

Package leaflet: information for the patient

NOOFEN 250 mg hard capsules Phenibutum

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Noofen is and what it is used for
2. What you need to know before you use Noofen
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1. What Noofen is and what it is used for

Noofen is a medicine, which decreases anxiety, agitation and fear; improves sleeping process; extends nystagmus (rapid, rhythmic eye movements) hidden period and decreases nystagmus duration and manifestation. Noofen diminishes also asthenia (physical and psychic weakness, general weakness) manifestation and symptoms including headache, feeling of hardness in the head, sleeping disorders, irritation, emotional lability (instability). Noofen increases mental activity. Attention, memory, speed of reaction and accuracy are improved under the effect of the medicine. In patients with asthenia and emotional lability Noofen improves the way one's feel, increases interest and initiative, activity motivation, not causing unnecessary calming effect or excitement.

Noofen is used:

- for the treatment of asthenic and anxious-neurotic states (anxiety, agitation and fear); in elderly – treatment of insomnia and night anxiety; prophylaxis of stress before surgery.
- for children – stuttering and ticks treatment.
- treatment of Meniere's disease (inner ear disorder) or dizziness related to dysfunction of vestibular apparatus of different origin.
- prophylaxis of kinetosis (specific state characterized by nausea, vomiting, prostration and vestibular disorders caused by unaccustomed motion, e.g. travelling by ship or airplane).

- an aid in alcoholism treatment to prevent cases of abstinence syndrome (withdrawal of alcohol).

2. What you need to know before you use Noofen

Do not use Noofen

- if you are allergic to phenibut and/or any of the other excipients (listed in section 6.);
- if you are pregnant or breastfeeding.

Warnings and precautions

Talk to your doctor or pharmacist before using Noofen:

- if you have gastric and duodenal ulcer, please tell your doctor. In this case the doctor decreases a dose for you.
- in case of prolonged administration the doctor may prescribe you to monitor blood and liver functions characteristics.

Other medicines and Noofen

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Noofen can be combined with psychotropics, decreasing dosage of Noofen and other drug used concomitantly with it.

Noofen prolongs and potentiates effects of hypnotics, narcotics, neuroleptics and antiparkinson drugs.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Noofen is contraindicated during pregnancy and breast-feeding.

Driving and using machines

Patients, who have somnolence or other central nervous system disorders during administration of the drug, should be careful.

Noofen contains 180 mg lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to use Noofen

Always use Noofen exactly as your doctor or pharmacist has told you. You should check with your doctor if you are not sure.

Capsule should be swallowed whole after meals with a sufficient amount of water. The capsule can't be chewed.

Asthenic and anxious-neurotic states: adults – 250-500 mg 3 times daily. Maximal single dose – 750 mg, for patients over 60 years – 500 mg. The course of treatment – 2-3 weeks. If necessary, the course of treatment can be prolonged till 4-6 weeks.

Meniere's disease and dizziness related to dysfunction of vestibular apparatus of different origin: in case of dysfunction of vestibular apparatus of infectious origin and during

exacerbation of Meniere's disease – 750 mg 3 times per day during 5-7 days, at decreased severity of vestibular disorders – 250-500 mg 3 times per day during 5-7 days, then – 250 mg a day for 5 days more. In case of mild state of disease – 250 mg twice per day during 5-7 days, then 250 mg one per day during 7-10 days. To prevent dizziness caused by dysfunction of vestibular apparatus of vascular and traumatic origin – 250 mg 3 times per day during 12 days.

Prophylaxis of kinetosis: 250-500 mg one hour before expected sway or at the first symptoms of kinetosis (ex. dizziness). In case of expressed symptoms (vomiting etc.) the use of the drug is less effective.

An aid to prevent alcohol abstinence syndrome: during the first days – 250-500 mg 3 times per day and 750 mg at bedtime; then a dose is gradually decreased.

In patients with liver function disorders high doses of Noofen can cause toxic effect on the liver. This group of patients should use low effective dose.

The data regarding Noofen unfavourable effect on *patients with renal disorders* using the medicine in therapeutic doses are not available.

The development of drug addiction and dependence, abstinence syndrome were not noticed.

Use in children and adolescents

Stuttering and ticks: 8 years till 14 years of age – a dose is 250 mg 3 times daily. Your doctor will determine the duration of treatment.

If you think that the drug effect is too strong or weak, consult your doctor.

If you have used more Noofen than you should

In case of overdose, immediately call your doctor or emergency service.

Symptoms: somnolence, nausea, vomiting, dizziness.

If you forget to use Noofen

Continue to use the drug as prescribed by the doctor. Do not take a double dose to make up for a forgotten dose.

If you stop using Noofen

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Rare (may affect up to 1 in 1,000 people)

Allergic reactions (rash, itch).

Not known (cannot be estimated from the available data)

Somnolence, nausea (at the beginning of treatment);

Headache, dizziness;
Hepatotoxicity (using high doses for a long time).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. How to store Noofen

Do not store above 25 °C. Store in the original package in order to protect from light and moisture.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the blister and the package after "Exp.". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Noofen contains

- *Active substance* is phenibut (Phenibutum).

Each Noofen hard capsule contains 250 mg of phenibut.

- *Other ingredients* are 180 mg of lactose monohydrate, potato starch, calcium stearate.

Content of a hard capsule: gelatin, titanium dioxide E171.

What Noofen looks like and contents of the pack

Hard white/white gelatin capsules No.0 containing white to white with a slightly creamy color powder.

10 capsules in blister, 2 blisters (20 capsules) and package leaflet in the carton box.

Marketing Authorisation Holder and Manufacturer

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