MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

INSTRUCTION

for medical use of the medicinal product

PHENIBUT

Registration number: LP-004478

Trade name: Phenibut

Group or chemical name: Aminophenyl butyric acid

Dosage form: pills

Composition per one pill

Active ingredient: Aminophenyl butyric acid hydrochloride - 250.0 mg;

Excipients: lactose (milk sugar) - 181.4 mg potato starch - 63.6 mg calcium stearate - 5.0 mg

Description: round, biconvex pills of white or white with a yellowish tint color with a facet and a risk

Pharmacotherapeutic group: other psychostimulants and nootropic agents.

ATC code: N06BX22

Pharmacological properties

Pharmacodynamics

Phenibut normalizes metabolic processes in the nerve cells of the brain. The active substance of the drug Phenibut (aminophenyl butyric acid hydrochloride) can be considered as a derivative of γ-aminobutyric acid (GABA) or as a derivative of β-phenylethylamine. Phenibut has nootropic activity and, as a derivative of GABA, possesses an anxiolytic (tranquilizing) effect. It does not affect cholinergic or adrenergic receptors.

The drug reduces tension, anxiety, fear, and improves sleep, hence it is used for the treatment of neuroses and preoperatively. Phenibut prolongs and enhances the action of hypnotics, narcotics, neuroleptics, and antiparkinsonian agents. Phenibut lacks anticonvulsant activity. It prolongs the latent period of nystagmus and shortens its duration and severity. The drug reduces manifestations of asthenia and vegetative symptoms, including headache, feeling of heaviness in the head, sleep disturbances, irritability, emotional lability, and increases mental performance.

Psychological indicators (attention, memory, speed, and accuracy of sensorimotor reactions) improve under the influence of Phenibut, unlike the effects of tranquilizers. Patients with asthenia and emotionally labile patients experience improved subjective well-being from the first days of therapy, increased interest and initiative, and motivation for activity.

Pharmacokinetics

Aminophenyl butyric acid is well absorbed after oral administration and penetrates into all tissues of the body, easily crossing the blood-brain barrier. In the brain tissue, approximately 0.1% of the administered dose of the drug penetrates, with significantly greater penetration observed in individuals of young and elderly age. It is metabolized in the liver, with 80-95% converted into pharmacologically inactive metabolites. About 5% is excreted unchanged by the kidneys, partially excreted in the bile. Cumulation is not observed with repeated administration.

Intended uses

Asthenic and anxiety-neurotic states; stuttering, tics, and enuresis in children; insomnia and nighttime anxiety in the elderly; Meniere's disease; dizziness associated with dysfunction of the vestibular analyzer of various origins; prevention of motion sickness in motion sickness; as part of complex therapy for alcohol withdrawal syndrome to alleviate psychosomatic and somatovegetative disorders.

Contraindications

Hypersensitivity to the active substance or excipients of the drug, pregnancy, breastfeeding, children under 3 years of age. The drug contains lactose. It should not be used in patients with rare congenital galactose intolerance, lactase deficiency, or glucose-galactose malabsorption.

With caution

Patients with erosive-ulcerative diseases of the gastrointestinal tract should be prescribed lower doses of the drug due to its irritating effect.

Dosage and administration

Orally after meals, with water. Do not chew. Pills can be divided.

Asthenic and anxiety-neurotic states

Adults: 250-500 mg 3 times a day. Maximum single dose - 750 mg (3 tablets), for patients over 60 years old - 500 mg. Administration course - 2-3 weeks. If necessary, the daily dose can be increased to 2500 mg. Administration course - 4-6 weeks. Children: from 3 to 8 years old - 125

mg 2-3 times a day; from 8 to 14 years old - 250 mg 2-3 times a day; children over 14 years old - adult doses.

Stuttering, tics, and enuresis in children

from 3 to 8 years old - 125 mg up to 3 times a day; from 8 to 14 years old - 250 mg 3 times a day; children over 14 years old - adult doses. Insomnia and nighttime anxiety in the elderly: 250-500 mg 3 times a day.

