

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

This medicine can be sold without a doctor's prescription.

Nurofen for Children Chewable Capsules 100 mg

Active ingredient and its quantity:

Each soft chewable capsule contains: Ibuprofen 100 mg

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

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

Use the product according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need additional information.

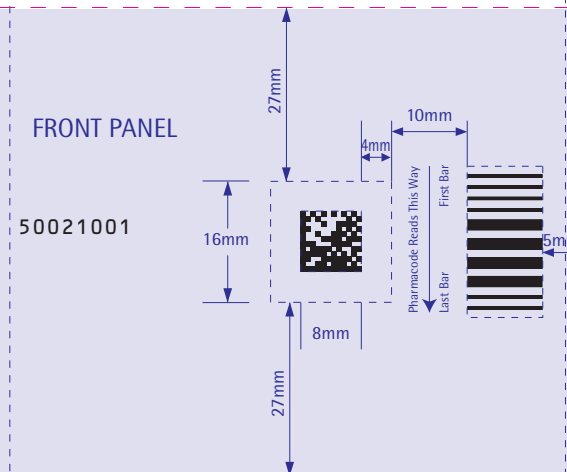
Refer to the doctor if the child's symptoms of illness worsen or do not improve after 3 days and after 10 days for adults.

The medicine is intended for **adults and children over the age of 7 years.**

Refer to the doctor if the patient is taking aspirin at a dosage above 75 mg a day, another medicine from the NSAIDs family (including selective cyclooxygenase 2 inhibitors) or if the patient develops a rash, breathing difficulties, diarrhea or increased tiredness.

1. What is the medicine intended for?

The medicine is intended for the relief of mild to moderate pain such as a sore throat, dental pain,



earache, headache, minor aches and sprains and also the reduction of fever.

Therapeutic group: Non Steroidal Anti Inflammatory Drugs (NSAIDs).

2. Before using the medicine

Do not use the medicine if you or your child:

- are hypersensitive (allergic) to ibuprofen or to any of the other ingredients this medicine contains (see section 6).
- have ever suffered from allergic reactions (such as asthma, rhinitis, angioedema or urticaria) after taking aspirin or other Non Steroidal Anti Inflammatory drugs (NSAIDs).
- have ever suffered from recurrent peptic ulcer/hemorrhage (two or more significant events of proven perforation or bleeding).
- have ever suffered from upper gastrointestinal bleeding or a perforation, related to previous treatment with NSAIDs.
- have severe kidney, heart or liver failure.
- are allergic to peanuts or soy, as this medicine contains soy lecithin.
- the child is under 7 years of age.
- you are in the last trimester of pregnancy.

Special warnings regarding the use of this medicine Before treatment with Nurofen for Children Chewable Capsules 100 mg, tell the doctor if you or your child:

- suffer or have suffered in the past from **high blood pressure, heart problems or stroke**, because there is a small increase in the risk of heart problems while using ibuprofen.
- have a risk factor for **heart problems such as diabetes or high cholesterol**
- suffers from **asthma or any allergic disease of the lungs**
- suffers or have suffered from **liver, kidney, heart or bowel problems**
- suffers from **dehydration**, as there is a risk of kidney problems.
- suffers from **SLE (Systemic Lupus Erythematosus**, a disease in which the immune system affects connective tissues and causes joint pain, skin changes and disorders in other organs), or a mixed connective tissue disease
- suffer from a **hereditary blood formation disorder** (Acute Intermittent Porphyrin)
- suffer from **chronic inflammatory bowel disease**, such as Crohn's disease, or ulcerative inflammation of the large intestine (ulcerative colitis)
- have recently undergone **major surgery**
- **Suffering from an infection** – as Nurofen for Children Chewable Capsules 100 mg may hide signs of infection such as fever and pain. Therefore, this medicine may delay appropriate treatment of an infection, which may lead to an increased risk of complications. This has been observed with bacterial pneumonia and bacterial skin infections related to chicken pox (varicella). If you are taking this medicine while you have an infection and the symptoms of infection persist or worsen, consult the doctor without delay.
- It is recommended to avoid using the medicine during the period when there is chicken pox (Varicella).

Skin reactions

Serious skin reactions have been reported in association with Nurofen for Children Chewable Capsules 100 mg treatment. Stop taking the medicine and seek medical attention immediately if the child develops a skin rash, lesions on mucous tissues, blisters or other signs of allergy as these can be initial signs of a very serious skin reaction. See section 4.

