

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

This medicine can be sold without a doctor's prescription

Nurofen® Forte Liquid Capsules 400 mg

Ingredients: Each liquid capsule contains 400 mg of ibuprofen.

For inactive ingredients, please see section 6 ("Additional Information").

Read this entire leaflet carefully before you start taking this medicine.

This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine is intended for use in adults and children over 12 years of age. Use in the correct manner. Consult your pharmacist if you need additional information.

Refer to your doctor if the symptoms of your illness get worse or do not improve within 3 days.

1. What is the medicine indicated for?

For the relief of mild to moderate pain such as: headache, toothache, menstrual pain, back and muscle aches. Anti inflammatory drugs for rheumatic diseases and for the reduction of fever.

Therapeutic group: Non steroidal anti inflammatory drugs (NSAIDs)

2. Before taking the medicine:

Do not use the medicine if:

- You are pregnant.
- You are hypersensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine, or if you have had an allergic reaction in the past after taking any fever-reducing or analgesic medicine (including aspirin, salicylates and other NSAIDs).
- You have just undergone or are about to undergo heart surgery.
- Do not take other medicines of the non steroidal anti inflammatory drugs group concomitantly.
- You suffer from severe liver or kidney problems, or from heart failure.
- You suffer or have suffered in the past from an ulcer or hemorrhage in the digestive system; if you have suffered in the past from a hemorrhage in the digestive system due to treatment with medicines of the NSAIDs group.
- You are elderly.

Before taking the medicine, tell your doctor if:

- You are breastfeeding.
- You suffer or have suffered in the past from impaired function of the respiratory system (e.g. asthma, nasal polyps, hay fever).
- You suffer or have suffered in the past from stomach problems such as heartburn, intestinal problems, irritable bowel syndrome or stomach aches, impaired function of the heart or kidney, impaired function of the liver (e.g. cirrhosis), blood clotting problems or hypertension.
- You suffer or have suffered in the past from lupus erythematosus or connective tissue diseases.
- You take diuretics.
- You are over the age of 60.
- You are sensitive to any type of food or medicine.
- You are under medical supervision due to a serious medical condition.
- You are trying to become pregnant (see "special warnings").
- You have suffered from a stroke or are in risk of suffering one (conditions increasing the risk for a stroke are: hypertension, diabetes, high cholesterol level, smoking).

Special warnings about the use of this medicine:

- Do not use this medicine frequently or for a prolonged period without consulting a doctor.
- Taking this medicine at a higher dose than recommended or for a prolonged period, may increase the risk of stroke or heart attack and gastrointestinal bleeding.
Taking this medicine may cause stomach bleeding especially if:
 - You are older than 60 years.
 - You have had stomach ulcers or bleeding problems.
 - You take other medicines of the non steroidal anti inflammatory drugs group (aspirin, ibuprofen, naproxen or others).
 - You take anticoagulants or steroidal medicines.
 - You consume more than 3 alcoholic beverages per day.
- If you are about to undergo surgery (including dental surgery), inform your anesthesiologist about taking this medicine.
- If you are about to undergo laboratory tests, inform your doctor about taking

- this medicine, as the treatment with this medicine may affect the test results.
- Ibuprofen belongs to the group of medicines (non steroidal anti inflammatory drugs) that may harm a woman's fertility. This effect is reversible, when stopping the use of the medicine. It is unlikely that occasional use of ibuprofen will affect your chances of conceiving, yet if you are having trouble conceiving, consult a doctor before taking this medicine.
 - Stop use and refer to a doctor: if the fever rises or lasts for more than 3 days, if the pains become worse or last more than 10 days, if the stomach aches worsen or persist, or if new symptoms appear.
 - See additional warnings in section "important information regarding some of the ingredients of this medicine".

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:

- Aspirin, salicylates and/or other non steroidal anti inflammatory drugs or corticosteroids or other medicines containing ibuprofen. Taking these medicines concomitantly with ibuprofen increases the risk of gastrointestinal bleeding.
- Anticoagulants (e.g. coumarin, warfarin and their derivatives). Taking these medicines concomitantly with ibuprofen may affect the results of blood coagulation tests and may increase the risk of bleeding, especially stomach bleeding.
- Antihypertensives (beta blockers, ACE inhibitors or Angiotensin II receptor blockers) and varying medicines such as furosemide and thiazides. Taking these medicines concomitantly with ibuprofen may decrease their activity in reducing blood pressure.
- Antiplatelet drugs and medicines of the SSRI group (for the treatment of depression). Taking these medicines concomitantly with ibuprofen increases the risk of gastrointestinal bleeding.
- Methotrexate (for the treatment of cancer and psoriasis), lithium, probenecid. Ibuprofen may extend the length of activity of these medicines.
- Cyclosporine. Taking this medicine concomitantly with ibuprofen increases the risk of kidney injury.
- Zidovudine (for the treatment of AIDS). Taking this medicine concomitantly with ibuprofen may increase the risk of bleeding.
- Tacrolimus (for immune system suppression), mifepristone, digoxin, antibiotics of the quinoline family (e.g. ciprofloxacin).
- If you take aspirin due to a heart attack or stroke, ibuprofen may reduce the efficiency of the aspirin.

