

LEAFLET COPY

Nurofen Advance 200mg Tablets
(Ibuprofen Lysine)

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 Nurofen Advance 200mg Tablets carefully to get the best results from them.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days
- If any of the side-effects gets 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 Advance 200mg Tablets are and what they are used for:
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1. WHAT NUROFEN ADVANCE 200mg TABLETS ARE AND WHAT THEY ARE USED FOR?

Nurofen Advance contains ibuprofen 200mg as ibuprofen lysinate. Ibuprofen belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines provide relief by changing the body's response to pain, swelling and high temperature. Nurofen Advance 200mg tablets provide fast and effective relief from headaches, migraine, dental pain, period pain, backache, muscular pain, for the symptomatic treatment of cold and flu symptoms and fever.

2. BEFORE YOU TAKE NUROFEN ADVANCE 200mg TABLETS

Do not take Nurofen Advance 200mg Tablets if you:

- Are allergic to ibuprofen or any of the ingredients of Nurofen Advance 200mg Tablets listed in section 6.
- Have experienced shortness of breath, worsening of asthma, allergic rash or an itchy runny nose or swelling of the lips, face, tongue or throat when taking ibuprofen, aspirin or other similar medicines have ever had stomach bleeding or perforation after taking ibuprofen, aspirin or other similar medicines have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding have severe heart failure, renal failure or hepatic failure are in the last 3 months of pregnancy are under 12 years of age.

Consult your doctor or pharmacist before taking Nurofen Advance 200mg Tablets if you:

- have an infection – please see heading 'Infections' below
- have asthma or have suffered from asthma
- have kidney or liver problems
- 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 stomach or intestinal problems (such as Crohn's disease or ulcerative colitis)
- have high blood pressure, diabetes, high cholesterol has a family history of heart disease or stroke, or if you are a smoker
- suffer from a connective tissue disease such as Systemic Lupus Erythematosus (SLE) (Lupus)
- are elderly. Elderly patients are more prone to side effects such as stomach bleeding and perforation which may be fatal.
- are in the first six months of pregnancy
- are receiving regular treatment from your doctor
- have previously experienced stomach bleeding or perforation after taking ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs)
- have chicken pox as it is advisable to avoid the use of Nurofen Advance 200mg film coated tablets.

Serious skin reactions have been reported in association with Nurofen Advance 200mg Tablets treatment. You should stop taking Nurofen Advance 200mg Tablets and seek medical attention immediately, if you develop any skin rash, lesions 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.

Infections: Nurofen Long Lasting Tablets may hide signs of infections such as fever and pain. It is therefore possible that Nurofen Long Lasting Tablets 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/they have an infection and the symptoms of the infection persist or worsen, consult a doctor without delay.

Adolescents

There is a risk of renal impairment in dehydrated adolescents.

Other warnings

Anti-inflammatory/pain-killer medicines like 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 (3 days).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. In particular, discuss with your doctor or pharmacist if you are taking any of the following:

- aspirin or other NSAIDs including cyclo-oxygenase-2 selective inhibitors
- corticosteroids (such as prednisolone) since this may increase the risk of gastrointestinal ulceration or bleeding
- diuretics: since NSAIDs may diminish the effects of these drugs
- serotonin-reuptake inhibitors (a medicine for depression) since these drugs may increase the risk of gastrointestinal side effects
- lithium (a medicine for depression) since there is evidence for a potential increase in plasma levels of lithium
- methotrexate (a medicine for cancer or rheumatism) since there is evidence for a potential increase in plasma levels of methotrexate
- oral hypoglycaemic agents (oral medicines to treat diabetes)
- aminoglycosides (a type of antibiotic)
- probenecid (to treat gout)
- ciclosporin or tacrolimus (medicines to suppress the immune reaction) since there is limited evidence of an increased risk for kidney toxicity)
- zidovudine (a medicine to treat HIV)
- quinolone antibiotics since patients taking NSAIDs and quinolone antibiotics may have an increased risk of developing convulsions
- mifepristone (now or in the last 12 days)
- cardiac glycosides such as digoxin
- 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, beta- blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)

Some other medicines may also affect or be affected by the treatment of Nurofen Advance 200mg Tablets. You should therefore always seek the advice of your doctor or pharmacist before you use Nurofen Advance 200mg Tablets with other medicines.