If you are an adult taking this medicine

The following warnings in addition to the warnings and information noted above apply to you:

Ibuprofen belongs to a group of medicines which may impair fertility in women. This is reversible upon discontinuing the use of the medicine. It is not likely that this medicine, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before using this medicine if you have difficulties in becoming pregnant.

You should only take this product on a doctor's advice during the first 6 months of pregnancy.

DO NOT use this medicine during the last 3 months of pregnancy.

Medicines such as Nurofen for Children Chewable Capsules 100 mg may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. The risk increases with higher dosage and prolonged use. Do not exceed the recommended dose or recommended duration of treatment.

If you suffer from heart problems, have had a stroke in the past or think that you may be at risk for these medical problems, (for example if you have high blood pressure, diabetes, high cholesterol or you smoke), talk to the doctor or pharmacist about your treatment.

If you suffer from a blood clotting disorder or have a different bleeding problem, talk to the doctor or pharmacist about your treatment.

In limited studies, ibuprofen has been found to be present in breast milk in a very low concentration, and it is not likely that it will adversely affect the breastfed infant.

Elderly patients

If you are elderly, talk to the doctor before taking the medicine, as you be more likely to suffer from side effects.

Drug interactions:

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

- Other medicines containing **ibuprofen or other NSAIDs**
- **Low dosage aspirin** (up to 75 mg a day)
- **Diuretics** (help with urination)
- **Anticoagulants** (blood thinners such as warfarin)
- Medicines for high blood pressure (such as **captopril, atenolol, losartan**).
- **Lithium** (for mood disorders)
- **Phenytoin** (antiepileptic)
- **Methotrexate** (for psoriasis, arthritis and certain types of cancer)
- **Zidovudine** (for AIDS, HIV)
- **Corticosteroids** (anti-inflammatories medicines such as prednisone)
- **Cardiac glycosides** (for heart problems)
- **Cyclosporine or tacrolimus** (to prevent organ rejection after transplant)
- **Mifepristone** (for termination of pregnancy)
- **Antibiotic from the quinoline group** (for infections)
- **Probencid and sulfapyrazone** (to treat gout)
- **SSRI antidepressant** medicines
- Antiplatelets (blood thinning medicines) such as **dipyridamole, clopidogrel**
- **Medicines from the sulfonylurea family** (to lower blood sugar level)

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

This medicine can be taken on an empty stomach without water. However, a small number of patients may experience mild indigestion with this medicine. If the patient experiences mild indigestion, it is recommended to take the medicine with food or milk to prevent gastrointestinal problems.

Pregnancy, breastfeeding and fertility:

Pregnancy

This medicine has a possible side effect of renal injury in the fetus and low levels of amniotic fluid as of the 20th week of pregnancy. It is recommended to avoid using medicines of the NSAIDs class as of the 20th week of pregnancy.

Consult the 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

In a few cases, very low concentrations of ibuprofen have been found in breast milk, however it is not likely that these amounts will affect the breastfed infant.

Fertility

Ibuprofen belongs to a group of medicines which may impair fertility in women. This is reversible upon discontinuing use of the medicine. It is not likely that occasional use of this medicine will affect your chances of becoming pregnant, however, tell the doctor before using the medicine if you suffer from difficulties in becoming pregnant.

Driving and using machines:

No effects on the ability to drive and operate machines are expected with the recommended dosages and duration of treatment.

Important information about some of the ingredients of this medicine

The medicine contains soy lecithin. If the patient is hypersensitive to peanuts or soy, do not take this medicine.

The medicine contains glucose and sucrose. If you have been told by the doctor that you have an intolerance to certain sugars, consult with the doctor before taking the medicine.

The medicine contains less than 1 millimole of sodium (23 mg) in a dose, i.e., it is essentially "sodium-free".

3. How to use this medicine

Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The usual recommended dosage is: 5-10 mg per each kg of bodyweight for each dose.

Weight (kg)	Age (approximate)	Dosage
20-29	7-9 years	1-2 chewable capsules, 3 to 4 times a day (24 hours)
30-40	10-12 years	2-3 chewable capsules, 3 to 4 times a day (24 hours)
Above 40 kg	Over 12 years	2-4 chewable capsules, 3 to 4 times a day (24 hours)

Children of the same age can have significantly different weights. Therefore, an effort should be made to check the child's weight and determine the dosage according to the weight table. Only if it is not possible to check the child's weight, dosage should be determined according to age.

Duration of treatment

For short term use only. Administer a dose approximately every 6-8 hours (or with an interval of at least 6 hours between doses, if necessary). Take the lowest dose for the shortest time in order to relieve the symptoms.

