

NEOFEN

60 mg suppository

IBUPROFEN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Neofen is and what it is used for
2. Before you use Neofen
3. How to use Neofen
4. Possible side effects
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1. WHAT NEOFEN IS AND WHAT IT IS USED FOR

NEOFEN suppositories contain ibuprofen, which belongs to the group of nonsteroidal antiinflammatory medicines (NSAIDs).

NEOFEN suppositories are used for:

- Fast lowering of elevated body temperature
- Relieve pain such as pain during teething, toothache, earache, headache, sore throat and pain with strains and sprains
- Relieve symptoms of colds and flu.

NEOFEN suppositories are intended for the treatment of children aged 2 years (minimum 12.5 kg body weight) to 6 years.

2. BEFORE YOU USE NEOFEN

Do not use NEOFEN suppositories

- in children under the age of 2 years, or body weight less than 12.5 kg
- in children who are allergic to the active substance or any of the other ingredients of the medicine
- in children with severe liver, kidney and/or heart failure
- in children who in the past had bleeding from the stomach when taking ibuprofen, acetylsalicylic acid and other similar medicines
- in children who have or have had the ulcers on the stomach or other disorders of the digestive system
- in children who have experienced difficulty in breathing, worsening asthma, allergic rash or itching and runny nose when taking ibuprofen, acetylsalicylic acid and other similar medicines.
- in adults NEOFEN suppositories should not be used by pregnant women in the last trimester of pregnancy.

Be especially careful with Neofen

Before the start of the application talk to your doctor if your child:

- suffers from asthma
- there's a disruption in the work of the kidney and/or liver
- has problems with the stomach or intestines (such as Crohn's disease or ulcerative colitis) or disorder in the rectum (the end portion of the large intestine) or anus
- suffers from connective tissue disorders such as systemic lupus erythematosus (SLE)
- has or has had high blood pressure and / or heart failure
- has idiopathic thrombocytopenic purpura (ITP), bleeding in the brain or is prone to bleeding.

Stop the further use of the medicinal product, and notify your doctor immediately if you notice any unusual symptoms in a child, especially bleeding from the gastrointestinal tract soon after you have applied the suppository.

Medicines like NEOFEN are associated with a small increase in the risk of heart attack or stroke. This risk increases at high doses or with prolonged therapy.

Do not exceed the recommended daily dose of the medicine nor recommended duration of therapy (3 days).

If your child suffers or was suffering from asthma or allergies, then there may be a shortness of breath when using this medicine.

Discontinue use of this product if you notice the appearance of skin rash, sores in the mouth or any other signs of allergic reactions.

If you are not sure whether any of the above applies to your child, contact your doctor.

If you apply suppositories NEOFEN in adults

If necessary, NEOFEN 125 mg suppositories can be administered in adults. Pregnant and lactating women and the elderly must consult a doctor before using NEOFEN 125 mg suppositories.

The above warnings and information also apply to adults.

In older people the frequency of adverse reactions with NSAIDs is increased, such as bleeding in the digestive system (stomach, intestine) which can be life threatening.

Taking other medicines with Neofen

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

Special caution is necessary if your child is taking:

- painkillers or NSAIDs such as acetylsalicylic acid, ibuprofen, or other NSAIDs
- medicines for the treatment of high blood pressure or heart failure such as diuretics (medications for urination), ACE inhibitors, Angiotensin II receptor antagonists, or beta blockers
- medicines for blood clotting (anticoagulants such as warfarin, heparin, Ticlopidine)
- methotrexate, cyclosporine, lithium or zidovudine
- antidepressants (such as selective serotonin reuptake inhibitors)
- corticosteroids (anti-inflammatory medicines)
- aminoglycosides or probenecid
- medicines for the treatment of diabetes

3. HOW TO USE NEOFEN

Always use NEOFEN suppositories exactly as your doctor tells you. You should check with your doctor or pharmacist if you are not sure.

Before applying wash and dry your hands, carefully remove the suppository from the pack and insert it into child's large intestine (rectum).

Wash your hands after applying suppositories.

If a child needs to defecate, make sure to do so before applying suppositories.

Make sure the child does not swallow suppository.

NEOFEN suppositories must not be used in children weighing less than 12.5 kg.

Children aged 2 to 4 years (12.5 – 17 kg body weight)

Apply one suppository every 6 – 8 hours.

