

Patient Package Insert according to Pharmacists' Regulations (Preparations), 1986.

Use in children under 6 month of age is according to a doctor's prescription only.

Over 6 months of age – this medicine is sold without a doctor's prescription.

Nurofen for Children orange flavor 100 mg/5 ml suspension

Nurofen for Children strawberry flavor 100 mg/5 ml suspension

The active ingredient and its concentration:

Each 5 ml contains: Ibuprofen 100 mg

For list of inactive ingredients, please see section 6. See also section "Important information about some of the ingredients of this medicine".

Read this leaflet in its entirety carefully before you start using this medicine. The leaflet contains concise information about this medicine. If you have any further questions, ask your doctor or pharmacist.

Use this medicine in accordance with the dosage instructions in this leaflet. Consult a pharmacist if you need additional information.

You must refer to a doctor if the signs of the illness (symptoms) worsen or do not improve after 24 hours in infants between 3-6 months of age, or after 3 days in 6-months-old or older children.

This medicine is intended for most infants over the age of 3 months, children, and adults. Use in children between 3-6 months of age is according to a doctor's prescription.

You must refer to a doctor if your child is taking more than 75 mg of aspirin a day, or if your child is developing a rash, breathing difficulties, diarrhea, or increased fatigue.

1. What is this medicine intended for?

For reduction of fever and relief of mild to moderate pain, for infants and children between 3 months old to 12 years of age (weighing about 40 kg).

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

2. Before using this medicine

This medicine is suitable for most people, but some people should avoid using it. If you are in any doubt, consult a doctor or pharmacist.

Do not use this medicine if:

- You or your child are hypersensitive (allergic) to ibuprofen or to any of the additional ingredients this medicine contains (see section 6).
- You or your child have had allergic reactions (such as asthma, runny nose (rhinitis), swelling of the lower layer of skin (angioedema) or hives (urticaria) after taking ibuprofen, acetylsalicylic acid (aspirin) or any other medicine from the non-steroidal anti-inflammatory group (NSAIDs).
- You or your child have (or you or your child have had) peptic ulcer or gastric bleeding (two separate confirmed incidents or more of perforation or bleeding).
- You or your child have suffered in the past from gastrointestinal hemorrhage or perforation as a result of taking non-steroidal anti-inflammatories (NSAIDs).
- You or your child have severe liver, kidney, or heart failure.
- You are in the last three months of pregnancy.

Special warnings regarding the use of this medicine

Before treatment with Nurofen for Children, tell the doctor if:

- You or your child suffer or have suffered from **hypertension, heart problems or stroke**, since there is a slight increase in the risk of heart problems when using ibuprofen.
- You or your child suffer from a risk factor for **heart problems**, such as **diabetes or high cholesterol**.
- You or your child suffer from **asthma** or an **allergic disease of the lungs**.
- You or your child suffer or have suffered from **liver, kidney, heart or bowel problems**.
- You or your child suffer from dehydration, since there is a risk of kidney problems.
- You or your child suffer from **systemic lupus erythematosus (SLE)**, an autoimmune disease) or from a similar disease.
- You or your child suffer from an **inflammatory bowel disease** such as Crohn's disease or inflammation of the colon (ulcerative colitis).
- You or your child suffer from **chickenpox (varicella)**. It is recommended to avoid using Nurofen for Children when the patient has chickenpox.

Additional warnings

The following warnings refer mainly to the use of this medicine in adults. In any case, they should be taken into consideration before taking or administering this medicine:

- There might be a connection between medicines like Nurofen and a slight increase in the risk of heart attack (myocardial infarction) or stroke. The probability of this risk will increase in a case of prolonged treatment and when taking high dosages. Do not exceed the recommended dose or duration of treatment.
- If you have heart problems, have undergone a stroke or you think you are at risk of these conditions (for example, if you have high blood pressure, diabetes or high cholesterol, or if you smoke), talk to a doctor or pharmacist.

If you are elderly, talk to a doctor before taking this medicine.

Refer to a doctor immediately if:

- **Your child's symptoms worsen or do not subside quickly.**
- **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

Tell the doctor or pharmacist if you or your child are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements. Especially if you or your child are taking:

- **Other medicines containing ibuprofen or other medicine from the non-steroidal anti-inflammatory group**, including those sold without a prescription.
- **Low doses of aspirin** (up to 75 mg daily).
- **Diuretics** (for treatment of fluid retention).
- **Anticoagulants** (blood-thinners such as warfarin).
- **Antihypertensives** (such as: captopril, atenolol, losartan).
- **Lithium** (for mood disorders).
- **Methotrexate** (for psoriasis, arthritis and different types of cancer).
- **Zidovudine** (for HIV, the Human immunodeficiency Virus).
- **Corticosteroids** (anti-inflammatory medicine).
- **Cardiac glycosides** (for treatment of heart problems).
- **Cyclosporine or tacrolimus** (to prevent organ rejection after a transplant).
- **Mifepristone** (for pregnancy termination).
- **Quinolone type antibiotics** (for infections).
- **Antidepressants from the SSRI group.**
- **Antiplatelets** such as: dipyridamole, clopidogrel.

