

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Nurofen 400 mg Tablets

Ibuprofen

PL 00063/0722

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

This medicine is available without prescription. However, you still need to take it carefully to get the best results from it. Nurofen 400 mg Tablets will be referred to as 'this medicine' throughout this leaflet.

- Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Keep this leaflet. You may need to read it again - Ask your pharmacist if you need more information or advice

- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

- You must contact a doctor if your symptoms worsen or do not improve after 3 days for children and adolescents between 12 and 18 years, and after 10 days for adults. This product contains sodium and sucrose.

What is in this leaflet:

1. What this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

1. What this medicine is and what it is used for

This medicine contains the active ingredient Ibuprofen which belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines provide relief by changing how the body responds to pain and fever. Nurofen 400 mg Tablets are used in adults and adolescents weighing from 40 kg (12 years of age and above) for the symptomatic treatment of:

- Headaches and migraine pain
- Dental pain and neuralgia
- Period pain
- Rheumatic, muscular and back pain
- Feverishness and symptoms of cold and flu

2. What you need to know before you take this medicine

Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Stop immediately this medicine and contact immediately your doctor or medical emergencies if you notice any of these signs.

DO NOT TAKE THIS MEDICINE IF YOU:

- are allergic to ibuprofen or any of the other ingredients (see section 6) or to aspirin or other similar painkillers
- have or ever had a stomach ulcer, perforation or bleeding
- have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking ibuprofen, aspirin or similar medicines
- have had a gastrointestinal bleeding or perforation, related to previous use of NSAIDs (Non-Steroidal Anti-Inflammatory Drugs)
- are taking other NSAIDs
- are taking more than 75mg of aspirin a day. If you are on low-dose aspirin (up to 75 mg daily)

Speak to your doctor or pharmacist before you take this medicine

- have severe liver or kidney problems
- have heart problems, high blood pressure or blood coagulation disorder
- have breathing difficulties
- are in the last 3 months of pregnancy
- are under 12 years old

Check with your pharmacist or your doctor before taking this product if you:

- have or have had asthma
- have kidney, heart, liver or bowel problems
- have high cholesterol or previously have had a heart attack or stroke
- have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease)
- have Systemic Lupus Erythematosus (a condition of the immune system causing joint pain skin changes and other organ disorders)
- are a smoker
- are in the first 6 months of pregnancy.
- **Have an infection.** This medicine may hide signs of infections such as fever and pain. It is therefore possible that this medicine may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

Skin reactions

- Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using this medicine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Taking other medicines:

To reduce the risk of side effects, do not take this product with other NSAID containing products (Aspirin, Ibuprofen)

This medicine may affect or be affected by some other medicines. For example: - medicines that are anti-coagulants (i.e. thin blood / prevent clotting e.g. aspirin / acetylsalicylic acid, warfarin, ticlopidine)

- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, medicines, angiotensin-II receptor antagonists such as losartan)
- corticosteroids (e.g. prednisolone); selective serotonin re-uptake inhibitors (SSRIs); cardiac glycoside (e.g. digoxin); lithium; methotrexate, ciclosporin, tacrolimus; zidovudine or quinolone antibiotics (e.g. norfloxacin).

Speak to your pharmacist or doctor before taking Ibuprofen with other medicines

Other warnings

Some other medicines may also affect or be affected by the treatment with this medicine. You should therefore always seek the advice of your doctor or pharmacist before you use this medicine with other medicines.

- This medicine belongs to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. It is unlikely that this medicine used occasionally will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.
- Medicines such as this medicine may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses or prolonged treatment. Do not exceed the recommended dose or duration of treatment (which is in adolescents 3 days and in adults 3 days for fever and 4 days for pain).
- If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes, or high cholesterol or are a smoker), you should discuss your treatment with your doctor or pharmacist.
- There is a risk of kidney problems in dehydrated children and adolescents.

If you are taking this medicine for longer than the recommended time or at higher than recommended doses you are at risk of serious harm. These include serious harm to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Pregnancy and breast feeding

Do not take this medicine if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take this medicine during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, this medicine can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring. Speak to your doctor if you are in the first 6 months of pregnancy. Speak to your doctor or pharmacist before taking this medicine if you are breastfeeding.

Important information about some of the ingredients of this medicine

- This medicine contains 27.42 mg sodium (main component of cooking/table salt) in each tablet.

This is equivalent to 1.37% of the recommended maximum daily intake of sodium for an adult.

