

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

Read this package insert carefully
in its entirety before using this medicine

NUROFFEN®

Liquid capsules 200 mg

COMPOSITION

Each capsule contains:

Ibuprofen 200 mg

Active ingredients
poly(vinyl alcohol 600, Vitamin E, Povidone K17, Gelatin, Maltitol liquid, Sorbitol liquid, Purified water, Ponceau 4R, Opacode, MS-78-18011 or Opacode S-1-7020, Titanium dioxide, Shellac, demaxad.

PHARMACEUTIC GROUP

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

THERAPEUTIC ACTIVITY

Nurofen® 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, for the reduction of fever.

WHEN SHOULD THE PREPARATION NOT BE USED?

Do not use this medicine if you are pregnant.

Do not use this medicine if you are sensitive to the medicine or to any of its ingredients. If you experienced in the past an allergic reaction to any analgesic drug, if you have just undergone, or are about to undergo heart surgery.

Do not take this medicine simultaneously with other medicines belonging to the NSAIDs group.
Do not use this medicine if you suffer, or have suffered in the past, from peptic ulcer.

Do not take this medicine without consulting a doctor before starting treatment

If you are breastfeeding or if you suffer, or have suffered in the past, from gastric disorders such as: heartburn, abdominal pains, coagulation disorders, hypertension, heart and kidney diseases, inflammation of the respiratory system (e.g., asthma), the liver, lungs, erythematosis, connective tissue diseases, if you use diuretics, if you are over 60 years of age, if taking medicine from this group or any other analgesic drug has caused serious side effects.

HOW WILL THIS MEDICINE AFFECT YOUR DAILY LIFE?

In certain people this medicine may cause drowsiness, dizziness or blurred vision. If you feel these effects after using the medicine, you should be cautious when engaging in activities such as driving a car or operating dangerous machinery and in any other activity which requires alertness.

Children should be cautioned against engaging in activities such as bicycle riding or playing near roads and the like.

This medicine may cause particular sensitivity upon exposure to the sun. Therefore, avoid exposing yourself to the sun and use appropriate protection (long clothes, a hat, sunscreen agents, etc.).

WARNINGS

Do not use this medicine frequently or for a long period without consulting your doctor. During prolonged treatment with this medicine, the following tests should be performed: blood, urine, liver and kidney function, as well as ophthalmological examinations.

If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

Inform your doctor if you are about to undergo an operation (including dental operation) or laboratory tests, as this treatment may affect the test results.

Taking this medicine may cause stomach bleeding especially if:

- you are over 60 years of age.
- you take other medicines belonging to the NSAIDs group.
- you consume more than 3 alcoholic drinks a day.
- taking this medicine in a higher than recommended dosage or for a prolonged period may increase the risk of stroke or heart attack and stomach bleeding.

This medicine may cause allergic reactions such as: skin rash, itch, skin blistering, swelling of the face, shortness of breath, worsening of asthma, shock.

If fever persists for more than 3 days, or if pain persists for more than 10 days, discontinue treatment and refer to the doctor.

DRUG INTERACTIONS

If you are taking another drug concomitantly, or if you have just finished treatment with another medicine, including non-prescription medicines and nutritional supplements, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions. This is especially important for medicines belonging to the following groups: aspirin, salicylates and/or other anti-inflammatory drugs, anticoagulants (e.g., coumarin and its derivatives), antiplatelet agents (e.g., beta blockers), corticosteroids, methotrexate (for cancer and psoriasis), diuretics (e.g., furosemide and thiazides), lithium, probenecid, zidovudine (for AIDS).

SIDE EFFECTS

In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, such as: diarrhea, nausea, abdominal pain, dizziness, heartburn.

Effects that require special attention

Facial edema, swelling of the tongue, larynx, shortness of breath, tachycardia, hypotension, severe shock (rare), refer to your doctor immediately!

Visual or hearing disturbances, upper abdominal pain, rash, skin peeling, symptoms of meningitis, e.g., stiff neck, headache, nausea, vomiting, fever, stiffness and pain in the spinal column (rare), refer to your doctor immediately!

If you experience fainting, bloody vomiting, bloody or black stools: discontinue treatment and refer to the doctor immediately. If you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

DOSE

Adults and children over 12 years of age: 1-2 capsules, afterwards if necessary 1-2 capsules every 4-6 hours.

Do not take more than 6 capsules in 24 hours.

Do not exceed the recommended dosage.

The smallest effective dosage should be used.

Use by children under 12 years of age will be under medical supervision.

For the relief of menstrual pain: start treatment immediately upon onset of pain.

DIRECTIONS FOR USE

Do not chew, crush or divide the capsules! Swallow the medicine with water.

Take the medicine with or after a meal.

AVOID POISONING!

This medicine and all other medicines must be stored in a safe place out of the reach of children and/or infants, in order to avoid poisoning. If you have taken an overdose or a child has accidentally swallowed the medicine, please contact your doctor or a hospital emergency room and bring the medicine with the packaging to the hospital.

Do not induce vomiting unless explicitly instructed to do so by a doctor! Do not take medicines, in the dark! Check the label and the dose each time you take your medicine.

Wear glasses if you need them.

STORAGE

Do not store above 25°C.

Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.

Do not store different medications in the same package.

Drug Registration No.:

12755303584

Manufacturer: Beckitt Benckiser Healthcare International Ltd., Nottingham, England.

License Holder: Beckitt Benckiser (Near East) Ltd.,

6 Henagar St., Hod Hasharon, P.O. Box 6440, Israel 45240.