Patient Package Insert according to Pharmacists' Regulations (Preparations), 1986
This medicine is sold without a doctor's prescription.

Nurofen® Tablets 200 mg

Active ingredient and its quantity:
Ibuprofen 200 mg

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

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

This medicine is intended for adults and children over 12 years of age. Under this age, refer to the doctor. 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 3 days in children and adolescents between 12 and 18 years of age, and after 10 days in adults.

1. What is this medicine intended for?

Nurofen Tablets 200 mg contains ibuprofen which belongs to a group of medicines known as non-steroidal anti-inflammatories.
These medicines act by altering the body's response to pain, swelling and high temperature.
Nurofen Tablets 200 mg is intended for relief of mild to moderate pain such as headache, toothache, menstrual pain, back and muscular pain, anti-inflammatory for rheumatic diseases and for fever reduction.

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

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to ibuprofen or to any of the additional ingredients this medicine contains (see section 6).
- You suffer or have suffered in the past from an ulcer/gastrointestinal bleeding (two separate confirmed incidents or more of ulcers or bleeding).
- You have suffered from hemorrhage or perforation in the digestive system in the past as a result of previous treatment with non-steroidal anti-inflammatories.
- You have suffered from hypersensitivity reactions in the past (such as asthma, rhinitis, angioedema or hives) as a result of taking aspirin or similar analgesic (from the non-steroidal anti-inflammatory group).
- You suffer from severe heart, renal, or liver failure.
- You are in the last three months of pregnancy (see section "Pregnancy, breastfeeding and fertility").

Special warnings regarding the use of this medicine

Before treatment with Nurofen Tablets 200 mg, tell the doctor if:
- You suffer or have suffered in the past from asthma.
- You suffer or have suffered in the past from kidney, heart, liver or bowel problems.
- You suffer from high cholesterol or have had a heart attack or stroke.
- You have a history of gastrointestinal disease (such as Crohn's disease or ulcerative colitis).
- You suffer from systematic lupus erythematosus (a condition of the immune system causing joint pain, changes in the skin and damage to other organs).
- You smoke.
- You are in the first 6 months of your pregnancy.

Additional Warnings

– There might be a connection between anti-inflammatory or analgesic medicines like Ibuprofen and a slight increase in the risk of heart attack or stroke, especially when taking high doses. Do not exceed the recommended dosage or duration of treatment.
– Talk to a doctor or pharmacist about the treatment before taking Nurofen Tablets 200 mg if:
– You suffer from heart problems, including heart failure, angina pectoris (chest pain), or if you have experienced a heart attack, bypass surgery, peripheral artery disease (poor blood flow in the legs or feet due to narrowing or blockage of the arteries) or from any type of stroke [including a temporary stroke ("mini-stroke") or a transient ischemic attack (TIA)].
– You suffer from high blood pressure, diabetes, high cholesterol, or have a family history of heart disease or stroke or if you smoke.
– There is a risk of kidney problems in dehydrated children and adolescents.

Interactions/drug interactions

Tell the doctor or pharmacist if you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements.
To reduce the risk of side effects, do not take this medicine with another medicine from the NSAID**s** group (such as aspirin, ibuprofen).
Consult the **doctor or pharmacist if you are taking l**ow doses of aspirin (up to 75 mg).
Nurofen Tablets 200 mg may affect or be affected by several other medicines, for example:

Avoid taking this medicine together with corticosteroids tablets, antibiotics from the quinolones group, or prescription medicines:

- like anticoagulants (blood thinners/anticoagulants such as aspirin/acetylsalicylic acid, warfarin, ticlopidine).
- for heart stimulation (such as glycosides).
- for lowering high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, angiotensin II receptor blockers such as losartan).
- that induce urine production (diuretics).
- to treat mania or depression [such as lithium or selective serotonin reuptake inhibitors (SSRIs)].
- for the temporary suppression of the immune system (such as methotrexate, cyclosporine, tacrolimus).
- for pregnancy termination (such as mifepristone).
- to treat the Human immunodeficiency Virus (HIV) (such as Zidovudine).

Some other medicines may also affect or be affected by the treatment of Nurofen Tablets 200 mg. Therefore, always consult a doctor or pharmacist before taking Nurofen Tablets 200 mg with other medicines.

Pregnancy, breastfeeding and fertility:

Pregnancy
Tell a doctor if you become pregnant while taking this medicine.
Do not take this medicine in the last 3 months of pregnancy.
Avoid taking this medicine in the first 6 months of pregnancy, unless instructed otherwise by the doctor.

