

# 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, ask your doctor or pharmacist.

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

### 1. What is the medicine intended for?

Nurofen Liquid Capsules 200 mg is intended for the 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 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 medicines from the NSAID group.
- you suffer or have suffered in the past from recurrent gastrointestinal ulcer (2 or more different cases of verified gastrointestinal ulcer or bleeding or other disorders in the digestive system).
- you have previously experienced hypersensitivity (such as: bronchospasm, asthma, rhinitis, angioedema or urticaria) when taking ibuprofen, aspirin or other anti-inflammatory drug (from the NSAID group).
- you are under 12 years of age.
- you suffer from severe liver, renal or 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, if you have a history of heart disease or stroke or if you are a smoker.
- suffer from a head injury, an unexplained bleeding or an increase in intracranial pressure.
- suffer from a connective tissue disease such as systemic lupus erythematosus (lupus).
- are above 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 medicinal treatment regularly.
- have previously suffered from stomach bleeding or perforation after taking ibuprofen or other medicines of the NSAID group.
- it is recommended to avoid using this medicine while you have chickenpox (Varicella).
- you have an infection. Nurofen Liquid Capsules 200 mg may hide signs of infections such as fever and pain. It is therefore possible that Nurofen Liquid Capsules 200 mg 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.
- are an adolescent suffering from dehydration. In this case there is a risk of renal damage.

#### Additional Warnings

Anti-inflammatory/pain relief medicines, such as ibuprofen, may be associated with a slight increase in the risk of a heart attack or stroke, especially when used at high doses. Do not exceed the recommended dose or duration of treatment.

Serious skin reactions have been reported in association with treatment with Nurofen Liquid Capsules 200 mg treatment. You should stop taking Nurofen Liquid Capsules 200 mg and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since these can be the first signs of a very serious skin reaction. See section 4.

### Drug Interactions

- If you are taking, or have recently taken other medicines, including non-prescription drugs and nutritional supplements, tell the doctor or pharmacist. 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 (such as atenolol), ACE inhibitors (such as captopril) and angiotensin II antagonists (such as losartan).
  - mifepristone (used for termination of pregnancy).

**A number of other medicines may also affect or be affected by Nurofen Liquid Capsules 200 mg treatment. Therefore always consult the doctor or pharmacist before taking this medicine together with other drugs.**

#### Fertility, Pregnancy and Breastfeeding

- This medicine belongs to a group of medicines which may impair fertility in women. This situation is reversible on stopping the medicine. The medicine may affect the chances of becoming pregnant. If you are planning to become pregnant or have had difficulties becoming pregnant, consult the doctor before using this medicine.
- 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 NSAIDs class as of the 20th week of pregnancy.
- Consult the 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 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 at the recommended dose.

#### Driving and use of machinery

There is no known effect of the medicine on driving and using machines.

#### Use of the medicine in adolescents

There is a risk of renal impairment in dehydrated adolescents.

#### Important information about some of the ingredients of this medicine

This medicine contains 22.26 mg sorbitol in each liquid capsule. If you have been told by your doctor that you suffer from intolerance to certain sugars, consult the doctor before using this medicine. In addition, the medicine contains Ponceau 4R (E124), which may cause an allergic reaction.

### 3. How to use this medicine

Check with the 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 old.

#### Do not exceed the recommended dose.

Adolescents (12–18 years old) – do not take the medicine for more than 3 days.

Adults – do not take the medicine for more than 10 days unless explicitly instructed to do so by the doctor.

#### Take the lowest dose for the shortest term to relieve symptoms.

If the signs of your illness do not pass or worsen, or if new signs of illness (Symptoms) appear, consult the doctor or pharmacist. If you have an infection and the symptoms (such as fever and aches) do not pass or become worse - refer to the doctor immediately (see section 2).

**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, 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. Symptoms may include nausea, abdominal pain, vomiting (may be bloody), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, strong heartbeat, loss of consciousness, convulsions (especially in children), weakness and dizziness, blood in the urine, feeling cold in the body and breathing problems have been reported.

– If you forgot to take this medicine at the set time, do not take a double dose. Take the next dose at the usual set 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 the medicine, consult the doctor or 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:

- stomach problems such as unexplained stomach pain, indigestion, feeling sick or vomiting, constipation, diarrhea, flatulence.
- any sign of bleeding from the stomach or bowels (vomiting blood and/or passing black stools) or worsening of colitis and Crohn's disease.
- stomach ulcers.
- liver or kidney problems.
- severe sore throat accompanied by fever and flu-like symptoms, extreme exhaustion, bleeding from the nose or skin, mouth ulcers.
- severe skin reaction such as: peeling of the skin, for example Stevens-Johnson syndrome.
- a severe headache, stiff neck, nausea, vomiting, fever, confusion.
- an allergic reaction such as unexplained wheezing, shortness of breath, swelling of the face, tongue or throat, palpitations, skin rash or itching (hives).
- asthma, exacerbation of asthma or wheezing.
- blood disorders, swelling (edema), high blood pressure, heart failure, blurred vision.
- bruising easily, or bleeding (thrombocytopenia – low levels of platelets).
- severe skin infections and soft tissue complications during chicken pox (varicella).
- a severe skin reaction known as DRESS syndrome (drug reaction with eosinophilia and systemic symptoms). Symptoms of DRESS include: skin rash, fever, swelling of the 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 Liquid Capsules 200 mg if you develop these symptoms and seek medical attention immediately. See also section 2.
- the skin becomes sensitive to light.

Side effects may be minimized by using low doses for a short term.

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

– The elderly are at an increased risk of side effects.

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

Tell your doctor if you notice any unusual symptoms, especially if you notice black stools, vomiting blood or stomach pains.

Serious skin reactions (such as Stevens-Johnson syndrome) have been reported very rarely in association with the use of NSAIDs. Stop using Nurofen Liquid Capsules 200 mg immediately at the first appearance of a rash, mouth ulcers or any other symptom of allergic reactions.

There is an increased risk of stomach bleeding, ulcers and perforation with increasing doses of NSAIDs in patients with a history of ulcers and the elderly. It is recommended to start treatment at the lowest dose. Consult the doctor regarding addition of a medicine to protect the stomach.

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

Side effects can be reported to the Ministry of Health via the link "דיווח על תופעות לוואי בעקב" that can be found on the home page of the Ministry of Health website ([www.health.gov.il](http://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 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 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 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, the medicine also contains:** Macrogol 600, Potassium hydroxide (minimum 85% purity), Sorbitol water, Gelatin, Sorbitol liquid, partially hydrated, Ponceau 4R (E124), Opacode WB white NS-78-18011.

#### What the medicine looks like and contents of the package:

– Soft, red capsule, oval shaped and transparent with identification printed in white. The capsules are packed 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](mailto:service.israel@rb.com).

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

Revised in May 2022 according to MOH guidelines.

Drug registration number at the national medicines registry of the Ministry of Health: 159-74-34707-00.

PLN Nurofen Liquid Capsules 200mg PB0521-01