

PATIENT PACKAGE INSERT ACCORDING TO THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is sold without a doctor's prescription

Nurofen for Children Suppositories 60 mg

Nurofen for Children Suppositories 125 mg

The active ingredient and its quantity:
Each suppository of Nurofen for Children Suppositories 60 mg contains: Ibuprofen 60 mg
Each suppository of Nurofen for Children Suppositories 125 mg contains: Ibuprofen 125 mg
For the list of inactive ingredients, see section 6.

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.

This medicine is not intended for infants under 3 months of age or weighing less than 6 kg.

Use in children younger than 6 months of age is with a doctor's prescription only and according to the doctor's instructions.

You must use the medicine according to the instructions in the dosage sections in this leaflet.

Consult a pharmacist if you need additional information. You must refer to your doctor if the symptoms of the illness worsen or do not improve:

In infants aged 3 – 5 months – after 24 hours.

In children and adolescents above 6 months of age – after 3 days.

Refer to the doctor if your child develops a rash, breathing problems, diarrhea or increased fatigue.

1. What is the Medicine Intended for?

For relief of mild to moderate pain and reduction of fever.

Therapeutic group: Non-steroidal anti-inflammatory (NSAIDs).

2. Before Using the Medicine

This medicine is suitable for most children but certain children must avoid using it. Consult a pharmacist or doctor if you are not sure.

Do not use the medicine if:

- The patient is hypersensitive (allergic) to ibuprofen or any of the additional ingredients that the medicine contains (see section 6).
- The patient has experienced an allergic reaction in the past (such as bronchospasm, asthma, runny nose, angioedema or urticaria), associated with aspirin (acetylsalicylic acid) or to another medicine from NSAIDs group.
- You are in the last three months of pregnancy.
- The patient has suffered in the past from gastrointestinal bleeding or perforation, associated with a previous treatment with NSAIDs.
- The patient suffers or has suffered in the past from recurring peptic ulcer (at least two different incidents of proven peptic ulcer in the gastrointestinal tract or bleeding, or other abnormalities in the gastrointestinal tract).
- The patient suffers from severe renal, cardiac or hepatic insufficiency.

Special warnings regarding the use of this medicine Before treatment with Nurofen for Children Suppositories, tell your doctor if:

- The patient suffers or has suffered in the past from **high blood pressure, heart problems or stroke**, since there may be a slight increase in the risk of occurrence of heart problems as a result of use of ibuprofen.
- The patient suffers from a risk factor for **heart problems such as diabetes or high cholesterol**.
- The patient suffers from **asthma or any other allergic disease of the lungs**.
- The patient suffers or has suffered from **problems of liver, kidney, heart, or intestine**. The patient suffers or has suffered from **systemic lupus erythematosus (SLE, an autoimmune disease)**, from inflamed skin accompanied by blisters and peeling skin (exfoliative dermatitis), from Stevens-Johnson syndrome or similar diseases.
- The patient suffers from a **chronic inflammatory bowel disease** such as Crohn's disease or ulcerative colitis.
- The patient suffers from problems in the rectum or anus.
- stop using the medicine if an ulcer or bleeding in the stomach appear during the use of Nurofen for children suppositories.
- The patient suffers from an infection - as Nurofen For Children Suppositories may hide signs of infections such as fever and pain. It is therefore possible that this medicine may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.
- The patient is dehydrated, because of a risk of renal impairment.
- Serious skin reactions have been reported in association with Nurofen For Children Suppositories treatment. You should stop taking Nurofen For Children Suppositories and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first sign of a very serious skin reaction. See section 4.

Additional warnings

The following warnings relate mainly to adults:

- Medicines like Nurofen for Children Suppositories may be associated with a slight increase in risk of heart attack (myocardial infarction) or stroke. The probability of risk increases with taking higher dosages and with prolonged duration of treatment. Do not exceed the recommended dosage nor a treatment duration exceeding 3 days.
- A **risk of heart attack or stroke**: if you suffer from heart problems, or you had a stroke, or you think that you are at a risk of these conditions (for example if you suffer from hypertension, diabetes, high cholesterol, or if you smoke) you must talk to the doctor or pharmacist about the treatment.
- Elderly**: elderly patients are more likely to suffer from side effects such as stomach bleeding or perforation which may be life threatening. You must talk to the doctor before the use of this medicine.

Refer to a doctor immediately if:

- Your child's symptoms do not disappear quickly or if they worsen.
- You are not sure what is your child's illness or the illness is accompanied by a rash, breathing difficulties, diarrhea or increased fatigue.

