

NUROFEN®

MELTLETS LEMON



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 Nurofen Meltlets Lemon 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 Lemon are and what they are 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.

Nurofen Meltlets Lemon are used for the relief of:

- Headaches and migraine pain
- Dental pain and neuralgia
- Period pain
- Rheumatic, muscular and back pain
- Feverishness and symptoms of cold and flu

2. Before taking Nurofen Meltlets Lemon

Do not take Nurofen Meltlets Lemon if you:

- are allergic to ibuprofen or any of the other ingredients (see section 6) or to aspirin or other painkillers
- have ever had 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 NSAIDs (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
- 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 phenylketonuria or are intolerant to phenylalanine. (see 'Important information about some of the ingredients of Nurofen Meltlets Lemon').

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 75mg daily), speak to your doctor or pharmacist before you take this medicine. Nurofen Meltlets 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:

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetilsalicylic acid, warfarin, ticlopidine)
- to stimulate your heart (e.g. glycosides)
- medicines that 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, ciclosporine, 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 Nurofen Meltlets. You should therefore always seek the advice of your doctor or pharmacist before you use Nurofen Meltlets with other medicines.

Other warnings

- Nurofen Meltlets Lemon 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 Lemon, 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 Nurofen Meltlets 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 or 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

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 Melittets Lemon

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.

3. How to take Nurofen Melittets Lemon

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 1 or 2 tablets up to three times a day as required.

Place a tablet on the tongue, allow it to dissolve and then swallow; no water is 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.

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 Melittets Lemon 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 Nurofen Melittets Lemon.

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 itchy skin, 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.
- **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).

STOP TAKING the medicine and tell your doctor if you experience the following uncommon side effects which affect 1 to 10 users in 1,000:

- 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 side effects which affect 1 to 10 users in 1,000:

- allergic reactions, such as skin rashes (urticaria), itching, peeling
- headaches

Rare side effects which affect 1 to 10 users in 10,000:

- flatulence (wind), diarrhoea, constipation and vomiting

Very rare side effects which affect less than 1 user in 10,000:

- 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 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

Side effects for which the frequency can not be estimated from available data:

- worsening of asthma or bronchospasm
- swelling (oedema), high blood pressure, heart failure or attack
- worsening of colitis and Crohn's disease

Medicines such as Nurofen Melittets Lemon 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 Nurofen Melittets Lemon

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 orodispersible tablet contains the active ingredient Ibuprofen 200mg. They also contain: Ethylcellulose (E462), Silicon Dioxide (E551), Hypromellose (E464), Mannitol (E420), Aspartame (E951), Croscarmellose Sodium (E468), Magnesium Stearate (E572), Flavour (lemon flavours, maltodextrin).

Nurofen Melittets Lemon are available in packs of 4, 6, 10, 12, 14, 16, 18, 20, 22, 24, 30, 36, 40 or 48 orodispersible tablets.

Not all packs will be marketed.

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

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

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