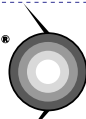


NUROFEN®

Pain Relief
200 mg Soft Capsules
Contains 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 take this medicine carefully to get the best results from it.
Nurofen Pain Relief 200 mg Soft Capsules will be referred to as this medicine throughout this leaflet.
Keep this leaflet. You may need to read it again.
If you have any further questions once 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 of the side effects gets serious, or if you notice any side effects 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
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

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 effective relief of fever and pain, such as:
• headaches and migraine pain
• nerve pain, backache, period pain, rheumatic and muscular pain
• cold and flu symptoms
• dental pain.

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. Immediately stop taking this medicine and contact your doctor or medical emergencies if you notice any of these signs.

Do not take these capsules if you:

- are allergic to ibuprofen or any of the other ingredients of this product (see section 4), or to aspirin or other related painkillers
- have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding
- have had a worsening of asthma, allergic rash or itchy, runny nose or facial swelling when taking similar medicines
- ever had stomach bleeding or a perforation when previously taking NSAIDs
- are taking other NSAIDs
- are taking more than 75 mg 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 doctor or pharmacist before taking this medicine if you:

- have or have had asthma
- have kidney, heart, liver, or bowel problems
- have high cholesterol or previously 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 generalised 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.
If symptoms persist or worsen, consult your doctor.

Taking other medicines

To reduce the risk of side effects, do not take this product with other NSAID containing products (e.g.) aspirin, ibuprofen). If you are on low dose aspirin (up to 75 mg daily), speak to your doctor or pharmacist before you take this medicine.

This medicine may affect or be affected by some other medicines.

For example:

- 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 product belongs to a group of medicines which may **impair fertility in women.** This is reversible on stopping the medicine. It is unlikely that this product, if 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

Tell your doctor if you become pregnant whilst taking this product. 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.
Do not take it if you are breastfeeding.
Avoid the use of this medicine in the first 6 months of pregnancy, unless the doctor advises otherwise.

Speak to your doctor or pharmacist for advice before taking any medicine if you are breast-feeding.

Important information about some of the ingredients of this medicine

These capsules contain

- **sorbitol** (21.28 mg per capsule). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these capsules.
- **potassium** (1.8 mg per capsule). To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

3. How to take this medicine

This product is for short term use only. You should take the lowest dose for the shortest time necessary to relieve your 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 one or two capsules (200 mg – 400 mg), up to three times a day as required.

Leave at least 4 hours between doses and do not take more than 6 capsules 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 a doctor should be consulted.

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

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you suffer from any of the following, at any time, during your treatment STOP TAKING the medicine and seek immediate medical help:

- pass blood in your faeces (stools/motions)
- pass black tarry stools
- vomit any blood or dark particles that look like coffee grounds
- difficulty in breathing, unexplained wheezing, worsening of existing asthma
- other allergic type reactions (e.g. swelling of the face or throat, low blood pressure, fast heart rate)
- 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 any of the following side effects, or anything unusual happens:

- indigestion or heartburn
- abdominal pain (pains in your stomach) or other abnormal stomach symptoms.
- skin reactions such as 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).

Medicines such as this medicine may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Please tell your doctor or pharmacist if you experience any of the following side effects, they become worse or if you notice any other effects not listed.

- oedema (fluid retention), high blood pressure (hypertension) and heart failure

- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- headache
- nausea, diarrhoea, constipation, vomiting and flatulence (wind)
- skin peeling
- kidney and liver disorders
- blood disorders. The first signs can be fever, sore throat, mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising, vomiting and stiff neck (in patients with existing auto-immune disorders such as systemic lupus erythematosus).
- worsening of colitis or Crohn's disease (inflammation of the bowel).
- **skin becomes sensitive to light (frequency not known)**

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.

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.

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 these capsules after the expiry date printed on the blister or carton. The expiry date refers to the last day of that month.

Keep the capsules in the original pack.

Do not store above 25°C.

In case of poor storage conditions, this product may deteriorate.

If you notice any signs of leakage of the capsules or change in colour, you should discard the capsules.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What this medicine contains

The active ingredient is: ibuprofen 200 mg.
The other ingredients are: macrogol 600, potassium hydroxide, gelatine, sorbitol (E420), purified water, Opacoed WB white NS-78-1801 T (titanium dioxide (E171), hypromellose, propylene glycol).

(see also end of section 2 'Important information about some of the ingredients of this medicine').

What this medicine looks like and contents of the pack

Each Soft capsule is an oval clear capsule printed in white with a logo.

This product is available in packs of 4, 10 and 16 capsules. Not all pack sizes may be marketed.

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