If you are unsure about the medicines your child is being treated with, show the medicine to a doctor or a pharmacist.

Use of this medicine and food

Patients with a sensitive stomach may take this medicine with or after a meal.

Pregnancy, breastfeeding and fertility

Pregnancy

Consult a doctor before using this medicine during the first 6 months of pregnancy. Do not use Nurofen for Children if you are in the last 3 months of pregnancy.

Breastfeeding

Several studies found very low concentrations of ibuprofen in breast milk, although it is unlikely that such amounts would have an effect on the nursing baby.

Fertility

Ibuprofen belongs to a group of medicines which may impair fertility in women. This condition is reversible after discontinuing the use of the medicine. If taken occasionally, it is unlikely that this medicine will affect your chances of getting pregnant. However, if you are having difficulties getting pregnant, consult a doctor before using this medicine.

Driving and use of machinery

Taken at the recommended dose and duration of treatment, this medicine has no effect on the ability to drive or operate machines.

Important information about some of the ingredients of this medicine

- This medicine contains maltitol. If you have been told by a doctor that you have intolerance to fructose, you must consult a physician before using this medicine.
- Maltitol may cause mild diarrhea.

3. How to use this medicine

Check with the doctor or pharmacist if you are unsure about the dosage and manner of treatment. The usual recommended dosage is:

Dosage chart by weight

Weight (kg)	Dosage	No. of times in 24 hours
	By ml for use in measuring syringe	
Below 5 kg	According to doctor's prescription	
5-5.4	2 ml	3-4
5.5-8.1	2.5 ml	3-4
8.2-10.9	3.75 ml	3-4
11-15	5 ml	3-4
16-21	7.5 ml	3-4
22-26	10 ml	3-4
27-32	12.5 ml	3-4
33-43	15 ml	3-4

Dosage chart by age

Age (years)	Dosage	No. of times per 24 hours
	By ml for use in measuring syringe	
3-6 months	According to doctor's prescription	
6-11 months	2.5 ml	3-4
12-23 months	3.75 ml	3-4
2-3	5 ml	3-4

4-5	7.5 ml	3-4
6-8	10 ml	3-4
9-10	12.5 ml	3-4
11-12	15 ml	3-4

The weight of children of the same age differ significantly.

Therefore, you should make an effort to determine the weight of the child and administer the dosage according to the dosage chart by weight. Only if you cannot verify the weight of the child, should the dosage be determined according to the dosage chart by age.

Do not administer this medicine to infants below the age of 3 months or to infants who weigh less than 5 kg, unless instructed by the doctor.

The doses should be administered every 6-8 hours at intervals of at least 4 hours between doses.

Do not take more than the recommended dose in 24 hours.

Use in infants between 3-6 months of age is according to a doctor's prescription. Over the age of 6 month, the use is without a doctor's prescription.

If you know the weight of the child – administer the dosage as indicated in the dosage chart by weight. **Only if the child's weight is unknown** – the dosage will be determined by the dosage chart by age.

Warning: do not exceed the recommended dose.

Treatment duration

For short-term use only.

Do not administer this medicine to infants between 3-6 months of age for more than 24 hours. If the symptoms worsen or persist after 24 hours, consult a doctor.

Do not administer this medicine to infants over the age of 6 months for more than 3 days. If the symptoms worsen or persist after 3 days, consult a doctor.

Directions for use

Always shake the bottle well before use.

Opening instructions

To remove the cap- press it downward and turn it anti-clock wise.

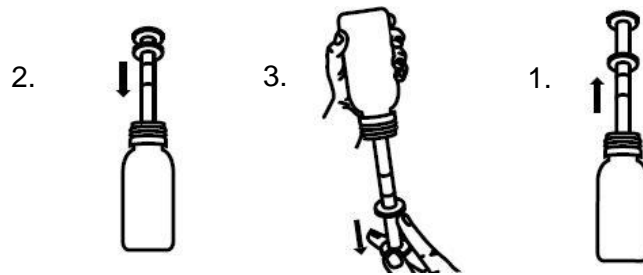
Child-resistant safety caps have significantly reduced the number of yearly drug-induced poisoning cases. However, if you have trouble opening the package, ask your pharmacist to remove the cap's safety mechanism and turn it into a standard, easy to open cap.

Directions for use:

The package contains a syringe for measuring a 5 ml dose.

Use the syringe intended for measuring the correct amount of medicine. If no measuring device is enclosed in the package, consult a pharmacist. Do not use a household teaspoon to measure the dosage. Household teaspoons vary in size and you may not get the correct dosage.

1. Push the syringe firmly into the special opening in the neck of the bottle.
2. To fill the syringe, turn the bottle upside down while holding the syringe in place. Gently pull the plunger down while drawing the medicine to the correct mark on the syringe. See dosages charts.
3. Turn the bottle right side up and remove the syringe by turning it gently.
4. Insert the tip of the syringe into the child's mouth and press the plunger down to gently administer the medicine.
5. After use, close the bottle using the cap, wash the syringe in warm water and let it dry.