Interactions/ drug interactions:

Refer to the doctor or pharmacist if the patient is

taking or having recently taken any other medicines, including non-prescription drugs and nutrition supplements. Especially if the patient is taking:

- Other medicines that contain **ibuprofen, aspirin, or other medicines of the NSAIDs group (such as cyclooxygenase 2 inhibitors (COX-2 inhibitors))** including medicines that you can purchase without prescription.
- Diuretics** (help with urination)
- Anticoagulants** (blood thinners such as warfarin, heparin)
- Medicines for treating hypertension** (such as: captopril, atenolol, losartan)
- Lithium** (for mood disorders)
- Methotrexate** (for psoriasis, arthritis and types of cancer)
- Zidovudine** (for HIV- human immunodeficiency virus)
- Corticosteroids** (anti-inflammatory medicine)
- Probenecid** (for the treatment of gout)
- Aminoglycoside** (type of antibiotics)
- Oral hypoglycemic medicines** (for diabetes).
- Cardiac glycosides** (for heart problems)
- Cyclosporine or Tacrolimus** (to prevent organ rejection after a transplant)
- Quinolone type antibiotics** (for infections)
- Anti-depressants of the SSRI group**
- Antiplatelets** such as dipyridamol, clopidogrel
- Mifepristone** – (for termination of pregnancy) - do not use the medicine around or 12 days after taking mifepristone.

Several anticoagulants (i.e. blood-thinners/anti-thrombotic, such as aspirin/acetylsalicylic acid, warfarin, ticlopidine), several medicines for reducing high blood pressure (ACE inhibitors such as captopril, beta-blockers such as atenolol or angiotensin II receptor blocker such as losartan) and other medicines may affect or be affected by the treatment with ibuprofen. Therefore you should always consult a doctor before using ibuprofen with other medicines.

If you are not sure about the medicines the patient is being treated with, show the medicines to a doctor or a pharmacist.

Pregnancy, breastfeeding and fertility:

Pregnancy: Ibuprofen belongs to a group of medicines that may harm women's fertility. This condition is reversible after discontinuing the use of the medicine. If taken occasionally, it is unlikely that this medicine will affect the chance of getting pregnant.

However if you are trying to conceive, consult a doctor before using the medicine.

It is not recommended to use ibuprofen during the first 6 months of pregnancy, consult a doctor before using this medicine during the first 6 months of pregnancy.

Do not use Nurofen for Children Suppositories if you are in the last 3 months of pregnancy.

Breastfeeding

Ibuprofen and its metabolites can pass through breast milk in very low concentrations. There is no knowledge of harmful effects on infants, therefore there is no need to stop breastfeeding in case of short-term treatment with the medicine when used according to the recommended dosage for the treatment of mild to moderate pain and fever reduction.

Driving and use of machinery

The medicine has no effect or has a negligible effect on the ability to drive or operate machinery.

3. How to use the medicine?

Check with your doctor or pharmacist if you are not sure about the dosage and the treatment regimen of the product.

The product is intended for children older than 3 months, weighing at least 6 kg. For children weighing under 12.5 kg, use Nurofen for Children Suppositories 60 mg. You should wait at least 6 hours between doses. The usual recommended dose is:

Age	Weight (kg)	Initial dosage	Giving another suppository	No. of suppositories per 24 hours
Infants aged 3-5 months weighing more than 6 kg	6-8	1 suppository of 60 mg	If necessary, after 6-8 hours	up to 3 suppositories
9 months-2 years	8-12.5	1 suppository of 60 mg	If necessary, after 6 hours	up to 4 suppositories
Children aged 2-4 years	12.5-17	1 suppository of 125 mg	If necessary, after 6-8 hours	up to 3 suppositories
Children aged 4-6 years	17-20.5	1 suppository of 125 mg	If necessary, after 6 hours	up to 4 suppositories

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.

Dosage for adults - consult a doctor.
Do not administer this medicine to an infant below the age of 3 months, unless instructed by the doctor.

Warning: do not exceed the recommended dose.

Treatment duration

For short-term use only.
If the symptoms worsen or last longer than 24 hours in infants aged 3-5 months, consult a doctor.
If the symptoms worsen or last longer than 3 days in infants aged 6 months and older, consult a doctor.
If the symptoms last over 3 days, if the pain or fever worsen or if new symptoms appear, discontinue the treatment immediately and consult a doctor or pharmacist.

Route of administration

Do not swallow. For rectal use (anus).

Directions for use

The child should attempt a bowel movement before inserting the suppository into the anus (rectum).
How to insert the suppository:
First wash your hands properly and wipe them. Unwrap the suppository and wet it with a little water. Lie on the side. Insert the suppository as deep as possible into the rectum, using a finger. If the suppository is too soft to penetrate, cool it in the refrigerator for 30 minutes or place it under a stream of cold water before removing the wrapper.