- This product contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine

3. HOW TO TAKE THIS MEDICINE

Adults and children aged 12 years and older:

This product is intended for short term use only. The lowest dose effective dose should be used for the shortest duration necessary to relieve your symptoms. If you have an infection, consult a doctor without delay in symptoms (such as fever and pain) persist or worsen (see section 2).

Take 1 tablet with water, up to three times a day. Leave at least four hours between doses. Do not take more than 3 tablets in 24 hours.

Do not give to children under 12 years.

In children and adolescents between 12 and 18 years

If this medicine is required for more than 3 days, or if symptoms worsen, a doctor should be consulted.

In adults

If this medicine is required for longer than 10 days or if the symptoms persist or worsen, consult your doctor.

If you have taken more of this medicine than you should, or if children have taken this medicine by accident, always contact a doctor or nearest hospital to get an opinion of the risk and advice on what action to be taken.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

If you forget to take this medicine:

Simply refer to the directions above on how to take the medicine and do not take more than is advised.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms. You may suffer one of the known side effects of NSAIDs (see below). If you do, or if

you have concerns, stop taking this medicine and talk to your doctor as soon as possible. Elderly people using this product are at increased risk of developing problems associated with side effects. **STOP TAKING this medicine and seek immediate medical help if you develop:**

- **signs of intestinal bleeding** such as: bright red faeces (stools/motions), black tarry stools, vomiting, blood or dark particles that look like coffee grounds.
- **signs of serious allergic reaction** such as difficulties in breathing and unexplained wheezing, dizziness or faster heartbeat, reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis)
- **signs of kidney problems** such as: passing less or more urine, cloudy urine or blood in urine, pain in the back and/or swelling (particularly in the legs)
- **signs of aseptic meningitis** with neck stiffness, headache, feeling sick, being sick, fever or consciousness. Patients with autoimmune disorders (lupus, mixed connective tissue disease) may be more likely to be affected
- **a severe skin reaction known as DRESS syndrome** can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- A red, scaly widespread rash with bumps under the skin and blisters mainly localised on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis) (frequency not known). See also section 2. STOP taking this medicine and tell your doctor if you experience the following uncommon side effects, which may affect up to 1 in 100 people:
 - indigestion, heartburn or feeling sick
 - pains in your stomach (abdomen) or other abnormal stomach problems

Tell your doctor or pharmacist if you notice any of the following:

-Liver, kidney problems or difficulty urinating

This medicine, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

Tell your doctor if you have any of the following side effects, if they become worse or you notice any effects not listed:

Uncommon: may affect up to 1 in 100 people -

- allergic reactions, such as skin rashes (urticarial), itching, peeling - headaches

Rare: may affect up to 1 in 1,000 people

- flatulence (wind), diarrhoea, constipation and vomiting

Very rare – may affect up to 1 in 10,000 people

- blood disorders resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion

- drop in blood pressure

- stomach or intestinal ulcers, sometimes with bleeding and perforation, inflammation of the lining of the mouth with ulceration (ulcerative stomatitis), inflammation of the stomach (gastritis) -

liver problems

Not known: frequency cannot be estimated from the data

- worsening of asthma or bronchospasm

- swelling (oedema), high blood pressure, heart failure or attack

- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

- worsening of colitis and Crohn's disease

- skin becomes sensitive to light

Any anti-inflammatory / pain-killer medicines such as this medicine may be associated with a small

increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking this medicine if you:

- have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack 'TIA') - have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please stop taking the product immediately and tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE THIS MEDICINE

Keep out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month. Do not store above 25°C. Store in the original package.

6. Contents of the pack and other information

Each tablet contains the active ingredient ibuprofen 400 mg.

Also contains: Croscarmellose Sodium, Sodium Lauryl Sulphate, Sodium Citrate, Stearic Acid, Colloidal Anhydrous Silica, Carmellose Sodium, Talc, Acacia Spray Dried, Refined Sugar, Opalux Pink AS 1537, Macrogol 6000.

This medicine is available in packs of 12, 16, 24, 48, 96. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Reckitt Benckiser Healthcare (UK) Ltd, Slough, SL1 3UH.

Manufacturer:

Reckitt Benckiser Healthcare International Ltd, 1 Thane Road, Nottingham NG90 2DB, UK.RB NL Brands B.V., WTC Schiphol Airport, Schiphol Boulevard 207, 1118 BH Schiphol, NL.

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