Breastfeeding
If you are breastfeeding, consult a doctor or pharmacist before taking this medicine.

Fertility
Nurofen Tablets 200 mg belongs to a group of medicines which may impair fertility in women. This condition is reversible after discontinuing the use of this 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.

Smoking
If you smoke, consult a doctor before taking this medicine (see "Additional Warnings" in section 2).

Important information about some of the ingredients of this medicine
Each tablet of Nurofen Tablets 200 mg contains 12.65 mg of Sodium. People on a low Sodium diet should take this into account.
Nurofen Tablets 200 mg contains Sucrose. If you were told by a doctor that you suffer from intolerance to certain sugars, consult the doctor before using this medicine.

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:

Adults and children over 12 years of age:
1-2 tablets 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 tablets within 24 hours.

This medicine is not intended for children under 12 years of age.

Do not exceed the recommended dose.

Treatment duration
For short-term use only. Take the lowest dose that achieves the purpose of use.

In children and adolescents aged 12-18- if treatment is needed for more than 3 days, or if the symptoms worsen, consult a doctor.
In adults- do not take this medicine for more than 10 days unless instructed by the doctor.
If the symptoms persist, the pain or fever worsens, or if new symptoms occur, consult a doctor or pharmacist.

Directions for use
Swallow this medicine with a glass of water.
There is no information regarding crushing/halving/chewing.

If you or your child have taken a higher dose than necessary or if a child has accidentally swallowed this medicine, always refer to a doctor or proceed to the nearest hospital in order to receive medical advice on the risk involved and recommended course of action.
Symptoms may include nausea, abdominal pain, vomiting (there may be blood spots), 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 take this medicine, take it according to the directions listed above. Do not exceed the recommended 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 Tablets 200 mg may cause side effects in some users. Do not be alarmed by the list of side effects. You might not suffer from any of them.

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

– **Signs of intestinal bleeding such as:** bright red-colored stools, black tar-like stool, vomiting blood or dark particles that look like coffee grounds.

– **Signs of serious allergic reaction such as:**

- Difficulties in breathing or unexplained wheezing.
- Dizziness or rapid heart rate.
- Severe forms of skin reactions such as itchiness, skin rash with redness, dandruff, skin peeling or blisters (such as Stevens–Johnson syndrome).
- Swelling of the face, tongue or throat.

- **Signs of kidney problems such as:**

- Passing less or more urine.
- Cloudy urine or blood in urine.
- Backache and/or swelling (particularly in the legs).

- **Signs of non-infectious meningitis** with neck stiffness, headache, nausea, vomiting, fever or disorientation. Patients with autoimmune diseases (such as lupus, mixed connective-tissue disease) may be more likely to be affected.

- **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 taking this medicine and tell the doctor as soon as possible if you experience one of the following uncommon side effects (appear in 1-10 users out of 1,000)

– Indigestion, heartburn or nausea.
– Abdominal pain or other abnormal stomach problems.

Additional side effects

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

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

– Allergic reactions such as skin rashes (urticaria), itchiness, skin peeling.
– Headaches.

Rare side effects (appear in 1-10 users out of 10,000): Flatulence (passing gas), diarrhea, constipation and vomiting.

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

– Blood disorder that causes abnormal or unexplained bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion.
– Drop in blood pressure or irregular heart rate.
– Peptic or intestinal ulcers, sometimes with bleeding and perforation, ulcerative inflammation of the oral mucosa together with inflammation of the stomach.
– Liver problems.

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

– Worsening of asthma, bronchospasm.
– Swelling (edema), high blood pressure, heart failure or heart attack.

– Worsening of inflammation of the colon (colitis) and Crohn's disease.

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@moh.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 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. The expiry date refers to the last day of that month.

Storage conditions: store at a temperature below 25ºC. Store in the original package.

6. Additional information

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

Sucrose, Sodium citrate, Talc, Croscarmellose sodium, Stearic acid, Titanium dioxide, Colloidal anhydrous silica, Carmellose sodium, Acacia spray dried, Sodium lauryl sulfate, Macrogol 6000, Opacode monogramming ink-S-1-277001 Black.

Each tablet contains approximately 116.1 mg Sucrose and approximately 12.65 mg Sodium.

What this medicine looks like and what the package contains:

– Round, white tablet with the word 'NUROFEN' printed in black.
– The tablets are packaged in a blister pack.

Each package contains 12, 24, 48, or 96 tablets.
Not all package sizes are marketed.

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 Ltd., Nottingham, England.

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

Drug registration numbers at the national medicines' registry of the Ministry of Health:
132 32 31025 00

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