

# Phenotropil®

**International Non-Proprietary Name (INN):** Phenylpiracetam

**Dosage Form:** pills (100 mg)

**Structure:** 1 capsule contains:

*Active ingredient:* N-carbamoylmethyl-4-phenyl-2-pyrrolidone 100 mg;

*Excipients:* lactose monohydrate (milk sugar) - 51.52 mg; potato starch - 46.48 mg; calcium stearate - 2 mg.

**Description:**

Flat-cylindrical pills in white colour with light cream or yellowish hue.

**Pharmacological classification:** nootropic

**ATC code:** N06BX

**Pharmacological action:** anti-asthenic, anticonvulsant, anxiolytic, nootropic, neuromodulatory

**Pharmacodynamics:**

Phenotropil acts as a neuromodulator, it exerts effect on the majority of neurotransmitter systems of the brain. The drug has a pronounced anti-amnesic effect, it activates the integrative activity of the brain, promotes memory consolidation, improves concentration and mental activity, facilitates learning processes, accelerates the information transfer between the cerebral hemispheres, increases the resistance of brain tissue to hypoxia and toxic effects, has anticonvulsant action and anxiolytic activity, regulates the processes of activation and inhibition of the central nervous system and improves mood.

Phenotropil has a positive effect on the metabolic processes and blood circulation of the brain, stimulates redox processes, increases the energy potential of the body through the glucose utilization and improves regional blood flow in the ischemic areas

of the brain. The drug increases the content of noradrenaline, dopamine and serotonin in the brain. It neither affects the GABA level or binds to GABAA and GABAB receptors, nor has a significant effect on spontaneous bioelectrical activity of the brain. Phenotropil does not influence respiratory or cardiovascular system. It has a mild diuretic effect and anorectic activity (with full treatment course). Phenotropil has a moderate activating effect on motor reactions, improves physical performance, antagonizes the catalepsy effect of neuroleptics and reduces the hypnotic action of ethanol and hexenal.

Psychostimulating effect of Phenotropil prevails in the ideational sphere. Moderate psychoactivating effect of the drug is combined with anxiolytic activity. Phenotropil improves mood and act as analgesic by raising the pain threshold. The drug also has an adaptogenic effect enhancing resistance to stress under increased mental and physical loads, fatigue, hypokinesia, immobilization and at low temperatures. Patients, who used Phenotropil, have noted vision improvement (increased acuity, brightness and fields of vision). The drug improves the blood supply of lower extremities. It stimulates the antibody response to antigen administration: therefore it shows immunostimulatory properties, but at the same time it does not cause immediate-type hypersensitivity reactions and does not change the allergic inflammatory reaction of skin caused by the introduction of foreign protein.

A course of treatment does not lead to drug dependence, tolerance or withdrawal syndromes. The action of Phenotropil appears after a single dose, which is important when using the drug in extreme conditions. Phenotropil does not have teratogenic, mutagenic, carcinogenic and embryotoxic properties. It is a low-toxic drug: the lethal dose in an acute experiment is 800 mg / kg.

**Pharmacokinetics:**

Phenotropil is quickly absorbed, it penetrates into various organs and tissues and easily passes through the blood-brain barrier

(BBB). Absolute bioavailability of the drug when taken orally is 100%.  $T_{max}$  in blood is 1 hour,  $T_{1/2}$  is 3-5 hours. Phenotropil is not metabolized in the body and is excreted unchanged: about 40% with urine and 60% with bile and sweat.

#### **Intended uses:**

- CNS disorders of various genesis, especially those related to vascular diseases and metabolic disorders in the brain, intoxication (particularly in posttraumatic states and chronic cerebrovascular insufficiency), accompanied by deterioration of intellectual-mnemonic functions and reduction of motor activity;
- neurotic states, manifested by atony, increased exhaustion, decreased psychomotor activity, attention failure and memory impairment;
- breakdown of the learning process;
- depressions of mild to moderate severity;
- psychoorganic syndromes, manifested by intellectual-mnemonic disorders and apathetic-abulic phenomena, as well as apathetic states in schizophrenia;
- convulsive states;
- obesity (alimentary-constitutional genesis);
- hypoxia prevention, increasing resistance to stress;
- correction of the functional state of organism in extreme conditions of professional activity with the purpose of fatigue prevention and increase of mental and physical working capacity;
- correction of daily biorhythm, inversion of the sleep-wake cycle;
- chronic alcoholism (in order to reduce asthenia, depression and intellectual-mnemonic disorders).

#### **Contraindications:**

Individual intolerance. It is not recommended for children, pregnant and lactating ladies due to the lack of clinical research data. (+See "With caution")

#### **With caution:**

Patients with severe liver and kidneys diseases, severe arterial hypertension, severe atherosclerosis, previous panic attacks and acute psychotic states accompanied by psychomotor agitation (due to the possible exacerbation of anxiety, panic, hallucinations and delirium), as well as patients prone to allergic reactions to nootropic drugs of the pyrrolidone group.

#### **Dosage and administration:**

Phenotropil should be taken orally straight after meal.

The dosage and duration of treatment should be determined individually by the doctor in accordance with the patient's condition. The average single dosage ranges from 100 to 250 mg and the average daily dosage from 200 to 300 mg. The maximally tolerated dosage is 750 mg per day. If the daily dose does not exceed 100 mg it is recommended to take it once a day in the morning, but if it is more than 100 mg, it should be divided into 2 administrations. Duration of the treatment course can vary from 2 weeks to 3 months, on average 30 days. If necessary, the course can be repeated in 1 month.

*To improve performance:* 100-200 mg once in the morning for 2 weeks (for athletes - 3 days).

*Alimentary-constitutional obesity:* 100-200 mg once a day (in the morning) for 30-60 days.

#### **Side effects:**

Insomnia (in case of drug administration later than 3 pm). During the first 1-3 days of admission some patients may suffer psychomotor agitation, hyperemia of the skin, warm flashes and hypertension.

#### **Overdose:**

No overdose cases have been reported. If necessary, conduct symptomatic therapy.

**Interaction with other drugs:**

Phenotropil can enhance the effect of CNS-stimulators, antidepressants and nootropics.

**Special instructions:**

It is not recommended to take Phenotropil after 3 pm. The administration of Phenotropil in patients with excessive psycho-emotional exhaustion resulted from chronic stress, fatigue and insomnia, in the first day of the treatment can cause a sharp need for sleep. Therefore it is recommended to begin the treatment course on non-working days.

**Pregnancy and lactation:**

Phenotropil is not recommended during pregnancy and lactation.

**Influence on the ability to drive vehicles and operate mechanisms:**

During the course of Phenotropil treatment it is recommended to avoid carrying out potentially dangerous jobs that require increased concentration of attention and quick psychomotor reactions, as well as driving vehicles.

**Terms of release from pharmacy:** on prescription.

**Storage conditions:** store in a dry dark place at temperatures no higher than 30°C. Keep out of reach of children.

**Shelf life:** 5 years. Do not use beyond the expiration date printed on the package.

**Country of manufacture:** Russia