PACKAGE LEAFLET: INFORMATION FOR THE USER

NOOFEN® 250 mg Tablets
Phenibutum

Read all of this leaflet carefully before you start using this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT NOOFEN® IS AND WHAT IT IS USED FOR

Noofen® is a medicine, which decreases anxiety, agitation and fear; improves insomnia; extends nystagmus (quick, rythmic eye-bulbe's movement) hidden period and decreases nystagmus duration and manifestation. Noofen® diminishes also asthenia (physical and psychic weakness, general feebleness) 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:
- asthenic and anxious-neurotic states (anxiety, agitation and fear); 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. BEFORE YOU USE NOOFEN®

Do not use Noofen®
- if you are allergic to fenibut and/or any of the other excipients of this medicine (mentioned in section 6).
- if you are pregnant or breastfeeding.

Warnings and precautions
Ask your doctor for advice before taking any medicine.
- if you have gastric and duodenal ulcer, please tell your doctor. In this case the doctor dicreases 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®
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
The medicine can be combined with psychotropics, decreasing dosage of Noofen® and other drugs used concomitantly with it.
Noofen® prolongs and potentiates effects of hypnotics, narcotics, neuroleptics and antiparkinson drugs.

Pregnancy and breast-feeding
Noofen® administration is prohibited during pregnancy and breast-feeding.

Driving and using machines
Patients, who have somnolence or other central nervous system disturbances during administration of the drug, should be careful.

Important information about some of the ingredients of Noofen®

The medicine contains 180 mg of lactose. If the doctor informed you that you have some sugar intolerability, consult the doctor before taking this medicine.

3. HOW TO USE NOOFEN®

Always use Noofen® exactly as your doctor has told you. You should check with your doctor if you are not sure.
Noofen® tablets are administered orally after meals with water.

Asthenic and anxious-neurotic states: adults – 250-500 mg 3 times daily. Maximum 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.

Children: till 8 years - a single dose is 125 mg, 8 till 14 years - 250 mg 3 times daily. The doctor indicates the treatment period.

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, to decrease vestibular disturbances– 250 mg– 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. nausea). 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.
If you think that the drug effect is too strong or weak, consult your doctor.
The development of drug addiction and dependence, abstinence syndrome were not noticed.

If you have used more Noofen® than you should
In case of overdose, immediately call your doctor or emergency service.

If you forget to take 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 taking Noofen®
If you have any further questions on the use of this product, ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Noofen® can cause side effects, although not everybody gets them. In the beginning of administration of the drug or in case of overdose there can be somnolence or nausea. Rare – allergic reactions. In case of prolonged administration, hepatotoxicity is possible (toxic effect on liver).
If you notice any side effects, please consult your doctor. This refers also to possible side effects not listed in this leaflet.

5. HOW TO STORE NOOFEN®

Do not store above 25 °C. Protect from light and moisture.
Keep out of the reach and sight of children.
Do not use Noofen® after the expiry date, which is stated on the blister and the package. The expiry date refers to the last day of that month.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND FURTHER INFORMATION

What Noofen® contains
Active substance is fenibut (Phenibutum)
Each Noofen® tablet contains 250 mg of fenibut.
Other excipients are Lactose 180 mg, potato starch, calcium stearate.

What Noofen® looks like and contents of the pack
White to white with a weak yellowish colour, round flat tablets with bevelled edge and break line on one side of the tablet.
10 tables in blister, 20 tablets (2 blisters) in the carton pack.

Marketing Authorisation Holder and Manufacturer
JSC Olainfarm
Address: 5, Rupnicu St., Olaine, LV-2114, Latvia.
Phone +371 67013701 • Fax +371 67013777 • e-mail: olainfarm@olainfarm.lv

This leaflet was last revised in 24.02.2009.

Translation from Latvian according to the original document.

Translation was carried and updated by
Larisa Želnina
Senior Regulatory Affairs specialist
Date:19.02.2013