Reads This Way

NUROFEN®

Pain Relief
256 mg Tablets
Contains Sodium Ibuprofen

INFORMATION FOR THE USER
Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription. However, you still need to use Nurofen Pain Relief 256 mg Tablets carefully to get the best results from them. Nurofen Pain Relief 256 mg Tablets will be referred to as 'this medicine' throughout this leaflet.
Keep this leaflet. You may want to read it again.
If you have any further questions after you have read it, ask your doctor or pharmacist.
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.
If any side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.
In this leaflet:

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

The active ingredient (which makes this medicine work) is Ibuprofen. It belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by changing the body's response to pain, swelling, and high temperature.
This medicine is used for the relief of fever and mild to moderate pain, such as:
- headaches and migraine pain
- nerve pain, backache, period pain, rheumatic and muscular pain
- cold and flu symptoms
- dental pain.

2. Before taking this medicine

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 painkillers
- have (or have had two or more episodes of) 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 gastrointestinal bleeding or perforation when previously taking NSAIDs (Nonsteroidal anti-inflammatory drugs)
- are taking other NSAID painkillers or more than 75 mg aspirin a day
- 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.
- are on a diet restricting your salt intake.
- **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 have been reported in association with this medicine. You should stop taking this medicine and seek medical attention immediately, if you develop any skin rash, lesion of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

Taking other medicines
This medicine may affect or be affected by some other medicines. For example:
Avoid taking this product with corticosteroid tablets, quinolone antibiotics or drugs that are prescribed
- as anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- to stimulate your heart (e.g. glycosides)
- to reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- to help you passing water (diuretics)
- for the temporary suppression of your immune system (e.g. methotrexate, ciclosporin, tacrolimus)
- for mania or depression (e.g. lithium or SSRIs)
- for pregnancy termination (e.g. mifepristone)
- for HIV treatment (e.g. zidovudine)

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

Other warnings:
- 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.
- Anti-inflammatory/pain-killer medicines such as ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the 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 of 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.
- 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 Nurofen Pain relief 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 Nurofen Pain relief 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, Nurofen Pain relief 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.
Do not take if you are breast feeding. Speak to your doctor if you are in the first 6 months of pregnancy.

Important information about some of the ingredients of this medicine:
This medicine contains 25.72 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 1.29% of the recommended maximum daily dietary 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 medicinal product.

3. How to take this medicine

This product is for short term use only. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).
Adults, the elderly and children and adolescents between 12 and 18 years:
Take 1 or 2 tablets with water, up to three times a day as required.
Leave at least four hours between doses. Do not take more than 6 tablets in 24 hours.
Do not give to children under 12 years.
Do not take this medicine for longer than 10 days unless your doctor tells you to.
If symptoms persist or worsen, or if any new symptoms occur, consult your doctor or pharmacist.
In children and adolescents between 12 and 18 years:
If in children and adolescents this medicinal product is required for more than 3 days, or if symptoms worsen, you should consult a 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 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:
Do not take a double dose to make up for a missed dose.
Simply refer to the directions above on how to take the medicine and do not take more than is advised.

4. Possible side effects

This medicine is generally well tolerated by most people. However side effects may occur.
STOP TAKING the 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 or unexplained wheezing
  - dizziness or faster heartbeat
  - severe forms of skin reactions such as itchiness, skin rash with redness, peeling, flaking or blistering (e.g. Steven-Johnson syndrome)
  - swelling of your face, tongue or throat
- **signs of kidney problems** such as: passing less or more urine, cloudy urine or blood in urine, pain in the back and/or swelling in the legs
- **signs of aseptic meningitis** with neck stiffness, headache, feeling sick, being sick, fever or disorientation. 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 the 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.

Like all medicines, this medicine can cause side-effects, although not everybody gets them. 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 or pharmacist if you have any of the following side effects, they become worse or you notice any affects not listed:
Uncommon: may affect up to 1 in 100 people:
- allergic reactions such as skin rashes (urticaria), 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 disorder resulting in unexplained or unusual bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion
- drop in blood pressure or irregular heartbeat
- stomach or intestinal ulcers, sometimes with bleeding and perforation, inflammation of the lining of the mouth with ulceration, inflammation of the stomach
- liver problems
- drop in haemoglobin levels which can cause tiredness, pale skin and gums, feeling short of breath and more noticeable heartbeats.

Not known: frequency cannot be estimated from the available data
- worsening of asthma or bronchospasm
- swelling (oedema), high blood pressure, heart failure or attack
- worsening of colitis and Crohn's disease.
- skin becomes sensitive to light

Medicines such as this medicine may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke. (See section 2 'Other warnings'.)
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please 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 all medicines out of the sight and reach of children.
Do not use after the expiry date stated on the carton after EXP. The expiry date refers to the last day of that month.
Store in the original pack.

6. Further information

Each tablet contains the active ingredient Ibuprofen 200 mg (as Sodium Ibuprofen 256 mg).
Also contains: Croscarmellose sodium, Xylitol, Microcrystalline cellulose, Magnesium stearate, Colloidal anhydrous silica, Carmellose sodium, Talc, Acacia spray dried, Sucrose, Titanium dioxide (E171), Macrogol 6000 powder, and Black ink (contains shellac, iron oxide black (E172) and propylene glycol).
This medicine is available in packs of 6, 12 and 16 white tablets printed with an identifying black logo. Not all packs are marketed
Manufacturers:
Reckitt Benckiser Healthcare International Ltd,
1 Thane Road, Nottingham NG90 2DB, UK.
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