Noopept®

International Non-Proprietary Name (INN): Omberacetam

Dosage Form: pills (10 mg)

Structure: 1 capsule contains:

Active ingredient: noopept (N-phenylacetyl-L-prolylglycine ethyl ester) – 10 mg;

Excipients: potato starch - 13.5 mg, lactose monohydrate - 55 mg, microcrystalline cellulose - 21.2 mg, magnesium stearate -

0.3 mg, povidone - 0.0008 mg.

Description:

Bevel-edged pills of flat-round shape in white color.

Pharmacological classification: nootropic

ATC code: N06BX

<u>Pharmacological action:</u> nootropic, neuroprotective, antioxidant, antiaggregational, fibrinolytic, anticoagulant, properties.

Pharmacodynamics:

Hoopept has nootropic and neuroprotective properties. It improves learning ability and memory exerting effects on all processing phases: initial processing of information, consolidation, extraction. It prevents development of amnesia caused by electric shock, blockade of central cholinergic structures, glutamatergic receptor systems, deprivation of the paradoxical phase of sleep.

The neuroprotective action of Noopept increases the resistance of brain tissue to damaging impacts (such as trauma, hypoxia, electroconvulsive or toxic impact) and weakens the degree of damage to brain neurons. The drug reduces the volume of the thrombotic stroke focus and prevents the death of neurons in the

tissue of the cerebral cortex and cerebellum after receiving neurotoxic concentrations of glutamate and free radical oxygen.

Noopept acts as an antioxidant and has an antagonistic effect if there is an excess of calcium, improves the rheological properties of the blood, possessing antiaggregational, fibrinolytic, anticoagulant properties.

The nootropic effect of the drug is associated with the formation of cycloprolylglycine, structurally similar to the endogenous cyclic dipeptide with its antiamnestic activity, as well as the presence of cholinopositive action.

Noopept® increases the amplitude of transcallosal response (TCR), facilitating associative connections between the cerebral hemispheres in cortical areas.

The drug promotes the restoration of memory and other cognitive functions disrupted by damaging effects like brain trauma, local and global ischemia, prenatal injuries (alcohol, hypoxia).

The therapeutic effect of the drug in patients with organic disorders of the central nervous system appears on the 5-7 day of administration. At the beginning the anxiolytic and light stimulatory effects of Noopept result in the reduction or disappearance of anxiety, increased irritability, affective lability, and sleep disturbances. Positive effects of the drug on cognitive functions, attention and memory parameters are visible after 14-20 days of the therapy.

Noopept normalizes vegetative system, reduces headaches, orthostatic disorders and tachycardia.

Discontinuation of the drug does not cause withdrawal syndrome.

Noopept has no damaging effect on internal organs; it does not change cellular composition of the blood or blood and urine biochemical indicators; the drug does not have immunotoxic, teratogenic and mutagenic properties.

Pharmacokinetics:

N-phenylacetyl-L-prolylglycine ethyl ester is absorbed in the gastrointestinal tract, unchanged enters the systemic

bloodstream and penetrates the blood-brain barrier. The substance is detected at higher concentrations in the brain than in the blood. It takes on average 15 minutes to reach the maximum concentration. The half-life in blood plasma is 0.38 hours. One part of the drug remains unchanged, while the other is metabolized to phenylacetic acid, phenylacetylproline and cycloprolylglycine. Noopept has a high relative bioavailability (99.7%), it does not cumulate in the body or cause drug dependence.

Intended uses:

Impaired memory, attention and other cognitive functions as well as emotionally labile disorders, including in elderly patients, with post-traumatic brain injury, post-concussion syndrome, cerebrovascular insufficiency (encephalopathies of various origins), asthenic disorders and other states characterized by reduced mental productivity.

Contraindications:

Hypersensitivity to the components of the drug, lactase deficiency, lactose intolerance, glucose-galactose malabsorption, liver or kidneys dysfunction, age below 18 years, pregnancy and lactation.

Dosage and administration:

It is recommended to take Noopept orally after meal. At the beginning of the treatment the daily dosage of the drug is 20 mg (10 mg twice a day, in the morning and then in the afternoon). In case of insufficient efficiency and good tolerability, the dosage is increased up to 30 mg (see "Special instructions"): 10 mg thrice a day. Do not take the drug after 6 pm. Duration of the treatment course is 1.5 - 3 months. If necessary, the second treatment course can be conducted in 1 month.

Side effects:

Allergic reactions. increase in blood pressure in patients with hypertension.

Overdose:

No specific overdose effects have been identified.

Interaction with other drugs:

The interaction of Noopept with alcohol, hypnotics, hypotensive and psychostimulating drugs has not been established.

Special instructions:

If it is necessary to increase the dose of the drug (up to 30 mg a day), prolong the use of the pills, use Noopept simultaneously with other drug, or the therapy cause adverse reactions, you should consult a doctor.

Pregnancy and lactation:

Noopept is contraindicated during pregnancy and lactation.

<u>Influence on the ability to drive vehicles and operate</u> machines:

Noopept does not affect the ability to drive vehicles and operate machines.

Terms of release from pharmacy: without prescription.

Storage conditions: store in a dry dark place at temperatures no higher than 25°C. Keep out of reach of children.

Shelf life: 3 years. Do not use beyond the expiration date printed on the package.

Country of manufacture: Russia