If you or your child have taken a higher dosage than necessary or if a child has accidentally swallowed this medicine, proceed immediately to a doctor or to the nearest hospital and seek medical advice on the risk involved and course of action. Symptoms may include nausea, abdominal pain, vomiting (there may be a small amount of blood), headache, ringing in the ears, confusion and jerky eye movement.

In high doses, drowsiness, chest pain, severe palpitations, loss of consciousness, convulsions (especially in children), weakness and dizziness, blood in the urine, cold sensation in the body, and breathing problems have been reported.

If you forgot to use this medicine

If you forgot to administer or take this medicine at the set time, administer or take the next dose as required, providing at least 4 hours have passed since the previous dose was taken. **Do not administer or take 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 pharmacist.

4. Side effects

As with any medicine, the use of Nurofen for Children may cause side effects in some users. Do not be alarmed while reading the list of side effects. You might not suffer from any of them.

The most common side effect is gastric irritation which can cause problems such as indigestion and heartburn.

Stop administering this medicine to your child and refer to a doctor immediately in case of:

- Blood in the stools.
- Black tar-like stools.
- Vomiting blood or dark particles that look like coffee grounds.
- Unexplained wheezing, asthma, shortness of breath, skin rash (might be severe and accompanied by blisters or skin peeling), itching or appearance of bruises, severe skin reactions including Stevens–Johnson syndrome, rapid heart rate, fluid retention (swollen ankles or decrease in amount of urine).
- Stiff neck, headache, nausea, vomiting, fever and disorientation.
- Swelling of the face, tongue or throat (these can be signs of severe allergic reactions).
- Severe skin reaction known as DRESS syndrome (Drug Reaction with Eosinophilia and Systemic Symptoms). DRESS symptoms include: skin rash, fever, swelling of the lymph nodes and an increase in the number of eosinophils (a type of white blood cell).

Stop use of this medicine and refer to a physician in case of:

- Unexplained abdominal pain, indigestion, heartburn, nausea or vomiting.
- Yellowing of the eyes, pale stool and dark urine (these can be signs of kidney or liver problems).
- Severe sore throat accompanied by high fever.
- Unexplained bruising or bleeding, fatigue, contracting more infections than usual such as mouth ulcers, colds, sore throat, fever (these can be signs of anemia or other blood disorders).

Additional side effects

Uncommon side effects:

- Headache.

Rare side effects:

- Diarrhea, flatulence or constipation. Tell the doctor if these side effects last several days or are bothersome to you or your child.

Very rare side effects:

- Kidney or liver problems may occur when using ibuprofen.
- Stroke or heart problems may occur when using ibuprofen. The likelihood of this is low at the dosage level administered to children.
- Worsening of inflammation of the colon (colitis) and Crohn's disease.
- Hypertension.
- Peptic ulcer, gastric bleeding, inflammation of the gastric mucosa.

Side effects with unknown frequency:

- In rare cases, severe skin and soft tissue infections have occurred during chickenpox (Varicella).

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

Reporting of side effects

Side effects can be reported to the Ministry of Health via the link "Report Side Effects of Drug Treatment" found on the home page of the Ministry of Health's website (www.health.gov.il), which directs to the online form for reporting side effects.

<http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@mo.h.health.gov.il>

5. How to store this medicine

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

Store at a temperature below 25°C.

The preparation can be used for 6 months after initial opening of the bottle.

6. Additional information

In addition to the active ingredient, this medicine contains:

Nurofen for Children orange flavor:

Xanthan gum, Sodium citrate, Citric acid, Orange 2M-16014, Sodium saccharin, Sodium chloride, Maltitol liquid, Domiphen bromide, Glycerin, Polysorbate 80, Purified water.

Nurofen for Children strawberry flavor:

Xanthan gum, Sodium citrate, Citric acid monohydrate, Strawberry flavor 500244E, Sodium saccharin, Sodium chloride, Maltitol liquid, Domiphen bromide, Glycerol, Polysorbate 80, Purified water.

This medicine contains maltitol. The caloric value of maltitol: 2.3 kcal/g.

Each 5 ml contains 9.24 mg Sodium.

What this medicine looks like and what the package contains:

Nurofen for Children orange flavor: Milky colored, orange flavored suspension, marketed in

packages of 100 ml, 150 ml and 200 ml. Not all packaging sizes may be marketed.
Nurofen for Children strawberry flavor: Milky colored, strawberry flavored suspension, marketed in packages of 100 ml, 150 ml and 200 ml. Not all packaging sizes may be marketed

Registration holder:

Reckitt Benckiser (Near East) Ltd., 6 Hanagar St., Hod Hasharon, 4527704.

Manufacturer:

Reckitt Benckiser Healthcare Ltd., Hull, England.

This leaflet was checked and approved by the Ministry of Health in January 2015 and was updated in accordance with the Ministry of Health's instruction in January 2019.

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

Nurofen for Children orange flavor: 116-31-29724-22

Nurofen for Children strawberry flavor: 138-05-31635-00

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