

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

This medicine can be sold without a doctor's prescription

Nurofen Quick 256 mg Tablets Nurofen Quick 512 mg Tablets

Active ingredient and its quantity:

Sodium Ibuprofen (Equivalent to 200 mg Ibuprofen) Sodium Ibuprofen (Equivalent to 400 mg Ibuprofen)

For the list of inactive ingredients, please see section 6. See also section 'Important information regarding some of the ingredients of the medicine'

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to your doctor or pharmacist. This medicine is not intended for children under 12 years of age. You must take this medicine according to the instructions in the dosage section in this leaflet. Consult your pharmacist if you need additional information.

You must refer to your doctor if the symptoms of the disease worsen or do not improve after 3 days in the case of children and adolescents aged 12-18 years, or after 10 days in the case of adults.

1. What is the medicine intended for?

This medicine is intended for the relief of mild to moderate pain such as: headaches, backaches, toothache, menstrual pain, nerve pain (neuralgia), migraine, rheumatic diseases, pain arising from arthritis that is not severe, symptoms of cold and flu, sore throat and to reduce fever.

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

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 section 6)
- You suffer or have suffered in the past from bleeding/ulcer in the digestive system (two or more separated occurrences of ulcers or demonstrated bleeding)
- You have suffered in the past from reactions of hypersensitivity (such as asthma, nasal inflammation, angioedema or urticaria) as a result of taking aspirin or non-steroidal anti-inflammatory drugs.
- You have suffered in the past from gastrointestinal bleeding or perforation of the gut as a result of a previous treatment with medicines from Non-steroidal anti-inflammatory (NSAIDs) group.
- You suffer from severe cardiac, renal, or hepatic insufficiency.
- You are in the last trimester of pregnancy.

Special warnings regarding the use of the medicine

Before treatment with Nurofen Quick tell the doctor if:

- You suffer or have suffered from asthma.
- You suffer from renal, cardiac, hepatic or intestinal problems.
- You suffer from high levels of cholesterol, high blood pressure, or have suffered in the past from heart attack or stroke.
- You have a history of gastrointestinal disease (such as: ulcerative colitis or Crohn's disease).
- You suffer from Systemic Lupus Erythematosus, SLE, (a condition in which the immune system causes joint pain, skin changes and disorders in other organs).
- You are a smoker.
- You are in the first 6 months of pregnancy.
- You are on a diet restricting salt intake.
- You have an infection – since Nurofen Quick may hide the signs of infections such as fever and pain. Therefore, the medicine may delay appropriate treatment of the infection, which could lead to an increased risk of complications. This has been seen in pneumonia caused by bacteria and bacterial skin infections associated with chickenpox. If you are taking this medicine while you have an infection and the symptoms of your infection persist or worsen, consult the doctor without a delay.

Additional warnings

- Anti-inflammatory/analgesic medicines, such as Ibuprofen, may be associated with a small increased risk of heart attack or stroke especially when using high dosages. Do not exceed the

recommended dose or duration of treatment.

- You must talk to your doctor or pharmacist regarding the treatment before taking Nurofen Quick if:
 - You suffer from heart problems including cardiac insufficiency, angina (chest pain), or if you have experienced heart attack, coronary artery bypass surgery, peripheral arterial disease (poor blood circulation in legs or feet as a result of arterial stenosis or occlusion), or any type of stroke (including transient stroke ("mini-stroke") or transient ischemic attack (TIA)).
 - You suffer from high blood pressure, diabetes, high cholesterol level, you 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 if you have recently taken any other medicines, including non-prescription drugs and nutrition supplements.

Nurofen Quick may affect or be affected by several other medicines.

- For example: avoid taking this product with corticosteroid tablets, antibiotics from quinolones group or prescription medicines:
 - Such as anticoagulants (blood thinning/ preventing coagulation such as aspirin/acetysalicylic 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).
 - For facilitating urination (diuretics).
 - For the temporary suppression of the immune system (such as: methotrexate, cyclosporine, tacrolimus).
 - For the treatment of mania or depression (such as: lithium or selective serotonin re-uptake inhibitors (SSRIs)).
 - For pregnancy termination (such as: mifepristone).
 - For the treatment of Human Immunodeficiency Virus (HIV) (such as: zidovudine).

Several other medicines may also affect or be affected by the treatment with Nurofen Quick. Therefore, always consult the doctor or pharmacist before taking Nurofen Quick with other medicines.

Pregnancy, breast-feeding and fertility

Consult the doctor before using this medicine during the first 6 months of pregnancy.

Do not use the medicine during the last 3 months of pregnancy.

Breast-feeding

Consult your doctor before taking this medicine if you are breast-feeding.

Fertility

Nurofen Quick belongs to a group of medicines which may impair fertility in women. This condition is reversible with discontinuing the use of the medicine. It is unlikely that Nurofen Quick, when taken occasionally, will affect your chances of becoming pregnant. However, if you have problems becoming pregnant, tell your doctor before using this medicine.

Driving and use of machinery

This medicine is not expected to affect the ability to drive and operate machines with the recommended dosages and treatment duration.

Smoking

If you are a smoker, consult your doctor before taking this medicine (See "additional warnings" in section 2).

Important information regarding some of the ingredients of the medicine

Each tablet of Nurofen Quick 256 mg contains 24 mg of sodium and 93.1 mg of sucrose.

Each tablet of Nurofen Quick 512 mg contains 48 mg of sodium and 186.2 mg of sucrose.

If you have been told in the past by a doctor that you suffer from intolerance to certain sugars, consult your doctor before using this medicine.

