NUROFEN®
Meltlets 200 mg
Orodispersible Tablets
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 use this medicine carefully to get the best results from it. Nurofen Meltlets 200 mg Orodispersible 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
This medicine dissolves quickly on the tongue without the need to use water, to provide effective relief. 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:
- **Headaches and migraine pain**

2. What you need to know before you take 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 related 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
- are taking other NSAID painkillers (Non-Steroidal Anti-inflammatory Drugs)
- 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
- are in the last 3 months of pregnancy
- have phenylketonuria or are intolerant to phenylalanine (see 'Important information about some of the ingredients of this medicine'), each tablet contains aspartame equivalent to 14 mg phenylalanine
- 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 - please see heading 'Infections' below

Infections
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:
- If you are taking any regular medicines, especially other pain relievers
- 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, betablockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- methotrexate or lithium
- medicines to stimulate your heart (e.g. glycosides)
- medicines to help you pass water (diuretics)
- medicines for the temporary suppression of your immune system (e.g, methotrexate, ciclosporin, tacrolimus)
- medicines to treat mania or depression (e.g., Lithium or SSRIs)
- medicines for pregnancy termination (e.g. mifepristone)
- medicines 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.
- There is a risk of renal impairment 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).
- Anti-inflammatory/pain-killer medicines like ibuprofen maybe 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.

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.

Pregnancy and breast feeding
Tell your doctor if you become pregnant whilst taking this medicine.
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.
Avoid the use of this medicine in the first 6 months of pregnancy, unless the doctor advises otherwise. 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 50 mg aspartame (E951) in each 2 tablet dose which is equivalent to 25 mg/tablet. Aspartame is a source of phenylalanine which may be harmful to people with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. This medicine contains 0.144 mg sorbitol in each 2 tablet dose which is equivalent to 0.072 mg/tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This medicine contains less than 1 mmol 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 2 tablets, then if necessary, take 1 or 2 tablets every 4 hours.
Place a tablet on the tongue, allow it to dissolve and then swallow; no water is required. Do not chew. 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.
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 or fever worsen, 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. 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.
Stop using this medicine if you develop these symptoms and seek medical attention immediately. See also section 2.
- **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 consciousness. Patients with autoimmune disorders (lupus, mixed connective-tissue disease) may be more likely to be affected.
- **blood disorder** resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and sever exhaustion.
- **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 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:
- drop in blood pressure or irregular heart beat
- 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, it is designed to protect the tablets.

6. Contents of the pack & other information
Each orodispersible tablet contains the active ingredient Ibuprofen 200 mg.
They also contain: Ethylcellulose (E462), Silicon Dioxide (E551), Hypromellose (E464), Mannitol (E420), Aspartame (E951), Croscarmellose Sodium (E468), Magnesium Stearate (E572), Flavour (mint flavours, maltodextrin acacia gum (E414), Sorbitol (E421)).

This medicine is available in packs of 4, 6, 10, 12, 14 or 16 self-dissolving tablets. Not all pack sizes may be marketed.

Licence Holder: Crookes Healthcare Limited, Nottingham, NG2 3AA.

Manufacturer: Reckitt Benckiser Healthcare International Ltd, Nottingham, NG90 2DB, UK.

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This leaflet gives you the most important information about this medicine. If you have any questions after you have read it, ask your doctor or pharmacist, who will give you further information.
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