Noopept®

Registration number:
LS-001577 (ЛС-001577)

Trade name:
Noopept®

International non-proprietary name (INN):
Omberacetam

Dosage form:
tablets

Composition per tablet:
Active ingredient: Omberacetam (noopept) – 10.0 mg;
Excipients: lactose monohydrate – 55.0 mg, potato starch – 13.5 mg, microcrystalline cellulose 101 – 21.2 mg, magnesium stearate – 0.3 mg, povidone (polyvinyl-pyrrolidone, povidone K-25) – 0.0008 mg.

Description:
White, round, flat-cylindrical tablets with a beveled edge.

Pharmacotherapeutic group:
nootropic agent

ATC code:
N06BX

Pharmacological properties:
Pharmacodynamics:

Noopept® has nootropic and neuroprotective properties. It improves learning ability and memory by acting on all phases of processing: initial information processing, consolidation, and retrieval.

It prevents the development of amnesia caused by electroshock, blockade of central cholinergic structures, glutamatergic receptor systems, and REM sleep deprivation.

The neuroprotective (protective) action of Noopept® is manifested in increased resistance of brain tissue to damaging effects (trauma, hypoxia, electroconvulsive, toxic) and reduction in the degree of brain neuron damage.

The drug reduces the focal volume in thrombotic stroke model and prevents neuronal death in cultured cerebral cortex and cerebellum tissue subjected to neurotoxic concentrations of glutamate and free radical oxygen.

Noopept® has antioxidant effects, blocks voltage-dependent calcium channels of neurons, reducing the neurotoxic effect of excess calcium, improves blood rheological properties, having antiplatelet, fibrinolytic, and anticoagulant properties.

The nootropic effect of the drug is associated with the formation of cycloprolylglycine, which is structurally similar to an endogenous cyclic dipeptide with anti-amnestic activity, as well as having cholinopositive action.

Noopept® increases the amplitude of transcallosal response, facilitating associative connections between brain hemispheres at the level of cortical structures.

It promotes the restoration of memory and other cognitive functions impaired as a result of damaging effects – brain trauma, local and global ischemia, prenatal damage (alcohol, hypoxia).

The therapeutic effect of the drug in patients with organic disorders of the central nervous system manifests starting from 5-7 days of treatment.

Initially, the anxiolytic and mild stimulating effects present in Noopept's® spectrum of activity are realized, manifesting in reduction or disappearance of anxiety, increased irritability, affective lability, and sleep disorders.

After 14-20 days of therapy, the positive influence of the drug on cognitive functions, attention parameters, and memory is revealed.

Noopept® has a vegetative normalizing effect, helps reduce headaches, orthostatic disorders, and tachycardia.

Upon discontinuation of the drug, no "withdrawal" syndrome is observed.

It does not cause damaging effects on internal organs; does not lead to changes in blood cell composition and biochemical parameters of blood and urine; does not possess immunotoxic, teratogenic effects, does not show mutagenic properties.

Pharmacokinetics:

Omberacetam, being absorbed in the gastrointestinal tract, enters the systemic circulation unchanged, penetrates the blood-brain barrier, and is detected in the brain in higher concentrations than in blood.

The time to reach maximum concentration averages 15 minutes.

The plasma half-life is 0.38 hours. It is partially preserved unchanged, partially metabolized to form phenylacetic acid, phenylacetylproline, and cycloprolylglycine. It has high relative bioavailability (99.7%), does not accumulate in the body, does not cause drug dependence.

Indications for use:

Memory, attention, and other cognitive function impairments and emotionally labile disorders (including in elderly patients) in:

- consequences of traumatic brain injury,
- post-concussion syndrome,
- cerebral vascular insufficiency (encephalopathies of various origins),
- asthenic disorders,
- other conditions with signs of decreased intellectual productivity.

Contraindications

- Pregnancy, breastfeeding period.
- Age under 18 years.
- Hypersensitivity to components of the drug.
- Lactase deficiency, lactose intolerance, glucose-galactose malabsorption.
- Severe liver and kidney function disorders.

Use during pregnancy and breastfeeding:

The drug is contraindicated during pregnancy. If it is necessary to use the drug during breastfeeding, the question of discontinuing breastfeeding must be decided.

Method of administration and dosage:

Noopept® is taken orally, after meals. Treatment begins with a dose of 20 mg, distributed into two 10 mg doses during the day (morning and afternoon). If therapy is insufficiently effective and the drug is well tolerated, the dose may be increased to 30 mg (see "Special instructions"), distributed into three 10 mg doses throughout the day. The drug should not be taken later than 18:00. The duration of course treatment is 1.5 — 3 months. A repeat course of treatment can be conducted after 1 month if necessary.

Side effects:

Allergic reactions are possible. In patients with arterial hypertension, primarily severe, blood pressure elevation may be observed while taking the drug.

Overdose:

No specific manifestations of overdose have been established.

Drug interactions:

No interactions between Noopept® and alcohol, sleeping pills, antihypertensive medications, and psychostimulant drugs have been established.

Special instructions:

If it is necessary to increase the drug dose (up to 30 mg/day), with long-term use, as well as when used concurrently with other medications, if side effects appear or condition worsens, consult a doctor.

Effect on ability to drive vehicles and operate machinery:

Noopept® does not affect the ability to operate machinery and vehicles.

Dosage form:

Tablets, 10 mg. 25 tablets in a blister pack made of PVC film and aluminum foil. 2 blister packs together with instructions for use are placed in a cardboard box.

Storage conditions:

At temperatures not exceeding 25°C. Keep out of reach of children.

Shelf life:

3 years. Do not use after the expiration date printed on the package.

Dispensing conditions:

Available over-the-counter.

Manufacturer

JSC “OTCPharm”, Russia 123112, Moscow, Testovskaya St., 10, floor 12, room II, office 29

These instructions translated from official manufacturer instructions in Russian by Extrapharma online pharmacy