Fertility, pregnancy and breast-feeding

Do not take 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 child. 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 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, it 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.

This medicine passes into breast milk but may be used during breast-feeding if it is used at the recommended dose and for the shortest possible time.

Nurofen Advance 200mg tablets belong to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. Patients should be aware that this product may make it more difficult to become pregnant or having problems becoming pregnant.

Driving and using machines

There are no known effects on driving or use of machines.

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

3. HOW TO TAKE NUROFEN ADVANCE 200mg TABLETS:

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 and children over 12 years:

Initial dose is 1-2 tablets swallowed with water then if necessary, 1-2 tablets every 4 hours. Do not exceed 6 tablets in 24 hours. Do not use in children under 12 years of age. If this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

NSAIDs should be used with caution in the elderly due to increased risk of adverse events and risk of gastrointestinal bleeding. If treatment is required this should be discussed with a healthcare professional and treatment reviews regularly.

If you take more Nurofen Advance 200mg tablets than you should:

If you have taken more Nurofen Advance 200mg 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 forget to take Nurofen Advance 200mg tablets

Take your tablets as usual. Do not take a double dose to make up for forgotten tablets.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Nurofen Advance 200mg tablets 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. Although side effects are uncommon, you may suffer one of the known side effects of NSAIDs. If you do, or if you have concerns, stop taking this medicine and talk to your doctor as soon as possible. Elderly people using this product are at increased risk of developing problems associated with side effects.

STOP TAKING this 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 very rare serious allergic reactions** 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 very rare 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 very rare 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.

STOP TAKING the medicine and tell your doctor if you experience the following uncommon side effects

which affect 1 to 10 users in 1000:

Abdominal pain, nausea and indigestion

TELL YOUR DOCTOR if you have any of the following side effects, they become worse or you notice any side effects not listed.

Uncommon side effects which affect 1 to 10 users in 1000:

- 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
- Decreased haemoglobin

Very rare: Severe skin infections and soft tissue complications during chicken pox (varicella) infection.

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

- Impaired hearing
- Worsening of asthma or bronchospasm
- Swelling (oedema), high blood pressure, heart failure or attack
- Worsening of colitis and Crohn's disease
- Abnormal liver function

Medicines such as Nurofen Advance 200mg tablets may be associated with a small risk of heart attack ("myocardial infarction") or stroke. See section 2 "Other Warnings".

Not known:

- 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 localized on the skin folds, trunk and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Nurofen Advance 200mg Tablets if you develop these symptoms and seek medical attention immediately. See also section 2.

- Skin becomes sensitive to light

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine. HPRA Pharmacovigilance. Website: www.hpra.ie

5. HOW TO STORE NUROFEN ADVANCE 200mg Tablets

KEEP OUT OF REACH AND SIGHT OF CHILDREN

Do not store above 25°C. Do not use after the expiry date which is stated on the carton and blister packaging after "Exp". The expiry date refers to the last day of the month. Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What Nurofen Advance 200mg Tablets contain.

The active substance is Ibuprofen lysine (the equivalent of 200mg of ibuprofen). The tablet core contains Povidone, sodium starch glycolate, magnesium stearate, hypromellose, talc, Opaspray white M-1-7111B (contains Hypermellose and Titanium dioxide (E171) and Opacaode S-1-8152HV (contains iron oxide (E172), shellac, soya lecithin, and Antifoam DC 1510 (contains polydimethylsiloxane).

What Nurofen Advance 200mg Tablets look like and contents of the pack

Nurofen Advance 200mg Tablets are white film coated tablets with a black logo on one face. Available in packs of 2, 4, 6, 10, 12, 16, 20, 24, 28, 32, 36, 40 and 48 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

PA Holder: Reckitt Benckiser Ireland Limited, 7 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

This leaflet was updated Upon Approval