Noopept package insert translated from Russian

Registration Number: LS-001 577 on 12.05.2006
Brand name: Noopept ®
Chemical management title: **GVS-111**, **N-phenylacetyl-L-prolylglycine ethyl ester**.
Dosage form: tablets.

Composition

Each tablet contains:
Active ingredient: Noopept ® - 10 mg.
Inactive ingredients: microcrystalline cellulose, lactose (milk sugar), potato starch, povidone, magnesium stearate.

Description

White pills, round with a facet.

Pharmacotherapeutic group: Nootropic drug. ATC code: [N 06 BX].

Pharmacological action

Noopept ® is a neuroprotective drug with nootropic and neuroprotective properties. Improves learning ability, memory, operating on all phases of processing: the initial processing of information, consolidation, retrieval. Prevents the development of amnesia induced by electroshock, blockade of central cholinergic structures glyutamatergicheskih receptor systems, deprivation of paradoxical sleep phase.

Neuroprotective (protective) effect Noopept ® increases the stability of brain tissue to damaging influences (trauma, hypoxia, electroconvulsive, toxic) and the weakening of the degree of damage to brain neurons. The drug reduces the amount of focus on thrombotic stroke model and prevents neuronal death in tissue culture of the cerebral cortex and cerebellum, subjected to the action of neurotoxic concentrations of glutamate, free radical oxygen.

Noopept ® has an antioxidant effect, an antagonistic effect on the effects of excess calcium, improves the rheological properties of blood, having antiaggregatory, fibrinolytic, anticoagulant properties.

Nootropic effect of the drug is associated with the formation of tsikloprolilglitsina similar in structure to endogenous cyclic dipeptides possessing antiamnesticheskoy activity, as well as the presence of holinopozitivnogo.

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

Noopept ® helps to restore memory and other cognitive functions, disturbed as a result of damaging influences - brain injury, local and global ischemia, prenatal damage (alcohol, hypoxia).

The therapeutic effect of the drug in patients with organic disorders of the central nervous system appears, from 5-7 days of treatment. Initially implemented in the existing spectrum of activity Noopept ® anxiolytic and stimulant effects of light that appear in the reduction or disappearance of anxiety, irritability, emotional lability, sleep disorders. After 14-20 days of treatment it revealed a positive effect of the drug on cognitive function, attention and memory parameters.

Noopept ® has vegetonormalizuyuschim effect, reduces headaches, orthostatic violations tachycardia.

Noopept ® bioaccumulates in the body, does not cause drug dependence. Removal of the drug does not cause withdrawal syndrome.

Noopept ® has no damaging effect on the internal organs, does not change the hematological and biochemical parameters, does not possess immunotoxic, teratogenic, mutagenic properties does not show.

Pharmacokinetics

Noopept ® is absorbed in the gastrointestinal tract an unchanged enters the systemic circulation, crosses the blood-brain barrier is found in the brain in higher concentrations than in blood. Time to reach maximum concentration averages 15 minutes. The half-life of plasma - 0.38 h. The drug is partially preserved unchanged, partly metabolized to form phenylacetic acid, and fenilatsetilprolina tsikloprolilglitsina. It has a high relative bioavailability (99.7%).

Indications for use

Impaired memory, attention and other cognitive functions and emotional labile disorders, including elderly patients, with

- consequences of traumatic brain injury
- postkommotsionnom syndrome
- cerebral vascular disease (encephalopathy of different genesis)
- asthenic disorders
- other conditions with symptoms reducing intellectual productivity

Contraindications

Pregnancy, lactation. Age 18 years. Individual intolerance of the drug. Expressed by the human liver and kidney.

Dosage and administration

Noopept ® should be taken after a meal. Normal daily dose is 20 mg - 10 mg twice daily (morning and afternoon). In case of insufficient efficacy and good tolerability the dose may be increased to Noopept ® 30 mg (see "Special Instructions"), distributed over 10 mg in three divided doses for the day. The duration of a course of treatment was 1.5 - 3 months. A second course of treatment if necessary can be carried out after discontinuing for 1 month.

Side effects

Allergic reactions are possible. In patients with hypertension, most severe, while taking the drug may be a rise in blood pressure.

Overdose

Specific manifestations of overdose has not been established.

Interaction with other medicinal products

Interaction is not established Noopept ® with alcohol, drugs and antihypertensive drugs and drugs stimulating effect.

Cautions
If necessary, increase the dose (30 mg / day), long-term use, as well as the simultaneous use of other drugs, the emergence of adverse events or deterioration should consult your doctor.

Form of
25 tablets in blisters of PVC and aluminum foil printed pack.
30 or 50 tablets in plastic banks to control the opening.
Two blister packs along with instructions for use in cardboard box.

Storage conditions
List B. Keep in dry, dark place at a temperature not above 25 Degrees C.
Keep out of reach of children.

Expiration date
2 years. Do not use after expiration date printed on the packaging.

Pharmacy purchasing terms
Without a prescription.

Manufacturer:
JSC "Masterclone", Moscow, tel. (495) 781-10-86
produced JSC "Pharmaceutical company" Lekko ", Russia.
601 125, Vladimir region., P Petushki, pos. Volginsky,
ph / fax (49243) 71-5-52.

Consumer Complaints sent to the JSC "Pharmaceutical company" Lekko ": 601 125, Vladimir region., P Petushki, pos. Volginsky, tel / fax (49243) 71-5-52.