Vinpotropile®

International Non-Proprietary Name (INN): Vinpocetine + Piracetam

Dosage Form: capsules

Structure: 1 capsule contains:
Active ingredient: vinpocetine 5 mg, piracetam 400 mg;
Excipients: lactose (milk sugar), talc;
Gelatin capsule's body composition: titanium dioxide, chinoline yellow, sunset yellow FCF, gelatin;
Gelatin capsule's cap composition: titanium dioxide, azorubine, gelatin.

Description: yellow capsule with a red cap. The capsule's content is powder of white or almost white color. Separate crystals and lumps can be present.

Pharmacological classification: psycho-stimulating and nootropic medication.

ATC code: N06BX

Pharmacological action: vasodilatory, antiaggregational, nootropic, antihypoxic, improving cerebral circulation

Pharmacodynamics:
Vinpotropile is a combination drug. It has properties of a medication improving the cerebral blood flow (Vinpocetine) and of a nootropic medication (Piracetam).
As a medication for improving the cerebral blood flow, it improves the metabolism of the brain increasing the glucose and oxygen consumption by the brain tissue. It increases the resistance of neurons to hypoxia; enhances the glucose transport to the brain, through the blood-brain barrier; makes the process of the glucose breakdown more energy efficient and aerobic; selectively blocks Ca2+-dependent phosphodiesterase; increases the levels of adenosine monophosphate (AMP), of cyclic guanosine monophosphate (cGMP) and adenosine triphosphate (ATP) of the brain. Increases the exchange of norepinephrine and serotonin of the brain; stimulates the ascending branch of the noradrenergic system, has an antioxidant effect. Reduces the platelet aggregation and increased blood viscosity; increases the elasticity of erythrocytes and blocks the utilization of adenosine by erythrocytes; helps to increase the return of oxygen by erythrocytes. Increases the cerebral blood flow; reduces the resistance of cerebral vessels without a significant change in indicators of the systemic blood circulation. Does not have the "steal" effect and enhances the blood supply, especially in ischemic areas of the brain. Penetrates through the placental barrier.
As a nootropic medication, it has a positive effect on the brain metabolic processes. It slightly increases the ATP concentration in the brain, enhances the synthesis of ribonucleic acid and phospholipids, stimulates glycolytic processes, enhances the utilization of glucose; improves the integrative activity of the brain, enhances memory consolidation, facilitates the learning process; changes the speed of the brain excitation spreading, improves microcirculation without having a vasodilatory action, inhibits the aggregation of activated platelets; has a protective effect in case of brain injury caused by hypoxia, intoxications, electric shock; strengthens alpha- and beta-activity, reduces delta-activity on the electroencephalogram, reduces the severity of the vestibular nystagmus; improves the connections between the cerebral hemispheres and synaptic conductivity in neocortical structures, increases mental activity, enhances cerebral blood flow; does not have sedative, psycho-stimulating effect. The effect develops gradually.
Vinpotropile has a pronounced effect on symptoms of initial manifestations of cognitive disorders of cerebrovascular origin in

elderly and senile patients. It is recommended in psychogeriatric practice.

Pharmacokinetics:

Vinpocetine

Absorption & distribution: Vinpocetine is quickly absorbed. The therapeutic concentration in plasma is 10-20 ng/ml. Time to reach the maximum concentration in blood plasma is 1 hour. Absorption occurs mainly in the proximal areas of the gastrointestinal tract.

Metabolism: It does not metabolize when it penetrates through the intestinal wall. The maximum concentration in tissues is reached 2-4 hours after the intake. Protein binding - 66%, bioavailability at the intake - 7%. The clearance of 66.7 l/h exceeds the plasma volume of the liver (50 l/h), which indicates extrahepatic metabolism. The main metabolite is apovincamine acid, which has some pharmacological activity. Other inactive metabolites are hydroxyvinpocetine, hydroxyapovinkaminic acid, hydroxyvinpocetin glycinate. At reingestion the kinetics is linear.

Excretion: The half-life in humans - (4.83 ± 1.29) hours. Excreted by the kidneys and through the intestine in the ratio of 3:2.

