

Patient package insert in accordance with the pharmacists' regulations (preparations) - 1986
This medicine can be sold without a doctor's prescription

Nurofen® Plus Tablets

Active ingredients:

Each tablet contains:
Ibuprofen 200 mg
Codeine phosphate hemihydrate 12.8 mg
(equivalent to codeine 10 mg)

Inactive ingredients: Please see section 6 – Additional information.

Read this entire leaflet carefully before you using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist. This medicine is not intended for children under 12 years of age.

Swallow the medicine in the correct manner. Consult the pharmacist if you need additional information. Refer to your doctor if the symptoms of your illness worsen or do not improve within 3 days.

Do not use this medicine for more than three consecutive days. In case longer treatment is necessary, consult a doctor or a pharmacist. If you have taken this medicine for the relief of headaches for more than 3 days, the medicine might worsen the pain.

Medicines containing codeine shall be used only for the treatment of acute (short lasting) moderate pain in children over 12 years of age and only if the pain cannot be treated with pain relievers such as paracetamol or ibuprofen or aspirin, since the use of codeine may increase the risk of respiratory depression.

1. What is the medicine indicated for?

This medicine is intended for short-term use for the relief of acute (short lasting) moderate pain, such as rheumatic pain (arthritis), muscular pain, backaches, neuralgia, migraine, headache, dental pain and menstrual pain.

Therapeutic group

Ibuprofen belongs to the non-steroidal anti-inflammatory drugs group.
Codeine belongs to the opioid analgesics group.

2. Before you take the medicine

Do not use the medicine if:

- you are in your last three months of pregnancy or you are breastfeeding.
- you are hypersensitive (allergic) to the active ingredients or to any of the other ingredients of this medicine or to aspirin (see section 6).
- you suffer or have suffered in the past (two events or more) from an ulcer, perforation or bleeding in the stomach.
- you suffer from breathing difficulties.
- you are taking pain relievers for the treatment of headaches which last for more than 3 days. The headaches may worsen.

- this medicine contains codeine which may cause an addiction when used for longer than three days. Upon discontinuation of prolonged use, withdrawal effects from the medicine may appear.
- you suffer from severe liver, kidney or heart failure and from severe problems of the kidney or heart.
- in patients suffering from chronic constipation.
- you have suffered in the past from bleeding in the digestive system or stomach perforation after taking a medicine of the non-steroidal anti-inflammatory group.
- you have suffered in the past of allergic reactions such as asthma, skin rash, itch, rhinitis (runny nose) or swelling of the face after taking ibuprofen, aspirin or similar medicines.
- do not take this medicine concomitantly with other medicines of the non-steroidal anti-inflammatory group or aspirin in a daily dosage of over 75 mg.
- you are younger than 12 years of age.
- you know that your body metabolizes (breaks down) codeine quickly (you belong to the ultra-rapid metabolizers group) from a dose of codeine and therefore you are at increased risk of suffering from serious side effects when using codeine.
- children and adolescents under 18 years of age after surgery for removing tonsils or adenoids due to obstructive sleep apnea, since these patients are more likely than others to suffer from breathing problems.

Special warnings about the use of this medicine

Naturally and rarely, the bodies of some people metabolize codeine faster than most of the population. In these rare cases, large amounts of metabolites may accumulate and cause severe side effects, such as: over-sleepiness, confusion or slow or shallow breathing, constricted pupils, malaise, nausea, constipation, loss of appetite. In these cases the patient should be immediately referred to receive medical treatment.

In most cases, it is impossible to know in advance whether the patient belongs to the group of people which are at risk of this phenomenon.

This medicine is not recommended for use in those suffering from breathing difficulties.

This medicine should not be used frequently or for a long period of time without consulting a doctor.

During prolonged treatment with this medicine blood, urine, ophthalmic, liver and kidney function tests should be performed.

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

Refer to your doctor if you are about to undergo surgery (including dental surgery) or laboratory tests as this treatment may affect the results. Taking this medicine may cause stomach bleeding especially if:

- you are above 60 years of age.

Taking this medicine at a higher dosage than recommended or for a prolonged period may increase the risk of stroke or heart attack and stomach bleeding. Discontinue use and refer to your doctor if the pain persists for more than 3 days.

If you have heart problems, had a stroke or you believe you are at risk for these conditions (for example if you have high blood pressure, diabetes or high cholesterol or if you smoke), consult the doctor before taking the medicine.

Before taking this medicine tell your doctor if

- you suffer or have suffered in the past from: impaired function of the respiratory system (e.g. asthma)
- you suffer from:
 - stomach problems such as: heartburn, stomach pain, inflammatory bowel diseases (such as: Crohn's disease, ulcerative colitis).
 - coagulation disorders, hypertension, hypotension, heart and kidney diseases.
 - the liver, the thyroid gland, the prostate gland, from head injury or raised intracranial pressure, lupus erythematosus or connective tissue diseases.
 - high cholesterol
- you have suffered from gastrointestinal diseases such as Crohn's disease or ulcerative colitis.
- you have suffered from a heart attack or stroke.
- you are taking diuretics.
- you are a smoker.
- taking medicine of this group or any other analgesic has caused serious side effects.
- you are in the first six months of pregnancy.