3. How to use the medicine?

You must check with your doctor or pharmacist if you are not sure about the dosage and treatment regimen of this product.

The usual recommended dose is:

Nurofen Quick 256 mg: adults, elderly, children and adolescents aged 12-18 years – take 1-2 tablets, with water, up to three times a day, as needed. Do not take more than 6 tablets in 24 hours.

Nurofen Quick 512 mg: adults, elderly, children and adolescents aged

12-18 years – take one tablet with water, up to three times a day, as needed.

Do not take more than 3 tablets in 24 hours.

Wait at least 4 hours between doses.

Do not exceed the recommended dose

Do not give to children under 12 years of age.

Treatment duration

This product is for short term use only.

Take the lowest dose and for the shortest period of time to relieve the symptoms.

In children and adolescents aged 12-18 years: if the product is required for more than 3 days in children and adolescents, or if the symptoms worsen, consult the doctor.

In adults: do not take the medicine for longer than 10 days unless your doctor tells you to do so.

If symptoms persist or worsen, or if any new symptoms appear, consult your doctor or pharmacist.

- **Administration method:** swallow the medicine with water
- There is no available information regarding crushing/halving/chewing.

If you have accidentally taken a higher dose you may feel nausea, abdominal pain, Vomiting (may be with signs of blood), headache, ringing in the ears, confusion and nystagmus.

In high doses the following symptoms were reported: napping, chest pain, palpitation, loss of consciousness, spasms (especially in children), weakness and dizziness, blood in the urine, feeling cold in the body and breathing problems.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or to hospital emergency room, even if you feel well, and bring the package of the medicine with you.

If you forgot to take the medicine do not take a double dose in order to make up for the missed dose. See the instructions listed in section 3 regarding how to use this medicine and do not take more than is recommended.

Do not take the medicine 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 a pharmacist.

4. Side Effects

Like any medicine, the use of Nurofen Quick 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.

Stop the use of this medicine and seek medical attention immediately if you develop:

- **Signs indicating intestinal bleeding** such as: bright red feces, black tarry stools, vomiting blood or dark particles that look like coffee grounds.
- **Signs indicating a severe allergic reaction** such as:
 - Breathing difficulties or unexplained wheezing.
 - Dizziness or tachycardia.
 - Severe skin reactions such as itching, skin rash accompanied by redness, peeling of the skin, flaking or blistering (such as Steven-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.
 - Back pain and/or swelling (particularly in the legs).
- **Signs of aseptic meningitis** with neck stiffness, headache, nausea, vomiting, fever or disorientation. Patients with autoimmune disorders (Systemic Lupus Erythematosus, 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) symptoms of (DRESS) include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils count (a type of white blood cells).

Discontinue the use of this medicine and consult your 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 abdominal severe problems.

Tell the doctor or the pharmacist if you suffer from one of the

following side effects, if they worsen or if you notice side effects which are not mentioned:

- Uncommon side effects** (appear in 1-10 users out of 1,000)
 - Allergic reaction such as skin rash (urticaria), itching, peeling of the skin.
 - headaches
- Rare side effects** (appear on 1-10 users out of 10,000)
 - Flatulence (gases), diarrhea, constipation and vomiting.
- Very rare side effects** (appear in less than one user out of 10,000)
 - Blood disorder resulting in severe or unexplained bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe fatigue.
 - Lowering of blood pressure or irregular heartbeats.
 - Stomach or intestinal ulcers, sometimes with bleeding and perforation, inflammation of the lining of the mouth with ulceration (ulcerative stomatitis), inflammation of the stomach (gastritis).
 - Liver problems

Other side effects (the frequency cannot be determined from the available data):

- Worsening of asthma or bronchospasm.
- Swelling (edema), hypertension, cardiac insufficiency or heart attack.
- Worsening of colitis and Crohn's disease.

Medicines such as Nurofen Quick may be associated with a small increased risk of heart attack (myocardial infarction) or stroke (see section 2, "special warnings regarding the use of the medicine").

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

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the homepage of the Ministry of Health's website (www.health.gov.il) which links to an online form for reporting side effects.

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 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) stated on the package and blister. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store at a temperature above 30°C.

6. Additional Information

In Addition to the active ingredient, the medicine also contains: Sucrose, Croscarmellose Sodium, Xylitol, Microcrystalline Cellulose, Talc, Magnesium Stearate, Coloidal Anhydrous Silica, Titanium Dioxide, Acacia Spray Dried, Macrogol 6000 Powder, {Nurofen Quick 256 mg: Black printing ink containing Shellac, iron oxide black, propylene glycol}, {Nurofen Quick 512 mg: Red printing ink containing Shellac, iron oxide, red, N-butyl alcohol, isopropyl alcohol, propylene glycol, ammonium hydroxide, Simethicone.}

Nurofen Quick 256 mg – each tablet contains 24 mg sodium and 93.1 mg sucrose.

Nurofen Quick 512 mg – each tablet contains 48 mg sodium and 186.2 mg sucrose.

What the medicine looks like and what the package contains:

- Nurofen Quick Tablets 512 mg and Nurofen Quick 256 mg are sugar coated tablets, white to off-white, round, biconvex tablets. On one side of the tablet appears a black (on Nurofen Quick tablets 256 mg) or red (on Nurofen Quick tablets 512 mg) identification logo.
- The tablets are packed in a blister pack. Each package contains 6, 10, 12, 24, 48 or 96 tablets. Not all package sizes may be 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 International Ltd., Nottingham, England. Revised in November 2020.

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

Nurofen Quick 256 mg: 142-71-31929-00
Nurofen Quick 512 mg: 142-72-31944-00