PACKAGE LEAFLET: Information for the user

NIKOTINAMID

Tablets – 200 mg

(Nicotinamide)

Read all of this leaflet carefully before you start taking 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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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 NIKOTINAMID IS AND WHAT IT IS USED FOR

Nicotinamide and nicotinic acid (vitamin PP), are water-soluble vitamin B substances. They are converted in organism to nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP). These two products are important coenzymes which are involved in the respiratory chain.

Nicotinic acid deficiency develops when the dietary intake is inadequate. Deficiency leads to the development of a syndrome known as pellagra, characterized by skin lesions, especially on areas exposed to sunlight, with hyperpigmentation and hyperkeratinisation. Other symptoms include diarrhoea, abdominal pain, glossitis, stomatitis, loss of appetite, headache, lethargy, and mental

and neurological disturbances.

It is indicated in:

- cases of increased needs for nicotinamide, eg. during pregnancy and breastfeeding;
- debilitated persons and diabetic persons;
- a range of organic and functional diseases of the brain blood vessels (obliterating atherosclerosis, cerebral embolism, spastic migraine);
- organic peripheral vascular disease (Morbus Buerger);
- functional peripheral vascular disease as Raynaud's disease, acrocyanosis;
- infectious diseases, metabolic disorders, allergies, anorexia, vomiting;
- ophthalmology; used in burns of conjunctiva and cornea from the heat of chemical substances, in diseases of fundus oculi and optic nerve due to vascular diseases;
- otorhinolaryngology; indicated in spastic damage of hearing and vestibular damage;
- stomatitis, glossitis, gingivitis, aphthae;
- dermatology; used in eczema, frostbite, toxic dermatitis, alopecia areata.

Your doctor may have given to you Nikotinamid for another purpose. Ask your doctor if you want to know why you were given Nikotinamid.

2. BEFORE YOU TAKE NIKOTINAMID

Do not take Nikotinamid if you:

- have hemorrhagic conditions (bleeding in the gastrointestinal tract, cerebral haemorrhage, hemoptysis, hematuria);
- suffer from acute glomerulonephritis;
- suffer from decompensated heart defects;
- have history of myocardial infarction.

Take special care with Nikotinamid

Inform your doctor if you:

- have history of peptic ulcers;
- have gout;
- have liver impairment;

- are elderly.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Nikotinamid.

Please, tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Remember to tell your doctor about the treatment with Nikotinamid if you are prescribed another drug during treatment, especially one of the following:

- beta-blockers, because their antihypertensive effect may be potentiated by Nikotinamid;
- lovastatin, because their concomitant use may increase the risk of myopathy.

Taking Nikotinamid with food and drinks

There are no data on the interaction of this drug with food and drinks.

Pregnancy

Tell your doctor or pharmacist if you are pregnant, or planning to get pregnant.

Nikotinamid is indicated in pregnancy.

Breastfeeding

Tell your doctor or pharmacist if you are breastfeeding.

Nikotinamid is indicated during breastfeeding.

Driving and using machines

Nikotinamid does not lower your ability to drive or use machines.

Important information about some of the excipients of Nikotinamid

Nikotinamid contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE NIKOTINAMID

The usual dose is 200 mg, 2 – 3 times daily.

Always take Nikotinamid tablets only as your doctor has told you. If you feel that the effects of Nikotinamid are too strong or too weak, talk to your doctor or pharmacist.

Your doctor may ask you to take Nikotinamid for a longer time. Ask your doctor for advice if you are not sure for how long you should take it.

If you take more Nikotinamid than you should

If you take more Nikotinamid than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.

If you forget to take Nikotinamid

If you forget to take one dose, take the next dose in its usual time.

Do not take a double dose to make up a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

All medicines can cause side effects. Sometimes they are serious, most of the times not. Do not panic by this list of possible side effects. You may not get any of them.

Tell your doctor if any of the following side effects concerns you. The use for a long time and with high doses may favor these effects:

- cognitive and fatty degeneration;
- liver hypertrophy.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE NIKOTINAMID

Keep away from children!

Do not use after the expiry date which is stated on the package.

Store under 25°C! Keep in the original packaging to protect it from light and humidity.

6. FURTHER INFORMATION

What Nikotinamid contains

The active substance is nicotinamide.

Each tablet contains 200 mg nicotinamide.

The excipients are: maize starch, lactose, povidone, microcrystalline cellulose, magnesium stearate, talc and sodium starch glycolate.

Contents of the pack

Box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in September 2023.