NUROFEN® MIGRAINE PAIN

Contains Ibuprofen Lysine

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 Migraine Pain carefully to get the best results from it. Nurofen Migraine pain will be referred to as this medicine thoughout 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:
- **Headaches and migraine 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 (Non-steroidal anti-inflammatory drugs)
- are taking other NSAID painkillers or more than 75mg 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.
- **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
To reduce the risk of side effects, do not take this product with other NSAID containing products (e.g, aspirin, ibuprofen…)
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 renal impairment in dehydrated children and adolescents.

Pregnancy and breast feeding
Do not take in the last 3 months of pregnancy or if you are breastfeeding.

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 less than 1mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

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 & adolescents between 12 and 18 years:
Take 1 or 2 caplets with water, up to three times a day as required. Leave at least four hours between doses. Do not take more than 6 caplets in 24 hours.
Do not give to children under 12 years.
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.
In adults:
Do not take for longer than 10 days unless your doctor tells you to. If symptoms persist or the pain worsens, or if any new symptoms occur, consult your doctor or pharmacist.

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 forgot 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. Some side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms. If any of the side effects get serious or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.
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 (particularly 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

TELL YOUR DOCTOR if you have any of the following side effects, 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 (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 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 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')

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.

Do not store above 25°C. Store in the original pack.

6. Further information

Each caplet contains the active ingredient Ibuprofen 200mg (as Ibuprofen Lysine 342mg).
Also contains: Povidone, Sodium Starch Glycollate Type A, Magnesium Stearate, Hypromellose, Talc, Opaspray White M-1-7111B (contains Hypromellose and Titanium Dioxide (E171) and Black Ink (contains, shellac, Iron oxide black (E172) and propylene Glycol).

This medicine is available in packs of 2, 4, 6, 8, 10, 12, 16 white, capsule-shaped tablets printed in black with identifying "NMP" logo.

Not all packs will be marketed.

Licence Holder: Reckitt Benckiser Healthcare (UK) Ltd, Slough, SL1 4AQ.

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Product licence number: PL 00063/0380

Date of revision: July 2021