases when the expected benefit to the mother exceeds the potential risk to the fetus. When prescribing Ceraxon during lactation, breastfeeding should be discontinued, as there is no data on the citicoline exertion with human milk.

Influence on the Ability to Drive Vehicles and Mechanisms:
During the treatment, caution should be taken when performing potentially dangerous activities requiring special attention and quick reactions (driving vehicles, working with moving mechanisms, control engineer and operator work, etc.).

Special Precautions:
In the cold, a small amount of crystals may build up due to the temporary partial crystallization of the preservative. With further storage under the recommended conditions, the crystals dissolve within a few months. The presence of crystals does not affect the quality of the medicine.

Terms of Release From Pharmacy: on prescription

Storage Conditions: store at a temperature no higher than 30°C. Keep out of the reach of children.

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

Country of Manufacture: Italy