The maximum daily dose is three suppositories per day.

Children aged 4 to 6 years old (17-20.5 kg body weight)

Apply one suppository every 6 hours.

The maximum daily dose is four suppositories per day.

NEOFEN suppositories are intended for short-term use.

Stop the use of the medicinal product and contact your doctor if your child's symptoms last longer than 3 days, or if they get worse, or if you notice the appearance of new symptoms.

If you use more NEOFEN suppository than you should

Application of multiple NEOFEN suppositories will rarely cause some problems.

Contact your doctor if you have exceeded the recommended daily dose of the medicine.

If you forget to use NEOFEN suppositories

If you have missed a dose of NEOFEN, in case there is still a fever or pain, apply the next dose. The time interval between doses should not be less than 6 hours. Never apply two doses of the medicine at once.

If you have any further questions on the use of NEOFEN suppository, talk to your doctor or to the pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, NEOFEN suppositories may cause side effects.

Unwanted effects may be reduced by applying the minimum effective dose during the shortest possible time.

Very common (affects more than 1 in 10 patients)

Common (affects 1 in 10 patients)

Uncommon (affects 1 out of 100 patients)

Rare (occurring in 1 in 1000 patients)

Very rare (affects 1 in 10000 patients)

Unknown (frequency cannot be estimated from the available data)

Disorders of the digestive system

The most common side effects of medications from a group of nonsteroidal anti-inflammatory medications are side effects to the digestive system.

Uncommon: pain in the abdomen, nausea, disorders of digestion.

Rare: diarrhea, bloating, constipation, vomiting.

Very rare: perforation (rupture of the wall) or bleeding from the digestive system with the appearance of black stools and/or vomiting of blood, the appearance of the lesion on the mucous membranes of the oral cavity, gastritis, worsening the symptoms of ulcerative colitis and Crohn's disease.

Disorders of the nervous system

Uncommon: headache.

Kidney and urinary system disorders

Very rare: renal disorders, increased values of urea in the blood.

Hepatobiliary disorders

Very rare: liver function disorders, jaundice, and inflammation of the liver, increased values of enzymes in the blood.

Blood and lymphatic system

Very rare: blood count disorders (reduction in the number of red and white blood cells, and platelets). These disorders are manifested as an elevated body temperature, sore throat, sores in the mouth, flu-like symptoms, strong fatigue, bleeding from the nose and mouth.

Disorders of skin and subcutaneous tissue

Very rare: severe forms of skin reaction such as Bullous (bubble) changes, including erythema multiform, Toxic Epidermal Necrolysis, Stevens - Johnson syndrome.

Disorders of the immune system

Very rare: in patients with current autoimmune disorders (such as systemic lupus erythematosus, mixed connective tissue disease) during treatment with NEOFEN, have been reported with individual cases the symptoms of unseptical meningitis, such as in a stump neck, headaches, nausea, vomiting, fever, or disorientation.

Hypersensitivity reactions

Uncommon: urticaria (hives), itching.

Very rare: severe hypersensitivity reactions whose symptoms may be swelling of the face, tongue, and larynx, difficulty breathing, fast heart rate, decreased blood pressure, swelling of the skin or mucous membrane, severe shock.

Cardiac disorders

Very rare: swelling, heart failure and high blood pressure in treatment with high doses of the medicines from the group of NSAIDs.

Disorders of the respiratory system

Very rare: the reactivity of the respiratory system that causes asthma, exacerbation of asthma, difficulty breathing.

If you notice any side effect, talk to your doctor or pharmacist.

5. HOW TO STORE NEOFEN

Keep out of reach and sight of children.

Store at a temperature below 30 ° C.

Shelf life is 24 months from the production date stated on the carton.

NEOFEN suppositories must not be used after the expiry date stated on the carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that you no longer need. These measures will help to protect the environment.

6. FURTHER INFORMATION

What NEOFEN contains

The active substance is ibuprofen.

1 suppository contains: 125 mg of ibuprofen.

Auxiliary substance is a solid fat.

How NEOFEN looks like and contents of the pack

NEOFEN 125 mg suppository is white or almost white in color.

10 (2 x 5) suppository in the strip (Al/PE) packaging, in a box.

Regime of dispensing

The medicine is issued without the doctor's prescription

Manufacturer

BELUPO Ijekovi i kozmetika, d.d.

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