Use of this medicine with food:

- Swallow this medicine with water, during or after a meal.
- Drink a lot during treatment to avoid dehydration.

Use of this medicine with alcohol consumption:

If you consume more than 3 alcoholic beverages per day, using this medicine may cause stomach bleeding.

Pregnancy and breastfeeding:

- Do not use this medicine if you are pregnant.
- If you are breastfeeding consult your doctor before using the medicine.

See also "warnings" section.

Driving and use of machinery:

- In certain patients this medicine may cause drowsiness, dizziness or blurred vision.
- If you have felt these effects after using this medicine, be careful while driving a car or operating dangerous machinery and while engaging in any other activity that requires alertness.

Using the medicine and exposure to the sun:

The medicine may cause special sensitivity with exposure to the sun. Therefore, avoid sun exposure and take appropriate protection measures (long clothes, a hat, sunscreen products, etc.).

Important information about some of the ingredients of this medicine:

- This medicine contains 28 mg of potassium in each liquid capsule. Take that into account if you require a low-potassium diet or if you suffer from kidney failure.
- The medicine contains 110.4 mg of liquid sorbitol in each liquid capsule, which is a source for 19.9 mg of fructose. If you have a known sensitivity to certain sugars, such as fructose, consult a doctor before taking this medicine.

3. How to use this medicine

Check with your doctor or pharmacist if you are not sure. Do not exceed the recommended dose.

Take the lowest dose that achieves the purpose of use.

For adults and children over the age of 12 years:

The recommended dosage is usually: 1 capsule every 6-8 hours, up to 3 times a day.

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

Do not take more than 3 capsules during a 24 hour period, unless instructed by the doctor.

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.

This is a liquid capsule! There is no possible way to open the capsule in a manner that will enable an exact dosage. Therefore, do not chew or attempt to open the capsule! Swallow the medicine with water, during or after a meal. Stop use and refer to a doctor if the fever lasts for more than 3 days or if the pains last for more than 10 days (see "warnings" section).

Tests and follow up:

In case of prolonged treatment with this medicine, blood, urine, liver and kidney function and eye tests should be performed.

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.

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

4. Side effects

Like all medicines, Nurofen Forte Liquid Capsules can cause side effects in some of the users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Stop use and refer to your doctor immediately if you feel the following effects:

- Signs of intestinal bleeding, e.g.: shiny red or black feces, bloody vomit or vomit containing black particles (similar to coffee powder). Gastrointestinal bleeding may occur more commonly in the elderly.
- Signs of an allergic reaction, e.g.: breathing difficulties, wheezing, dizziness or rapid heart rate, severe skin effects (itching, rash, skin peeling, appearance of blisters). Swelling of the face, tongue or throat.

Refer to your doctor as soon as possible if you feel the following side effects:

- Fever, flu-like symptoms, throat ache, mouth ulcers, headaches, neck stiffness, vomiting, extreme tiredness.
- Digestive disorders, stomach aches, constipation, flatulence, nausea, chest pain or irregular heart rate.
- Liver and kidney problems related to the appearance of swelling of the arms and legs.

If any of the side effects worsens, or if you experience side effects not mentioned in this leaflet, consult your 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 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 ingredient, this medicine also contains: Polyethylene glycol (Macrogol) 600, Gelatin, Sorbitol liquid partially dehydrated, Purified water, Potassium hydroxide 50% solution, Ponceau 4R, Titanium dioxide, Lecithin, Fractionated coconut oil, White Printing Ink - Opacode NSP-78-18022.

- What the medicine looks like and contents of the pack: a red opaque oval capsule, containing a clear liquid. The caption 'N400' is printed in white on the capsule.

- Registration holder and address: Reckitt Benckiser (Near East) Ltd., 6 Hanagar St. Hod-Hasharon P.O. Box 6440, Israel 45240.

- Manufacturer and address: Reckitt Benckiser Healthcare Ltd., Hull, UK.

- This leaflet was checked and approved by the Ministry of Health in: July 2012.

- Drug registration number at the national medicines registry of the Ministry of Health: 148-44-31886-00

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