Piracetam

Absorption: After the intake Piracetam is well absorbed and it penetrates into various organs and tissues. Bioavailability is about 100%. After a single intake of 3.2 g the maximum concentration is 84 mcg/ml, after a multiple intake (3.2 g 3 times a day) - 115 mcg/ml. Time to reach the maximum concentration in plasma is 1 hour, in cerebrospinal fluid - 5 hours.

Distribution: The distribution volume is about 0.6 l/kg. It penetrates through the blood-brain and placental barriers, accumulates selectively in the tissues of the cerebral cortex.

Excretion: Almost does not undergo biotransformation and is excreted in the unchanged form by the kidneys through the glomerular filtration. The total clearance is 80-90 ml/min. The half-life from the blood plasma - 4-5 hours, from the cerebrospinal fluid - 8.5 hours.

Intended uses:

Cerebrovascular insufficiency (the recovery period after an ischemic and hemorrhagic stroke), Parkinsonism of the vascular genesis, intoxications, psycho-organic syndrome with prevailing symptoms of asthenia and adynamia, symptomatic treatment of dizziness, prevention of migraine and kinetosis.

Encephalopathy of various genesis, including alcoholism; brain trauma and other diseases of the central nervous system accompanied by the decrease of intellectual and mnestic functions; asthenic syndrome; labyrinthopathy, Meniere's syndrome.

Contraindications:

Hypersensitivity, severe cardiac rhythm disorders, cardiac ischemia (severe state), acute stage of hemorrhagic stroke, renal and/or hepatic impairment, intolerance to galactose, lactase deficiency or glucose-galactose malabsorption, children under 18 years old (due to insufficient data), pregnancy and lactation.

With caution: in case of disturbed hemostasis, severe bleeding; benign hyperbilirubinemia (including Gilbert's syndrome); viral hepatitis; alcoholic liver damage; alcoholism; deficiency of glucose-6-phosphate dehydrogenase; epilepsy; elderly age.

Dosage and Administration:

Ingest before eating with sufficient amount of water. For patients over 18 years old: 1-2 capsules 2-3 times a day. The last intake should be no later than 4 hours before sleep. Maintenance dose is 1 capsule 3 times a day. The duration of treatment lasts from 2-3 weeks to 2-6 months. Before cancellation the dose should be gradually reduced.

Side effects (rare):
The cardiovascular system: changes in the ECG (depression of the ST segment, prolongation of the QT interval), tachycardia, extrasystole, lability of arterial pressure (AP) (mainly a decrease).
The central nervous system (CNS): motor disinhibition, irritability, depression, asthenia, dizziness, headache, sleep disturbances (insomnia, increased drowsiness), mental agitation, balance disorder, exacerbation of epilepsy, anxiety, hallucinations, confusion, extrapyramidal disorders, decreased ability to concentrate.
The digestive system: nausea, vomiting, epigastric burning, diarrhea, abdominal pain, decreased appetite, gastralgia, constipation.
Metabolism: weight gain, increased sweating.
Hearing disorders: vertigo.
Dermatological reactions: dermatitis, itching, urticaria, skin hyperemia.
Allergic reactions: hypersensitivity, anaphylactic reactions, angioedema.

Overdose:
Symptoms: increased severity of side effects. Treatment: stomach lavage, activated carbon intake, symptomatic therapy.

Interaction with other drugs:
Increases the risk of hemorrhagic complications against heparin therapy, effects of thyroid hormones, antipsychotics (neuroleptics), indirect anticoagulants, psychostimulants.
Reduces the effect of anticonvulsants (reduces the convulsive threshold). Despite the lack of data confirming the possibility of interaction, it is recommended to exercise caution when co-prescribing drugs with central and antiarrhythmic mode of action.

Pregnancy and lactation:
The drug is contraindicated during pregnancy and lactation.

Influence on the ability to drive vehicles and mechanisms:
Taking into account possible undesirable effects, caution needs to be taken when operating mechanisms and driving vehicles.

Special precaution:
If the patient has the long QT syndrome (the length of the ventricular complex reflecting the length of the electrical systole of the ventricles) or takes medications that cause prolongation of the QT interval, periodic ECG (electrocardiogram, electrocardiography) monitoring is required.
In case of lactose intolerance, it should be taken into account that one capsule contains about 225 mg of lactose.

Terms of release from pharmacy: on prescription

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

Shelf life: 4 years. Do not use beyond the expiration date.

Country of manufacture: Russia