

# Patient Package Insert according to Pharmacists'

## Regulations (Preparations) - 1986

This medicine can be sold without a doctor's prescription

### Nurofen Forte Liquid Capsules 400 mg

**Composition:** Each liquid capsule contains ibuprofen 400 mg

For the list of inactive ingredients and allergens in the medicine, see section 6 "Additional information", and section "Important information about some of the ingredients of this medicine".

**Read this entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

The medicine is intended for adults and children over the age of 12. Take the medicine according to the instructions in the dosage section in this leaflet. Consult the pharmacist if you need additional information.

Contact the doctor if the symptoms worsen or do not improve within 3 days in adolescents 12 to 18 years old, and within 10 days in adults.

#### 1. What is the medicine intended for?

Relief of mild to moderate pain such as: headache, tooth ache, menstrual pain, back ache, muscular pain.

Anti-inflammatory for rheumatic diseases, reduction of fever.

**Therapeutic group:** Non-steroidal anti-inflammatory drugs (NSAIDs).

#### 2. Before using the medicine

**Do not use the medicine if:**

- you are hypersensitive (allergic) to ibuprofen or to any of the other ingredients this medicine contains (see section 6).
- you have or have had in the past bleeding/peptic ulcer (2 or more separate events of verified ulcers or bleeding).
- you have suffered in the past from hypersensitive reactions (such as: rhinitis, angioedema or hives due to taking aspirin or a similar pain killer (from the non-steroidal anti-inflammatory group).
- you have suffered in the past from bleeding or a perforation in the digestive system due to previous treatment with non-steroidal anti-inflammatory drugs.
- you have severe heart, kidney or liver failure.
- you are in the last trimester of pregnancy (see section "Pregnancy, breastfeeding and fertility").

#### Special warnings regarding the use of this medicine

**Before treatment with Nurofen Liquid Capsules 400 mg, tell the doctor if:**

- you have asthma or have had it in the past.
- you have kidney, heart, liver or intestinal problems.
- you have high cholesterol or have had a heart attack or stroke in the past.
- you have a history of digestive system problems (such as ulcerative large intestine colitis or Crohn's disease).
- you have systemic lupus erythematosus [a condition in which the immune system causes joint pains, changes in the skin and disorders in other organs].
- you are in the first 6 months of your pregnancy.
- you suffer from heart problems such as heart failure, angina pectoris (chest pain), or you have had a heart attack, bypass surgery, peripheral artery disease (impaired blood flow from the legs or feet due to narrowing or blockage of arteries), or any type of stroke (including a "mini-stroke" or transient ischemic attack).
- you suffer from high blood pressure, diabetes, high cholesterol or you have a family history of heart disease or stroke, or if you smoke.
- you have an infection – since Nurofen Forte Liquid Capsules 400 mg may hide the signs of infections such as fever and pain. Therefore, the medicine may delay appropriate treatment of the infection, which could lead to an increased risk of complications. This has been seen in pneumonia caused by bacteria and bacterial skin infections associated with chickenpox. If you are taking this medicine while you have an infection and the symptoms of your infection persist or worsen, consult the doctor without delay.
- **skin reactions** – severe skin reactions have been reported in association with treatment with this medicine. Stop taking the medicine and proceed without delay to receive medical treatment, if you or your child develop skin rash, lesions on mucosal tissues, blisters or other signs of allergy since this can be the first sign of a very severe skin reaction. See section 4.

#### Additional Warnings

- Taking this medicine or other pain killers from the NSAIDs group may slightly increase the risk of a stroke or heart attack, especially when taking high dosages. Do not exceed the recommended dose and recommended duration of treatment.
- There is a risk of kidney damage in children and adolescents suffering from dehydration.

#### Drug Interactions

If you are taking, or have recently taken, other medicines including non-prescription drugs and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Medicines from the NSAIDs group such as: aspirin (over 75 mg a day), ibuprofen and the like. In order to reduce the risk of side effects, do not take this medicine together with medicines containing these substances.
- Avoid taking this medicine together with corticosteroid tablets, antibiotics from the quinolone family or prescription medicines such as:
- Anticoagulants (blood thinning/preventing clotting such as aspirin/acetylsalicylic acid, warfarin, ticlopidine).
- For heart stimulation (such as glycosides).
- To reduce blood pressure (ACE inhibitors such as captopril, beta blockers such as atenolol, angiotensin II receptor blockers such as losartan).
- That help with urination (diuretics).
- For temporary suppression of the immune system (such as: methotrexate, tacrolimus or cyclosporine).
- For treatment of mania or depression (such as: lithium or selective serotonin reuptake inhibitors (SSRIs)).
- To end pregnancy (such as mifepristone).
- For the treatment of the human immunodeficiency virus (HIV) (such as: zidovudine).

**A few other medicines may also affect or be affected by the treatment with Nurofen Forte Liquid Capsules 400 mg. Therefore, always consult the doctor or pharmacist before taking this medicine together with other medicines.**

#### Pregnancy, Breastfeeding and Fertility

##### Pregnancy

This medicine has a possible side effect of renal injury in the fetus and low levels of amniotic fluid as of the 20th week of pregnancy. It is recommended to avoid using medicines of the NSAIDs class as of the 20th week of pregnancy and consult a healthcare professional, if necessary.

Talk to the doctor if you are in the first 6 months of pregnancy as the medicine may adversely affect the pregnancy and/or the development of the fetus.

Do not use this medicine if you are in the last 3 months of pregnancy.

##### Breastfeeding

Consult the doctor before taking this medicine if you are breastfeeding.

