

Use in babies under 6 months of age is according to doctor's prescription.
Read this package insert carefully in its entirety before using this medicine.

NUROFEN[®] SUPPOSITORIES 60 mg

Composition: Active ingredient: Ibuprofen 60 mg
Inactive ingredients: Hard fat.

Therapeutic Group: Non steroidal anti-inflammatory (NSAID).

Indications:

Nurofen Suppositories is intended for the relief of mild to moderate pain and for the reduction of fever (antipyretic).

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 this medicine or to any of its ingredients, if you experienced in the past an allergic reaction after taking analgesic medicines: shortness of breathing, aggravation of asthma, allergic rash, common cold and nasal itching, if you have just went through, or you intend to go through an open heart operation.
Do not use this medicine if you are suffering or have suffered in the past from peptic ulcer or any other disturbance in the digestive system's activity.
Do not use concomitantly with other medicines from the non-steroidal anti-inflammatory group.
If you suffer from severe deficiency of the liver, kidney or heart functioning.

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 stomach and digestive system (such as: heartburn, stomach pain, Crohn disease, peptic inflammation of the large intestine, problems in rectum functioning), problems in blood coagulation (such as a disease called Idiopathic Thrombocytopenic Purpura - ITP, which causes damage to the blood platelets, or if you suffer from intra-skull hemorrhage), high blood pressure, heart or kidney disease, respiratory system (e.g. asthma, nasal polyps), malfunction of the liver, lupus erythematosus, connective tissues diseases, if you take diuretics, if taking a medicine of this group or any other pain reliever has caused in the past serious side effects, if you are trying to become pregnant (see also in "Warnings" below), or if you are under physician's supervision due to another severe situation.

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, or in any other activity 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 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 examinations.

If you are sensitive to any type of food or medicine, you must inform your physician before commencing treatment with this medicine. The physician should be informed if you are about 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 taking other medicines from the non-steroidal anti-inflammatory group.
- 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. See details in "Side effects that require special attention" below.
- Stop use and ask the physician, if fever or pain continues more than 3 days.

Use in adults: Nurofen suppositories may be used by adults also, if needed. However, breastfeeding women and elderly people should consult the doctor before use.

Warnings and detailed information appears in this leaflet are valid in adults. Nurofen Suppositories belongs to a group of medicines (NSAID) which may impair fertility in women. This side effect is reversible upon cessation of treatment. Women that are treated with this medicine and trying to become pregnant, should consult the doctor on this matter.

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: other

other non-steroidal anti-inflammatory preparations (NSAIDs), anticoagulants (such as coumarin and its derivatives), diuretics, antihypertensives (such as beta blockers or captopril) or for heart failure, aminoglycosides or probenecid, lithium or methotrexate (for cancer and psoriasis), cyclosporine, zidovudine, anti-depressive medicines, steroids, medicines for the treatment of diabetes.

Side effects:

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

Side effects that require special attention:

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

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!

Allergic reactions such as: skin rash, urticaria, skin vesicles, facial swelling, short breathing, worsening of asthma, shock: stop treatment and refer to the 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.

Side effects and drug interactions in children and babies:

Parents should report to the doctor about any side effect and about any other drug being given to the child!

See special side effects and drug interactions described above.

Use of this medicine in babies under 6 months of age requires a doctor's prescription.

Recommended dosage unless otherwise prescribed by the physician:

The preparation is intended for babies older than 3 months old, weighing at least 6 kilograms.

Weight (Kg)	Initial dose	Giving another supp.	Supp. quantity in 24 hours
6-8	1 suppository	If needed, after 6-8 hours	until 3 supp.
8-12.5	1 suppository	If needed, after 6 hours	until 4 supp.

Do not exceed the recommended dosage.

Take the lowest dose that obtains the target of use.

Do not give for more than 3 days.

Dosage for adults - consult your physician.

Directions for use:

Do not swallow.

The child should have a bowel movement before inserting the suppository into his rectum.

Wash your hands and wipe them before use. Remove one suppository from the package and insert it gently into the child's anus. Wash your hands afterwards.

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 in a cool place (below 25°C).

NOTE! If the suppository is too soft, you can cool it in the refrigerator for 30 minutes approximately, or cool it under a flow of cold water, before removing the wrapping.

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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The format of this leaflet has been determined by the Ministry of Health and its content has been examined and approved by it in March 2010.