

NUROFEN LONG LASTING
300mg Prolonged Release Hard Capsules
ibuprofen

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet:

1. What Nurofen Long Lasting is and what it is used for
2. What you need to know before you take Nurofen Long Lasting
3. How to take Nurofen Long Lasting
4. Possible side-effects
5. How to store Nurofen Long Lasting
6. Contents of the pack and other information.

1. WHAT NUROFEN LONG LASTING IS AND WHAT IT IS USED FOR?

Nurofen Long Lasting contains ibuprofen which 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. The capsules have been specially designed to control the release of the active ingredient and so provide relief for up to 12 hours. Nurofen Long Lasting Capsules are for the short term management of backache and muscular pains and period pain (dysmenorrhea).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NUROFEN LONG LASTING:

Do not take Nurofen Long Lasting if you:

- are allergic to ibuprofen, aspirin, or any of the ingredients listed in Section 6.
- have experienced shortness of breath, worsening of asthma, allergic rash or an itchy, runny nose 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 ever had a stomach ulcer, perforation or bleeding
- suffer from severe kidney or liver problems
- have severe heart failure
- have coagulation disorders or bleeding diathesis.
- have severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake).
- are more than 27 weeks pregnant or breastfeeding See pregnancy and breastfeeding.
- are under 12 years of age

Talk to your doctor, pharmacist or nurse before taking Nurofen Long Lasting 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”)
- are already taking non-steroidal anti-inflammatory medication (NSAIDs)
- have stomach or intestinal problems (such as Crohn’s disease or ulcerative colitis)
- have breathing difficulties
- have high blood pressure, diabetes, high cholesterol, have 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)
- have problems with bleeding or blood clotting
- are elderly
- are receiving regular treatment from your doctor
- have chicken pox, as it is advisable to avoid the use of Nurofen Long Lasting.

Signs of an allergic reaction to this medicine including breathing problems, swelling of the face and neck region (angioedema) and chest pain have been reported with ibuprofen. Stop taking Nurofen Long Lasting immediately and contact your doctor or medical emergencies if you notice any of these signs.

Nurofen Long Lasting may make it difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Tell your doctor if you notice any unusual symptoms - especially dark bowel motions, vomiting blood or stomach pains

Take special care with Nurofen Long Lasting:

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using Nurofen Long Lasting and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in Section 4.

Infections: Nurofen Long Lasting may hide signs of infections such as fever and pain. It is therefore possible that Nurofen Long Lasting 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.

There is increased risk of bleeding from the stomach, ulceration, perforation with increasing NSAID doses, in patients with a history of ulcers, and the elderly. It is recommended to commence treatment at the lowest dose. The option of adding a protective agent should also be discussed with your doctor.

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].

If you have heart problems, previous stroke, any problems with or disease of your blood vessels or think that you might be at risk of these conditions (for example, if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Prolonged use of any type of painkiller for headaches can make them worse. If your headache or other symptoms persist or if your pain or fever worsens, or if new symptoms occur talk to your doctor or pharmacist

Other medicines and Nurofen Long Lasting

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription. In particular, take care when taking this product if you are taking any of the following:

- aspirin or other NSAIDs
- corticosteroids (such as prednisolone) since this may increase the risk on gastrointestinal ulceration or bleeding
- diuretics: since NSAIDs may diminish the effect of this drug
- selective serotonin-reuptake inhibitors (a medicine for depression) since this may increase the risk of gastrointestinal side effects
- Cardiac glycosides such as digoxin since the effect of these may be enhanced
- Lithium (a medicine for depression) since the effect of lithium may be enhanced
- Methotrexate (a medicine for cancer or rheumatism) since the effect of methotrexate may be enhanced
- Cyclosporin (a medicine to suppress the immune reaction) since there is limited evidence on an increased risk for kidney toxicity
- Aminoglycosides (a type of antibiotic) since there is evidence of an increased risk of kidney toxicity
- Probenecid (a medicine for gout) since it may enhance the effect of the Nurofen Long Lasting
- Oral hypoglycemic agents (tablets for diabetes) since the effects of these may be enhanced, leading to a higher risk of hypoglycaemia
- Zidovudine: there is evidence of an increased risk of haemarthroses (bleeding into joint spaces) and haematoma (internal bleeding) in HIV (+) haemophiles receiving concurrent treatment with Zidovudine and ibuprofen
- 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)
- Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone
- Tacrolimus, as there is a possible increased risk of kidney toxicity when NSAIDs are given with tacrolimus
- Quinolone antibiotics (such as levofloxacin, ciprofloxacin, moxifloxacin) as patients taking NSAIDs and quinolones may have an increased risk of developing convulsions

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

Taking Nurofen Long Lasting with food and drink:

Nurofen Long Lasting should be taken with a sufficient quantity of liquid on an empty stomach or during a meal.

