PACKAGE LEAFLET: INFORMATION FOR THE USER

NOOFEN 100 mg powder for oral solution
NOOFEN 500 mg powder for oral solution
Phenibutum

Read all of this leaflet carefully before you start taking 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

Noofen is a medicine that reduces anxiety, agitation and fear; improves sleep; prolongs hidden period of nystagmus (rapid, rhythmic eyeball movements) and reduces its duration and intensity. Noofen also diminishes symptoms of asthenia (physical and mental weakness, general weakness) including headache, feeling of heaviness in the head, sleep disturbances, irritability, emotional lability (instability). Noofen increases mental work capacity. The medicine ameliorates attention, memory, improves reaction rate and accuracy. In patients with asthenia and emotional lability, Noofen improves the way one feels, increases interest and initiative, motivation for activity, without causing unwanted sedation or agitation.

Noofen is used:
- for the treatment of asthenic and anxious-neurotic states (anxiety, agitation and fear); in elderly patients – for the treatment of sleeplessness and night anxiety; for the prophylaxis of stress before surgery;
- in children – for the treatment of stuttering and ticks;
- for the treatment of Meniere's disease (an inner ear disorder) and dizziness related to dysfunction of vestibular apparatus of different origin;
- for the prophylaxis of kinetosis (specific state characterized by nausea, vomiting, prostration and vestibular dysfunction caused by the location in a moving object such as a ship or airplane);
- as an aid in complex alcohol withdrawal (abstinence from alcohol) syndrome relief.

2. What you need to know before you take Noofen

Do not take Noofen
- if you are allergic to phenibut or any of the other ingredients of this medicine (listed in section 6);
- if you are pregnant or breast-feeding;
- if you have phenylketonuria.

Warnings and precautions
Talk to your doctor before taking Noofen:
- if you have gastric and/or intestinal ulcer. In this case, the doctor may reduce your dose of the medicine;
- if the medicine should be taken long-term, the doctor may ask you to perform tests to monitor blood and liver function parameters.

Other medicines and Noofen
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
The medicine can be combined with psychotropics, reducing the dosage of Noofen and drugs used concomitantly with it.
Noofen potentiates and prolongs effects of hypnotics, narcotics, antipsychotics and antiparkinson agents.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Noofen should not be used during pregnancy and breast-feeding period.

Driving and using machines
Patients who experience somnolence or other central nervous system disturbances while taking the medicine, must not drive or operate machinery during the manifestation of these adverse reactions.

Important information about ingredients of Noofen
Noofen100 mg and 500 mg powder for oral solution contains sugar substitute aspartame. Its use is contraindicated in patients with phenylketonuria.

3. How to take Noofen

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.
The content of sachet should be dissolved in half a glass of warm water and taken orally before meals.

Asthenic and anxious-neurotic states: for adults – 500 mg 1-3 times daily. The daily dose may be increased to 2.5 g, if required. The treatment course is 2-3 weeks. If necessary, the treatment course may be prolonged up to 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 – 500 mg 4 times daily during 5-7 days, when vestibular disturbances decrease – 500 mg 2-3 times daily during 5-7 days, then – 500 mg once daily for 5 more days. In case of mild course of disease – 500 mg daily during 5-7 days. To prevent dizziness caused by dysfunction of vestibular apparatus of vascular and traumatic origin – 500 mg 1-2 times daily during 12 days.

Prophylaxis of kinetosis: 500 mg one hour before expected rocking motion or at the first symptoms of kinetosis (e.g. nausea). In case of pronounced symptoms (vomiting etc.), the drug shows low efficacy.

As an aid in complex alcohol withdrawal syndrome relief: during the first days – 500 mg 2-3 times daily and 500 mg at bedtime, then the dose is gradually decreased.

In patients with impaired liver function, high doses of Noofen may cause toxic effects on the liver. The lowest effective dose should be used in this patient group.

There are no data available on adverse impact of Noofen on *patients with impaired kidney function* when taken the medicine at therapeutic doses.

Use in children and adolescents
In children from 3 to 4 years of age, the dose is 100 mg 2 times daily, from 5 to 6 years of age – 100 mg 2-3 times daily, from 7 to 10 years of age – 100 mg 3-4 times daily, from 11 to 14 years of age – 200 mg 2-3 times daily, in children from 14 years of age – adult doses are used.

The maximum single dose in children less than 6 years of age – 100 mg, from 7 to 10 years of age – 200 mg, from 11 to 14 years of age – 300 mg.

If it seems to you that the effect of the medicine is too strong or too weak, consult your doctor.

Development of tolerance or drug dependence, withdrawal syndrome has not been observed with this medicine.

If you take more Noofen than you should
Symptoms: somnolence, nausea, vomiting, dizziness. If you have taken more Noofen than you should, seek medical attention immediately.

If you forget to take Noofen
Continue to take the medicine as indicated by your doctor. Do not take a double dose to make up for a forgotten dose.

If you stop taking Noofen
If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, Noofen can cause side effects, although not everybody gets them.
Rare (affects up to 1 in 1000 patients):
- allergic reactions (skin rash, itch).

Not known (the frequency cannot be estimated from the available data):
- somnolence and nausea (in the beginning of treatment);
- headache and dizziness;
- toxic effects on the liver (with prolonged use of high doses).

If you notice any side effects not listed in this leaflet, or any of the side effects get serious, consult a doctor.

5. How to store Noofen

Do not store above 25 °C. Store in the original package in order to protect from moisture.
Keep out of the sight and reach of children.
Do not use this medicine after the expiry date, which is stated on the package. 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
The active substance: phenibut (Phenibutum).
The other ingredients: mannitol, aspartame, flavour „Orange Durarome".
Each sachet of Noofen 100 mg powder contains 100 mg of phenibut.
Each sachet of Noofen 500 mg powder contains 500 mg of phenibut.

What Noofen looks like and contents of the pack
NOOFEN 100 mg powder for oral solution
White to almost white with yellowish shade powder. The presence of yellow inclusions is allowed.
1 g of powder in a laminate (paper/polyethylene film/aluminium foil/polyethylene film) sachet.
15 sachets together with the package leaflet in a cardboard box.

NOOFEN 500 mg powder for oral solution
White to almost white with yellowish shade powder. The presence of yellow inclusions is allowed.
2.5 g of powder in a laminate (paper/polyethylene film/aluminium foil/polyethylene film) sachet.
15 sachets together with the package leaflet in a cardboard box.

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