Meniere's disease, dizziness associated with dysfunction of the vestibular analyzer of various origins

During exacerbation, 750 mg is prescribed 3-4 times a day for 5-7 days, then 250-500 mg 3 times a day for 5-7 days, and then - 250 mg once a day for 5 days. For the treatment of dizziness with vestibular analyzer dysfunctions of vascular and traumatic origin - 250 mg 3 times a day for 12 days.

For the prevention of motion sickness

250-500 mg once 1 hour before the planned journey or at the onset of the first symptoms of motion sickness. The anti-motion sickness effect is enhanced with increasing doses of the drug. The drug is not very effective in severe cases of motion sickness ("intractable" vomiting and others).

As part of complex therapy for alcohol withdrawal syndrome to alleviate psychosomatic and somatovegetative disorders

In the first days of treatment, 250-500 mg 3 times a day and 750 mg at night are prescribed, with a gradual reduction of the daily dose to the usual adult dose.

Side effects

Phenibut, like other medications, may cause side effects, which do not occur in all patients. Usually, Phenibut is well tolerated.

Possible side effects include:

Nervous system disorders: drowsiness and exacerbation of symptoms (at the beginning of treatment), dizziness, headache;

Gastrointestinal disorders: nausea (at the beginning of treatment);

Skin and subcutaneous tissue disorders: allergic reactions (skin rash, itching);

Liver and biliary tract disorders: hepatotoxicity with prolonged use of high doses.

Overdose

The medicinal product is of low toxicity. There have been no reports of overdose.

Symptoms: drowsiness, nausea, vomiting, dizziness. Prolonged use of high doses may lead to eosinophilia, decreased blood pressure, renal impairment, and hepatic steatosis (with intake exceeding 7 g).

Treatment: gastric lavage, symptomatic treatment, maintenance of vital functions. There is no specific antidote.

Drug interaction

For mutual potentiation, aminophenyl butyric acid can be combined with other psychotropic drugs, reducing the doses of aminophenyl butyric acid and the combined medicinal products. Prolongs and enhances the effects of hypnotics, neuroleptics, antiepileptic drugs, and antiparkinsonian drugs.

Special precautions

During prolonged use (more than 2-3 weeks), it is necessary to monitor peripheral blood parameters and liver function every 2-3 weeks.

Pregnancy and lactation

The use during pregnancy and lactation is not recommended due to insufficient clinical observations. In experimental animal studies, no mutagenic, teratogenic, or embryotoxic effects of the drug have been established.

Influence on the Ability to Drive Vehicles and Operate Mechanisms

During treatment, caution should be exercised when driving vehicles and engaging in other potentially hazardous activities requiring increased concentration and psychomotor speed, as some patients may experience disturbances of the central nervous system, such as drowsiness and dizziness.

Dosage form

Pills 250 mg.

10 pills in a blister pack made of polyvinyl chloride film and aluminum foil with printed lacquer. 1, 2, 3, 4, 5 blister packs along with the instructions for use are placed in a cardboard box. 200, 400, 500, 600, 1000 blister packs along with an equal number of instructions for medical use are placed in a cardboard box (for hospitals).

Storage conditions

Store in a dry dark place at temperatures no higher than 25°C. Keep out of reach of children.

Shelf life

5 years. Do not use the drug after the expiration date indicated on the packaging.

Terms of release from pharmacy: On prescription.

Owner of the registration certificate

JSC "Usolie-Sibirsky Chemical and Pharmaceutical Plant" Russia, 665462, Irkutsk Region, Usolye-Sibirskoye city

Manufacturer/Organization handling claims

JSC "Usolie-Sibirsky Chempharm Plant" Russia, 665462, Irkutsk Region, Usolye-Sibirskoye city, northwest part of the city, northeast side, 115 meters from the Baikal Highway. Tel./Fax: +7 (39543) 58910, +7 (39543) 58908