##### Fertility

Nurofen Forte Liquid Capsules 400 mg belong to a group of medicines which may harm fertility in women. This effect is reversible upon stopping use of the medicine. It is not likely that occasional use of this medicine will affect your chances of becoming pregnant. However, tell the doctor before using the medicine if you have encountered difficulties becoming pregnant.

#### Driving and use of machines

No effects on the ability to drive and use machines are expected with the recommended dosages and duration of treatment.

#### Important information about some of the ingredients of this medicine

- The medicine contains 36.6 mg sorbitol in each liquid capsule, which is a source of fructose. If you have been told by your doctor that you have an intolerance to certain sugars, refer to your doctor before taking the medicine.
- The medicine contains Ponceau 4R (E124) which may cause allergic reactions.
- The medicine contains 31.23 mg potassium per capsule. Take this into consideration if you require a low potassium diet or if you suffer from reduced kidney function.

#### 3. How to use this medicine

Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The usual recommended dosage is:

**For adults and children over 12 years:**

The usual recommended dosage is: 1 liquid capsule every 6-8 hours, up to 3 times a day. The interval between doses will be at least 4 hours. Do not take more than 3 capsules in 24 hours.

**Do not give this medicine to children under the age of 12 years.**

**Duration of treatment in children and adolescents 12-18 years old:** If this medicine is required for more than 3 days in children and adolescents, or if the symptoms worsen, consult the doctor.

**In adults** – do not take the medicine for more than 10 days, unless the doctor has instructed to do so.

If the symptoms do not pass, if the pain or fever worsen, or if new symptoms appear, consult your doctor or pharmacist.

**Do not exceed the recommended dose.** Take the lowest dose for the shortest term necessary to ease the symptoms.

#### Directions for use:

Swallow the capsule whole with a cup of water.

Do not chew. Do not open and spread the contents of the capsule.

If you took an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or the closest hospital to receive an opinion on the risk and for advice on the action to be taken.

Symptoms of an overdose may include nausea, abdominal pain, vomiting (may be bloody), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (especially in children), weakness and dizziness, blood in the urine, cold feeling and breathing problems have been reported.

**If you forgot to administer the medicine:** Note the instructions in section 3 "How to use the medicine" regarding how to take the medicine and do not take more than the recommended dose.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

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

#### 4. Side Effects

As with any medicine, the use of Nurofen Forte Liquid Capsules 400 mg may cause side effects in some users. Do not be alarmed when reading the list of side effects. You might not suffer from any of them.

**Stop taking the medicine and refer immediately to a doctor or medical assistance if you develop:**

- **Signs of intestinal bleeding** such as: bright red stools, black tarry stools, vomiting of blood or dark particles that look like coffee grounds
- **Signs of serious allergic reaction** such as:
  - Difficulties in breathing or unexplained wheezing
  - Dizziness or accelerated heartbeat
  - Severe skin reaction (rashes, itching, peeling of the skin, scaly skin or blisters)
  - Swelling of the face or throat

**Severe skin reaction known as DRESS syndrome** (drug reaction with eosinophilia and systemic symptoms). DRESS symptoms include: skin rash, fever, swelling of the lymph nodes and an increase in the number of eosinophils (a type of white blood cells).

- Red rash, with scales, widespread, with bumps under the skin and blisters located primarily on the skin folds, center of the body, and upper limbs, accompanied by fever at the beginning of the treatment (acute generalized exanthematous pustulosis) (frequency unknown). See section 2.

**Tell the doctor if you experience:**

- Fever, flu-like symptoms, sore throat, ulcers in the mouth, headache, stiff neck, vomiting, unexplained bleeding and bruising, severe exhaustion.
- Digestive difficulties, stomach ache, constipation, diarrhea, gas or nausea, chest pain or fast and irregular heartbeat.
- Liver and kidney problems accompanied with swelling in the arms and legs.
- The skin becomes sensitive to light (frequency unknown).

Medicines such as Nurofen Forte Liquid Capsules 400 mg may be associated with a slight increase in risk of heart attack (myocardial infarction) or stroke (see section 2, "Additional Warnings").

**If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.**

#### Reporting of side effects

Side effects can be reported to the Ministry of Health via the link

"דיווח על תופעות לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to the online form of side effects reporting or via the following link: <https://sideeffects.health.gov.il>.

#### 5. How to store the medicine

- Avoid poisoning! This medicine and all other medicines must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears 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, the medicine also contains:**

Macrogol 600, Gelatin, Sorbitol liquid partially dehydrated, Purified water, Potassium hydroxide, Ponceau 4R (E124), Lecithin (E322), Triglycerides (medium chain), Isopropyl alcohol, White printing ink- Opacode WB White NS-78-18011.

**What the medicine looks like and contents of the package:**

Soft red gelatin capsule, oval shaped and transparent with the Nurofen logo embossed in white ink.

Approved package sizes: a box that contains blister packs with 10, 12, 16, 18, 20, 24, 28, 30, 32, 36, 48 or 96 capsules.

Not all pack sizes may be marketed.

**Registration holder and address:** Reckitt Benckiser (Near East) Ltd., 6 Hanagar St., Hod Hasharon, 4527704.

**Manufacturer and address:** Reckitt Benckiser Healthcare Limited, Nottingham, England.

Revised in August 2021 according to MOH guidelines.

**Drug registration number at the national medicines registry of the Ministry of Health:**

148-44-31886-00

Nurofen Forte Liquid Caps 400 mg PIL PB1221-01