

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

This medicine can be sold without a doctor's prescription

Nurofen® Liquid Capsules 200 mg

Composition:
Each liquid capsule contains: Ibuprofen 200 mg

Inactive ingredients: see the list in section 6.

– **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, refer to the doctor or pharmacist.

– This medicine is intended for adults and children over 12 years of age. Under this age, refer to a doctor. Take medicine in the correct manner. Consult a pharmacist if you need additional information. You must refer to the doctor if the signs of the illness (symptoms) worsen or do not improve within 10 days in adults and within 3 days in adolescents (12-18 years).

1. What is the medicine intended for?

Nurofen Liquid Capsules 200 mg is intended for relief of mild to moderate pain such as: headache, toothache, menstrual pain, backache and muscular pain, anti-inflammatory for rheumatic diseases and for the reduction of fever.

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

Nurofen Liquid Capsules 200 mg contains ibuprofen, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs. These medicines act by changing the body's response to pain, swelling and high temperature.

2. Before using the medicine

Do not use the medicine if:

- you are hypersensitive (allergic) to ibuprofen or to any of the other ingredients this medicine contains (see list in section 6) or to aspirin or to other non-steroidal anti-inflammatory drugs (NSAIDs).
- you have suffered from gastrointestinal bleeding or perforation following the use of ibuprofen, aspirin or other medicines of the non-steroidal anti-inflammatory drug group (NSAIDs).
- you suffer or have suffered in the past (2 or more cases) from gastrointestinal ulcers, perforation, bleeding or disturbances.
- you have previously experienced hypersensitivity (such as: shortness of breath, worsening of asthma, runny and itchy nose, swelling of the face, lips, tongue or throat, or allergic rash) when taking ibuprofen, aspirin or a similar analgesic (of the NSAID group).
- you are under 12 years of age.
- you suffer from severe liver failure or severe renal failure or severe heart failure.
- you are in the last three months of pregnancy (see "Fertility, Pregnancy and Breastfeeding" section).

Special warnings regarding the use of this medicine
Before treatment with Nurofen Liquid Capsules 200 mg, tell the doctor if you:

- suffer or have suffered in the past from asthma.
- suffer from kidney or liver problems.
- suffer from heart problems including heart failure, angina pectoris or if you have previously had a heart attack, coronary artery bypass surgery, peripheral artery disease (impaired blood circulation from legs or feet as a result of narrowed or blocked arteries) or any kind of stroke (including a "mini-stroke" or transient ischemic attack (TIA)).
- suffer from gastrointestinal problems (such as Crohn's disease or ulcerative colitis).
- suffer from high blood pressure, diabetes, high cholesterol, or you have a history of heart disease or stroke or if you are a smoker.
- suffer from a head injury, unexplained bleeding or an increase in intracranial pressure.
- suffer from connective tissue diseases such as systemic lupus erythematosus (lupus).
- are over 65 years of age, since the elderly have a higher risk of suffering from side effects such as stomach bleeding and perforation, which may be fatal.
- are receiving drug treatment regularly.
- have previously suffered from stomach bleeding or perforation after taking ibuprofen or other medicines of the NSAID group.
- have chickenpox – it is recommended to avoid using this medicine.
- are an adolescent suffering from dehydration, in which case there is a risk of renal damage.

Additional Warnings

Taking this medicine or other NSAID analgesics may slightly increase the risk of a stroke or heart attack. The risk appears to be associated with taking high doses, **Do not exceed the recommended dose** and the recommended duration of treatment.

Drug Interactions

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

- aspirin or other NSAID medicines (for example: COX-2 inhibitors)
- corticosteroids (such as prednisolone) since they may increase the risk of an ulcer and gastrointestinal bleeding.
- medicines used for treatment of heart failure, such as digoxin.
- medicines belonging to the selective serotonin uptake

inhibitors group used to treat depression (SSRIs), since they may increase the risk of gastrointestinal side effects.

- diuretics, since medicines of the NSAID group may diminish their impact.
- lithium (used to treat depression) since a possible increase of lithium levels in the blood has been reported.
- methotrexate (for cancer and rheumatism) since a possible increase of methotrexate levels in the blood has been reported.
- hypoglycemic drugs (oral medicines used to treat diabetes).
- aminoglycosides (antibiotics).
- probenecid (used to treat gout).
- cyclosporine or tacrolimus (immunosuppressive medicines) since there is a risk of increase in nephrotoxicity.
- zidovudine: there is an increased risk of hematoma and hemarthrosis in HIV (+) patients with hemophilia being treated concurrently with zidovudine and ibuprofen.
- quinolones (antibiotics) – since there is a risk of convulsions in patients treated with medicines of the NSAID group and antibiotics of the quinolone group.
- anticoagulants (for example blood thinners such as aspirin, warfarin, ticlopidine).
- antihypertensive medicines, such as beta-blockers (e.g. atenolol), ACE inhibitors (such as captopril) and angiotensin II antagonists (such as losartan).
- mifepristone (used for termination of pregnancy).

Fertility, Pregnancy and Breastfeeding

- Ibuprofen belongs to a group of medicines, NSAIDs, which may impair fertility in women. This effect is reversible once you stop taking the medicine. The medicine may affect the chances of becoming pregnant. If you are planning to become pregnant or have had trouble becoming pregnant consult a doctor before using this medicine.
- Consult a doctor if you are in the first 6 months of your pregnancy. Do not use this medicine if you are in the last 3 months of your pregnancy.
- Ibuprofen may pass into breast milk in very low concentrations. It is unlikely that the medicine will affect your infant. There is no need to avoid breastfeeding during short-term treatment with the recommended dose.