If treatment is needed for more than 3 days in children, or if the symptoms worsen, consult the doctor.

Adults and children 12 years of age and older: Do not take more than 12 chewable capsules in 24 hours.

If the patient has an infection, consult the doctor without delay if the symptoms (such as fever and pain) do not

improve or worsen (see section 2).

Warning: Do not exceed the recommended dose.

Method of administration:

The capsules should be chewed and then swallowed, with or without a drink.

Do not split or crush the capsule.

If the child has accidentally taken a higher dosage, proceed immediately to a doctor or to a hospital emergency room and bring the package of medicine with you.

The symptoms can include nausea, stomach pain, vomiting (there may also be vomiting streaked with blood), headache, ringing in the ears, confusion and shaky eye movements. At high dosages there have been reports of: drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in the urine, cold body feeling and breathing problems.

If you forgot to administer this medicine, administer the next dose when needed, provided that the previous dose was given at least 4 hours earlier. **Do not administer a double dose** to make up for a forgotten 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 use of the medicine, consult a doctor or pharmacist.

4. Side effects

Like any medicine, the use of Nurofen for Children Chewable Capsules 100 mg may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

The most common side effect is stomach irritation which can cause problems such as digestive difficulties and heartburn.

Stop giving the medicine and tell the doctor immediately in the case of:

- Blood in the stools
- Black tarry stool
- Vomiting blood or dark particles that look like coffee grounds
- Unexplained wheezing, asthma, shortness of breath, skin rash (which may be serious, accompanied by blisters or peeling of the skin), serious skin reactions including Stevens-Johnson syndrome, itching or bruising, light-headedness, racing heart, fluid retention (swollen ankles or decreased amounts of urine)
- Stiff neck, headache, nausea, vomiting, fever and disorientation
- Swelling of the face, tongue or throat (these can be signs of serious allergic reactions)

Stop administering the medicine and tell the doctor if the patient experiences one of the following side effects:

- Unexplained stomachache, indigestion, heartburn, nausea or vomiting
- Yellowing of the eyes and/or skin, pale stools and dark urine
- Serious sore throat accompanied by high fever
- Unexplained bruising or tiredness or an increased tendency for infections such as colds.

Other side effects which may occur:

Uncommon side effects (affects 1 to 10 users in 1,000):

- Headache

Rare side effects (affects 1 to 10 users in 10,000):

- Diarrhea, gas, vomiting or constipation. Tell the doctor if these side effects last more than a few days or if they become bothersome.

Very rare side effects (affects less than 1 user in 10,000):

- Kidney and liver problems
- Stroke or heart problems. This is unlikely to occur at the

dosage level given to children.

- Worsening of inflammation of large intestine (colitis) and chronic inflammatory bowel disease (Crohn's disease)
- High blood pressure
- Peptic ulcer, abdominal bleeding, inflammation of the gastric mucosa

Side effects with unknown frequency:

In exceptional cases, serious infections of the skin and soft tissues have occurred during chicken pox (varicella).

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

• A red, scaly widespread rash, with bumps under the skin and blisters located mainly on the skin folds, on the body (excluding the legs and head) and on the upper limbs, accompanied by fever at the beginning of the treatment (acute generalized exanthematous pustulosis). See also section 2.

• The skin becomes sensitive to light.

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" that can be found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link: <https://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. Medicines should not be disposed of via wastewater or household waste. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. Additional information

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

Purified water, glucose liquid, sucrose, gelatin, glycerin, fumaric acid, citric acid, sucralose, natural orange flavour*, acesulfame K, disodium edentate, red iron oxide, yellow iron oxide, medium chain triglycerides, isopropyl alcohol, lecithin, stearic acid, opacode WB white NS-78-18011.

*The flavour contains: (R)-p-mentha-1,8-diene (d-limonene), Ethyl acetate and Alpha-Pinene

What the medicine looks like and what the package contains:

Orange, square shaped, soft gelatin capsules with the inscription "N100" in white.

Each package contains 12 capsules in a blister pack.

Registration holder and its address: Reckitt Benckiser (Near East) Ltd., 6 Hanagar St., Hod Hasharon, 4527704.

Manufacturer and its address: Reckitt Benckiser Healthcare International Ltd., Nottingham, England.

Revised in December 2021 according to MOH guidelines.

Drug registration number at the National Drug Registry of the Ministry of Health: 167-26-35768-00

Nurofen Child Chewable Caps 100 mg PIL PB1221-01