Wash your hands after inserting the suppository.

If you have used or have given an overdose to your child or if a child accidentally taken the medicine - always refer to a doctor or proceed to the nearest hospital in order to get an opinion on the risk and advice on action to be taken. The symptoms may include nausea, gastrointestinal bleeding, abdominal pain, vomiting (there may be a small amount of blood), headache, ringing in the ears, confusion, nystagmus (shaky eye movement) and more rarely diarrhea.

At high doses vertigo, blurred vision, low blood pressure, excitation, disorientation, coma, hyperkalemia (raised

blood potassium levels), increased prothrombin time/INR, acute renal failure, liver damage, respiratory depression, cyanosis, exacerbation of asthma in asthmatics, drowsiness, chest pains, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

If you forgot to use or administer the medicine

If you forgot to use or administer a dose, use or administer the next dose if necessary, only if at least 6 hours have passed since the previous dose was used/administered. Do not use/administer a double dose.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult a doctor or a pharmacist.

4. Side effects

Like any medicine, the use of Nurofen for Children Suppositories may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them. The most common side effect is stomach irritation which may cause problems such as indigestion and heartburn.

Stop use of this medicine and tell your doctor immediately in case of:

- Blood in the stools
- Black tarry stools
- Vomiting blood or dark particles that look like coffee granules
- Unexplained wheezing, shortness of breath, skin rash (which may be severe and accompanied by blisters or peeling skin), severe allergic reactions such as Stevens-Johnson syndrome, itching and bruising, tachycardia, fluid retention (swollen ankles or a decrease in the amount of urine passed)
- Swelling of the face, tongue or throat
- Neck stiffness, headache, nausea, vomiting, fever and disorientation

Stop use of this medicine and tell your doctor in case of:

- Unexplained abdominal pain, indigestion, heartburn, nausea or vomiting
- Yellowing of the eyes, pale stools and dark urine, liver problems
- Severe throat pain accompanied by high fever
- Unexplained bleeding or intracranial hemorrhage, bruising or fatigue, increased frequency of infections such as the common cold

Additional side effects:

Uncommon side effects (appear in 1-10 users out of 1,000)

- Headache

Rare side effects (appear in 1-10 users out of 10,000)

Diarrhea, swelling or constipation. Tell the doctor if these symptoms last for more than a few days or are bothersome.

Very rare side effects (appear in less than one user out of 10,000):

- Renal problems or renal failure may occur while using ibuprofen
- Stroke or heart problems may occur while using ibuprofen. These conditions are unlikely with dose level administered to children.
- Worsening of colitis and Crohn's disease.
- high blood pressure
- Severe skin infections and soft tissues complications when infected with chicken pox (Varicella)

Side effects with unknown frequency (effects for which a frequency has not yet been determined):

A severe skin reaction known as DRESS syndrome (Drug Reaction with Eosinophilia and Systemic Symptoms). Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase in the number of eosinophils (a type of white blood cells).

A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk and upper extremities accompanied by fever at the initiation of treatment (acute generalized exanthematous pustulosis, AGEP). Stop using Nurofen for Children Suppositories if you develop these symptoms and seek medical attention immediately. See also section 2.

If a side effect appears, if one of the side effects worsens, or if you or the patient suffer from a side effect which is not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link 'Report Side Effects of Drug Treatment' found on the homepage of the Ministry of Health's website (www.health.gov.il) which links to an online form for reporting side effects, or by the following link: <http://sideeffects.health.gov.il>

5. How to Store the Medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Storage conditions:** Store below 25°C.

6. Additional Information

In addition to the active ingredient, the medicine also contains:

Nurofen for children suppositories 60 mg: Hard fat 1 (Witespol H15), Hard Fat 2 (Witespol W45)
Nurofen for children suppositories 125 mg: Hard fat
What the medicine looks like and what the package contains:
Nurofen for Children Suppositories 60 mg: Smooth white torpedo shaped suppository
Nurofen for Children Suppositories 125 mg: Smooth white, yellowish-white torpedo shaped suppository
Every package contains 10 white suppositories packaged in aluminum/polyethylene foil.

Registration Holder's name and address:
Reckitt Benckiser (Near East) Ltd., 6 Hanagar St., Hod Hasharon 4527704.

Manufacturer's Name and address:
Reckitt Benckiser Healthcare International Ltd., Hull, England.

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Drug registration numbers at the national medicine registry of the Ministry of Health:

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