If you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements, please inform your doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking:

- Anti-coagulants (e.g. coumarin and its derivatives), aspirin, ticlopidine, warfarin.
- Anti-hypertensive medicines such as ACE inhibitors (e.g. captopril), beta blockers (e.g. atenolol), angiotensin type II receptor blockers (e.g. losartan), diuretics (e.g. furosemide).
- MAO inhibitors for the treatment of depression.
- Salicylates and/or other anti-inflammatory drugs.
- Medicines which affect the central nervous system (such as: sedatives, hypnotics, medicines for parkinsonism, epilepsy), corticosteroids, methotrexate (for cancer and psoriasis), and thiazides, lithium, probenecid, zidovudine (for AIDS).

Pregnancy and Breastfeeding:

Do not use this medicine if you are in the last three months of pregnancy **or if you are breastfeeding.**

Nurofen Plus may affect fertility in women. This effect is reversible and depends on stopping treatment with this medicine. This effect is reversible. It is unlikely that occasional use of ibuprofen will affect the chances of becoming pregnant, however, if you are having difficulty becoming pregnant consult a doctor before using the medicine.

Driving:

In certain patients this medicine may cause drowsiness, dizziness or blurred vision. If you feel these effects after using this medicine, caution should be exercised when engaging in activities such as driving a car or operating dangerous machinery. Children (over 12 years of age) should be warned against riding a bicycle or playing near roads etc.

Smoking:

Do not use this medicine without consulting a doctor before commencing treatment if you are a smoker.

Use of this medicine and exposure to the sun:

This medicine may cause special sensitivity upon exposure to the sun; therefore avoid sun exposure and take appropriate protection measures (long clothes, a hat, sunscreen products etc.).

3. How to use this medicine?

- Check with your doctor or pharmacist if you are not sure.

- The recommended dosage is:

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

Adults and children above 12 years of age:

1-2 tablets up to 3 times a day. Wait at least 4 hours before taking the next dose.

Do not exceed 6 tablets in 24 hours.

Do not take the medicine over 3 days without an explicit instruction from the doctor.

This medicine contains codeine which may cause addiction in prolonged use of over three days. Upon discontinuation of prolonged use, withdrawal effects from the medicine may appear.

Do not exceed the recommended dose.

Take the lowest dose that achieves the purpose of using this medicine.

Directions for use

Do not chew, crush or halve the tablets!

Swallow the tablets with water.

In patients with a sensitive stomach, it is recommended to take this medicine with or after a meal.

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

If you forget to take this medicine at the specified time, do not take a double dose. Take the next dose at the regular time and consult your doctor.

If you have further questions regarding the use of this medicine, consult your doctor or a pharmacist.

4. Side effects:

Like all medicines, the use of Nurofen Plus 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.

Side effects which appear rarely – stop using the medicine and refer to the doctor immediately:

- signs indicating bleeding in the intestine such as: bright red stools, black, tar-like stools, vomiting blood or dark particles that look like coffee particles.
- signs indicating a serious allergic reaction: severe skin reaction (rashes, irritations, skin peeling and the appearance of blisters).
- breathing difficulties or unexplained wheezing.
- swelling of the face or throat, excessive drowsiness.
- facial edema, swelling of the tongue, the throat, shortness of breath (dyspnea), tendency to bruise or hemorrhage.

Additional side effects:

Appear commonly – refer to the doctor as soon as possible:

- indigestion, heartburn.
- constipation, stomach pain or other symptoms indicating impaired function of the digestive system.
- itch, rash, worsening of asthma condition

- sweating, feeling thirst, muscle weakness, tremor, insomnia.
- rapid or irregular heart rate, chest pain.
- liver or kidneys problems.
- headache, nausea, dizziness and drowsiness.

There is a slight increase in the risk of developing a heart attack or stroke in people who take medicines such as Nurofen Plus.

If any of the side effects worsens, or if you experience side effects not mentioned in this leaflet, consult the doctor.

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 of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not take medicines in the dark! Check the label and dosage each time you take your medicine. Use glasses if you need them.
- Do not use the 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 25°C.
- Store in the original package.

6. Additional information

- In addition to the active ingredients, this medicine also contains:
- Microcrystalline cellulose, Sodium starch glycolate, Hypromellose, Starch pregelatinised, Opaspray white M-1-7111B (solids), Talc.

• What the medicine looks like and contents of the pack: White tablet. The mark "N+" is debossed on the tablet.

• Pack size: 12 tablets.

• Registration holder: Reckitt Benckiser (Near east) Ltd., 6 Hanagar St., Hod Hasharon, P.O. Box 6440, Israel 4527704 Email: service.israel@rb.com Fax: 09-9577055

• Manufacturer: Reckitt Benckiser Healthcare International Ltd. Nottingham, UK.

• This leaflet was checked and approved by the Ministry of Health in May 2015.

• Drug registration number at the national medicines registry of the Ministry of Health: 132 54 31026

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