

**NORMA KIDS**  
**Instructions**  
**on medical use of the drug**

**Trade name of the drug:** Norma Kids.

**Active ingredient:** Phenibut.

**Dosage form:** Powder for the preparation of solution for oral administration.

**Composition:** *1 sachet contains:*

Phenibut 100 mg;

*Excipients:* isomalt (E953), mannitol (E421), acesulfame potassium, natural orange flavor.

**Description:** Powder from white to light cream color, inclusions of yellow are allowed.

**ATX code:** N06BX22.

**Pharmacotherapeutic group:** Other psychostimulants and nootropics.

**Pharmacological properties:**

*Pharmacodynamics:*

The dominant effect of the drug is antihypoxic and antiamnestic action. **Norma Kids** stimulates learning processes, improves memory, and increases physical and mental performance. **Norma Kids** also has tranquilizer properties: it eliminates psycho-emotional stress, anxiety, fear, emotional lability, irritability, improves sleep, prolongs and enhances the effect of sleeping pills, narcotics, neuroleptics and anticonvulsants. Psychological indicators (attention, memory, speed and accuracy of sensory-motor reactions) improve under the influence of **Norma Kids**, in contrast to the effects of tranquilizers. The drug lengthens the latent period and reduces the duration and severity of nystagmus, and has an antiepileptic effect. Does not affect cholinergic and adrenergic receptors. **Norma Kids** significantly reduces the manifestations of asthenia and vasovegetative symptoms, including headaches and a feeling of heaviness in the head. In patients with asthenia and in emotionally labile individuals, from the first days of therapy with **Norma Kids**, their well-being improves, their interest and initiative increases, and motivation for activity occurs without unwanted sedation or agitation. It has been established that **Norma Kids** improves the bioenergetics of the brain.

*Pharmacokinetics:*

The drug is well absorbed after oral administration and penetrates well into all tissues of the body, passes well through the blood-brain barrier. Distribution in the liver and kidneys is close to uniform, but in the brain and blood it is less uniform. Within 3 hours, a noticeable amount of the drug is detected in the urine, while at the same time the concentration of the drug in the brain tissue does not decrease; it is detected in the brain after another 6 hours. The next day, the drug can only be detected in urine; it is found in urine 2 days after consumption, but the amount detected is only 5% of the administered dose. Greatest binding occurs in the liver (80%), it is not specific. With repeated administration, no accumulation is observed.

**Indications for use:**

- memory impairment, decreased concentration;
- insomnia;

- asthenic and anxious-neurotic states: anxiety, fear, anxiety;
- obsessive-compulsive neurosis, psychopathy;
- treatment of stuttering, enuresis, tics;
- hyperactivity in childhood;
- prevention of motion sickness during kinetosis;
- prevention of stressful conditions, before operations or painful diagnostic tests;
- Meniere's disease, dizziness associated with dysfunction of the vestibular apparatus of various origins.

**Directions for use and dosage:** The contents of the sachet are dissolved in half a glass of warm water and taken orally before meals. The course of treatment is 2-6 weeks.

*Children from 3 to 4 years:* 100 mg 2 times a day;

*Children from 5 up to 6 years:* 100 mg 2-3 times a day;

*Children from 6 to 10 years old:* 100 mg 3-4 times a day;

*Children from 10 to 14 years old:* 200 mg 2-3 times a day.

*To prevent motion sickness,* take 100 mg of the drug one hour before traveling by sea, land or air. If you miss a dose, take the drug as soon as you remember, but skip it if it is almost time for your next dose.

*Highest single doses for children :* up to 6 years – 100 mg, from 7 to 10 years – 200 mg, from 11 to 14 years – 300 mg.

**Contraindications:**

- hypersensitivity to the active substance or excipients of the drug;
- acute renal failure;
- children under 3 years of age.

**Drug interactions:** Prolongs and enhances the effects of hypnotics, narcotic analgesics, antiepileptic and antiparkinsonian drugs, tranquilizers and neuroleptics.

**Special instructions:** Patients with erosive and ulcerative diseases of the gastrointestinal tract should be careful due to the irritating effect of the drug . These patients are prescribed smaller doses of the drug . With long-term use, it is necessary to monitor liver function indicators and peripheral blood patterns.

**Overdose:**

**Norma Kids** is a low-toxic drug, only in a daily dose of 7-14 g with long-term use it can be hepatotoxic . The indicated doses significantly exceed the average therapeutic doses, according to the age of the child. Only at the highest dose, eosinophilia and fatty liver were observed. If the drug was used in lower doses, such changes were not observed.

*Symptoms:* drowsiness, nausea, vomiting, possible development of arterial hypotension, acute renal failure.

*Treatment:* gastric lavage, symptomatic therapy.

In case of complications (arterial hypotension, renal failure), auxiliary and symptomatic measures are taken.

**Side effects:**

After the first use of the drug, drowsiness, nausea, dizziness, headache are possible. Rarely - allergic reactions, including skin rash, itching.

**Storage conditions:** Shelf life 2 years.

Store in a dry place, protected from light, at a temperature not exceeding 25 °C.

Keep out of the reach of children.

**Release form:** 100 mg of the drug in a laminated bag. 10 sachets in a cardboard box.

**Dispensing conditions:** By prescription.

**Made for:**

**MAXX PHARM LTD.**

**London, Great Britain**