Pregnancy, breastfeeding, and fertility:

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 or heart problems in your unborn child. It may affect you or 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 pregnant 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 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.

Ibuprofen can pass in very small concentration into breast milk with no harmful effects to the infant. It is not necessary to interrupt breast feeding for short term treatment at the recommended dose.

Nurofen Long Lasting 300mg Prolonged Release Hard Capsules 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 and should inform their doctor if planning to become pregnant or having problems becoming pregnant.

Driving and using machines:

This product may affect your ability to drive or use machines as dizziness may occur.

Important information about some of the ingredients of Nurofen Long Lasting:

This product contains 34.5mg of sucrose per capsule. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE NUROFEN LONG LASTING TABLETS:**Adults, the elderly and children over 12 years of age (weighing over 40kg):**

For oral administration and short-term use only. Take 1 or 2 capsules twice daily. The capsules should be taken together with water and swallowed whole. Do not chew the capsules. Leave at least 8 hours between doses. Do not take more than 4 capsules (1200mg) in any 24 hour period. Do not give to children under 12 years of age.

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) or the product is required for more than 3 days consult a doctor.

Elderly: NSAIDs should be used with caution particularly in elderly patients who are prone to adverse events. The lowest dose compatible with adequate safe clinical control should be employed.

Treatment should be reviewed at regular intervals and discontinued if no benefit is seen or intolerance occurs. Undesirable effects can be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms.

If you take more Nurofen Long Lasting than you should:

If you have taken more Nurofen Long Lasting 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 of overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding (see also part 4 below), diarrhoea, headache, ringing in the ears, confusion and shaky eye movement. Also agitation, somnolence, disorientation or coma may occur. Occasionally patients develop convulsions. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, low levels of potassium in the blood, cold body feeling, and breathing problems have been reported. Further, the prothrombin time/INR may be prolonged, probably due to the interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics. Furthermore, there may be low blood pressure and reduced breathing.

If you forget to take Nurofen Long Lasting

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 Long Lasting can cause side-effects, although not everyone gets them.

Tell your doctor or pharmacist if you notice any of the following:

- stomach problems such as unexplained stomach pain, indigestion, feeling sick and/or vomiting, diarrhoea or constipation, flatulence
- any sign of bleeding from the stomach or bowels (vomiting blood and/or passing black stools) or worsening of colitis or Crohn's disease
- stomach ulcers
- liver or kidney problems
- severe sore throat with a high fever and flu-like symptoms, severe exhaustion, nose or skin bleeding, mouth ulcers (blood disorders)
- severe skin reactions such as skin peeling
- a severe headache, stiff neck, nausea, vomiting, fever or confusion.
- allergic reactions such as unexplained wheezing, shortness of breath, swelling of the face, tongue or throat, palpitations, skin rash or itching ('nettle rash').
- asthma, aggravation of asthma or wheezing
- severe skin infections and soft tissue complications during chicken pox (varicella) infection
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin-peeling, ulcer of the mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis]
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome) A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis) Skin becomes sensitive to light

Undesirable effects may be minimized by using the minimum effective dose for the shortest duration.

If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

The elderly are at an increased risk of side effects.

Shortness of breath may occur if you suffer from or have a history of allergic disease.

Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

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.

Reporting of Side Effects

Reporting suspected adverse reactions after authorization of a medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report and suspected adverse reactions via HPRA Pharmacovigilance. Website: www.hpra.ie

5. HOW TO STORE NUROFEN LONG LASTING

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Nurofen Long Lasting contain

Nurofen Long Lasting Capsules are prolonged release hard capsules that contains ibuprofen 300mg in sustained release formulation.

Also contains: Sugar spheres, Povidone, Basic Butylated Methacrylate copolymer, Ammino Methacrylate Copolymer Type A, Talc Colloidal anhydrous silica, Capsule shell (contains gelatin), Printing ink (contains red iron oxide E172 and yellow iron oxide E172).

What Nurofen Long Lasting look like and contents of the pack

The capsules have a colourless transparent cap and body printed with “N 300” in red ink containing white granules.

Available in packs of 12, 24, 28, 30, 56 and 60 prolonged-release hard capsules. Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

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