

NUROFEN®

Meltlets 200mg
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.

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.

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1. What Nurofen Meltlets 200mg Orodispersible Tablets are and what they are used for

Nurofen Meltlets 200mg Orodispersible Tablets dissolve 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.

Nurofen Meltlets 200mg Orodispersible Tablets are used for the effective relief of:

- Headaches and migraine pain

2. Before taking Nurofen Meltlets 200mg Orodispersible Tablets

Do not take Nurofen Meltlets 200mg Orodispersible Tablets 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 75mg of aspirin a day. If you are on low-dose aspirin (up to 75mg 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 Nurofen Meltlets 200mg Orodispersible Tablets'), each tablet contains aspartame equivalent to 14mg 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.

Taking other medicines

Nurofen Meltlets 200mg Orodispersible Tablets 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/acetysalicylic 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, ciclosporine, 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 Nurofen Meltlets 200mg Orodispersible Tablets. You should therefore always seek the advice of your doctor or pharmacist before you use Nurofen Meltlets 200mg Orodispersible Tablets with other medicines.

Other warnings

- Nurofen Meltlets 200mg Orodispersible Tablets belongs to a group of medicines which may **impair fertility in women**. This is reversible on stopping the medicine. It is unlikely that Nurofen Meltlets 200mg Orodispersible Tablets, 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.
- 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 Nurofen 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 Nurofen. Do not take this medicine in the last 3 months of pregnancy. 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 Nurofen Meltlets 200mg Orodispersible Tablets

Each tablet contains aspartame (E951) which is a source of phenylalanine which may be harmful to people with phenylketonuria or who are intolerant to phenylalanine. Each orodispersible tablet contains a source equivalent to 14 mg of phenylalanine. Sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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3. How to take Nurofen Meltlets 200mg Orodispersible Tablets

This product is for short term use only. You should take the lowest dose for the shortest time necessary to relieve your symptoms.

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 Nurofen Meltlets 200mg Orodispersible Tablets 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 Nurofen Meltlets 200mg Orodispersible Tablets. 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, Nurofen 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 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)
- **signs of kidney problems** such as: 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).

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