Driving and Use of Machinery

There are no known effects of the medicine on driving and use of machinery.

Use of the Medicine in Adolescents

There is a risk of damage to renal function in adolescents suffering from dehydration.

Important information about some of the ingredients of the medicine

Nurofen Liquid Capsules 200 mg contains 42.1 mg of sorbitol in each liquid capsule. If you suffer from intolerance to certain sugars consult a doctor before using the medicine. In addition, the medicine contains Ponceau 4R (E124) which may cause an allergic reaction.

3. How to use this medicine

Check with your doctor or pharmacist if you are not sure.

The usual recommended dosage is:

Adults and children over 12 years of age

1-2 liquid capsules with a glass of water, up to 3 times a day. Wait at least 4 hours until taking the next dose. Do not take more than 6 liquid capsules within 24 hours. The medicine is not intended for children under 12 years of age.

Do not exceed the recommended dose.

Adolescents (12-18 years) – do not take this medication for more than 3 days,
Adults - do not take the medicine for more than 10 days without explicit instruction from a doctor.

If the signs of your illness do not disappear or become worse, or if new signs of illness (symptoms) appear, consult your doctor or a pharmacist.

Directions for use: Swallow the medicine with a glass of water. Swallow the liquid capsule whole. Do not chew.

– **If you have accidentally taken a higher dosage** you may suffer from nausea, vomiting, stomachache or bleeding, diarrhea, headache, ringing in the ears, drowsiness and dizziness. Even if you don't experience these symptoms, or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

– **If you forgot to take this medicine** at the required time, do not take a double dose. Take the next dose at the regular time and do not exceed the recommended dose.

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

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

4. Side Effects

As with any medicine, the use of Nurofen Liquid Capsules 200 mg 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.

Refer to a doctor if you suffer from:

- abdominal problems such as unexplained abdominal pain, indigestion, feeling sick or vomiting, constipation, diarrhea, gas.
- signs of bleeding in the stomach or intestines (bloody vomit and/or black stool or exacerbation of ulcerative colitis and Crohn's disease).
- stomach ulcers.
- liver or kidney problems.
- severe throat pain accompanied by fever and flu-like symptoms, extreme fatigue, bleeding from the nose or skin, mouth ulcers.
- severe skin reaction, such as: peeling of the skin, for example Stevens-Johnson syndrome (a very rare and life-threatening skin reaction).
- severe headache, neck stiffness, nausea, vomiting, fever, confusion.
- an allergic reaction such as unexplained wheezing, shortness of breath, swelling of the face, tongue or throat, heart palpitations, skin rash or itchy skin (hives).
- asthma, exacerbation of asthma or wheezing.
- circulatory system disorders, swelling (edema), high blood pressure, heart failure, blurred vision.
- tendency to bruising or bleeding (thrombocytopenia – low levels of platelets).
- complications of chickenpox (Varicella) involving severe infections of the skin and soft tissue.

The side effects may lessen when low doses are taken and for a short period of time.

– Medicines such as Nurofen Liquid Capsules 200 mg may be associated with a slight increase in the risk of a heart attack (myocardial infarction) or stroke.

– The elderly population is at higher risk of experiencing side effects.

– If you have a history of an allergic disease, you may suffer from shortness of breath.

Tell your doctor if you experience irregular symptoms, especially if you have a black stool, bloody vomit or abdominal pain. There have been rare reports of severe skin reactions (for example Stevens-Johnson syndrome) as symptoms related to the use of NSAID medicines. Stop using Nurofen Liquid Capsules 200 mg immediately if a rash, mouth ulcers or any other symptom of allergic reactions appears. There is a higher risk of stomach bleeding, ulcers and perforation

when taking higher doses of NSAID medicines in patients who have a history of ulcers and in the elderly population. It is recommended to start the treatment with the lowest dosage possible. Consult your doctor regarding the addition of a medicine to protect your stomach.

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

Side effects can be reported to the Ministry of Health using the online form for reporting side effects found on the home page of the Ministry of Health's website (www.health.gov.il) or by entering the link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store the medicine?

Avoid poisoning! This medicine and all other medicines must be stored in a safe place out of the reach of children and/or infants to avoid poisoning. **Do not induce vomiting** unless explicitly instructed to do so by a doctor!

– Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.

Storage Conditions:

Store at a temperature below 25°C. Store in the original package. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required, in order to protect the environment.

6. Additional Information

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

Capsule contents: Macrogol 600, Potassium Hydroxide (minimum 85% purity), Purified water, Capsule shell: Gelatin, Sorbitol liquid, partially hydrated, Ponceau 4R (E124), Purified water, Opacode WB white NS-78-18011 (ink used for the capsule print).

What the medicine looks like and what the package contains:

– Soft, red capsule, oval shaped and transparent with identification printed in white. The capsules are packaged in a blister pack.

– Package size: the medicine is provided in a cardboard box containing a blister with 4, 10, 16, 20 or 40 capsules. Not all package sizes may be marketed.

Registration holder and address: Reckitt Benckiser (Near East) Ltd., 6 Hanagar St., Hod Hasharon 4527704, Email: service.israel@rb.com.

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

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