

Patient package insert in accordance with the pharmacists' regulations (preparations) - 1986

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

NUROFEN® FORTE Tablets

Composition: Each tablet contains:

Active ingredient: Ibuprofen 400 mg.

Inactive ingredients:

Croscarmellose sodium, Sodium lauryl sulfate, Sodium citrate, Stearic acid, Colloidal anhydrous silica, Carmellose sodium, Talc, Acacia spray dried, Sucrose, Titanium dioxide, Macrogol 6000, Opacode Monogramming Ink S-1-15904 red. Each tablet contains 232.2 mg sucrose.

Therapeutic Group: Non steroidal anti inflammatory (NSAIDs).

Indications:

Nurofen Forte is intended for the relief of mild to moderate pain, such as: headache, toothache, menstrual pain, backache, muscular pain.

For the relief of symptoms associated with rheumatic diseases.

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 any of its ingredients, if you experienced in the past an allergic reaction after taking analgesic medicines, if you have just went through, or you intend to go through an open heart operation.
Do not use concomitantly with other medicines from the non-steroidal anti-inflammatory group.
Do not use this medicine if you are suffering or have suffered in the past from peptic ulcer.
Use of this medicine in children under the age 12 years requires medical supervision.

Do not take this medicine without consulting a physician before starting treatment: If you are breastfeeding or if you are suffering or have suffered in the past from problems in the digestive system such as: heartburn, stomach pain, problems in blood coagulation, high blood pressure, heart or kidney disease, respiratory system (e.g. asthma, nasal polyps), malfunction of the liver, lupus erythematosus, connective tissues diseases or from sensitivity to aspirin and salicylates, if you take diuretics, If you are over 60 years of age, if taking a medicine of this group or any other pain reliever has caused in the past serious side effects.

How will this medicine affect your daily life?

In certain patients this medicine may cause drowsiness, dizziness or visual disturbances. If you experience these symptoms after using the medicine, you should be cautious when engaging in activities such as driving a car or operating dangerous machinery.
Children (above 12 years of age) should be cautioned against engaging in activities such as bicycle riding or playing near roads and the like.

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

Warnings:

Do not use this medicine frequently or for a long period without consulting a physician.

During prolonged treatment with this medicine, the following tests should be performed: blood, urine, liver and kidney function tests, ophthalmological examination.

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

Your anesthetist should be informed if you are to undergo an operation (including dental operation) or laboratory tests, as this medicine may affect the results.

Administration of this preparation may cause stomach bleeding, in particular if you:

- are over 60 years of age.
- take other medicines from the non-steroidal anti inflammatory group.
- consume more than 3 alcoholic drinks per day.

Taking this medicine in a dosage higher than recommended or for a long period, may increase the risk of stroke, heart attack and stomach bleeding.

This medicine may cause allergic reactions such as skin rash, urticaria, skin vesicles, facial swelling, short breathing, worsening of asthma, shock.

Stop use and ask the physician, if fever lasts more than 3 days or if pain continues more than 10 days.

The tablets contain sucrose.

Drug interactions:

If you are taking another drug concomitantly or if you have just finished treatment with another medicine, inform the attending physician 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 and salicylates or other anti-inflammatory preparations, anticoagulants (such as coumarin and its derivatives), antihypertensives (such as beta blockers or captopril), probenecid, lithium or methotrexate (for cancer and psoriasis).

Side effects:

In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, for example: diarrhea, abdominal pain, nausea, drowsiness or dizziness.

Side effects that require special attention:

Disturbances in vision or hearing (rare): stop treatment and consult your physician.

Rash, symptoms of meningitis (such as: headache, fever, stiff neck), strong and longlasting nausea, vomiting, rigidity, spinal pain or edema (rare): stop treatment and consult your physician immediately.

Epigastric pain, headache or skin peeling (rare): stop treatment and consult your physician.

If you feel faintness, bloody vomiting, blood or black feces - stop treatment and consult your physician immediately.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your physician immediately.

Dosage:

Recommended dosage unless otherwise prescribed by your physician:

Adults and children over 12 years of age: 1 tablet, every 4-6 hours.

Do not take more than 3 tablets in 24 hour period.

Do not take during more than 10 days, unless directed to do so by a physician (see in Warnings above).

If the symptoms of the disease aggravate or continue, refer to the physician.

Do not exceed the recommended dosage.

Take the lowest dose that obtains the target of use.

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

Directions for use:

Do not chew! Swallow the medicine with a large amount of water, with or after a meal.

Since there is no crossing line on the tablet, it is not possible to split the tablet.

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

Do not induce vomiting unless explicitly instructed to do so by a physician!

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: Store this medicine below 30°C.

Close tightly to prevent penetration of air and humidity.

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.

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Registration Holder:

Reckitt Benckiser (Near East) Ltd., 6 Hanagar St., Hod Hasharon, P.O.Box 6440, Israel 45240.

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