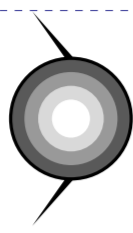


NUROFEN®

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 (dysmenorrhoea).

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.

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

Serious skin reactions have been reported in association with Nurofen Long Lasting. You should stop taking Nurofen Long Lasting 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 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

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First Bar
Last Bar

295mm

- 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:

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.

Ask your doctor or pharmacist for advice before taking any medicine. Consult your doctor before use if you are in the first 27 weeks of pregnancy. Do not use Nurofen Long Lasting after the 27th week of pregnancy.

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.

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 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 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
- 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

- 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). Stop using Nurofen Long Lasting Tablets if you develop these symptoms and seek medical attention immediately. See also section 2.

- 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.

If any of the side effects gets serious, or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.

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 HPRC Pharmacovigilance. Website www.hpra.ie

By reporting side effects you can help provide more information in the safety of this medicine.

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

Manufacturers: Reckitt Benckiser Healthcare International Ltd. Thane Road, Nottingham, NG90 2DB, UK and

RB NL Brands B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL.

For product enquiries, please telephone (01) 6305429 or contact Reckitt Benckiser Ireland Ltd., 7 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

This leaflet was updated in February 2022

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Pharmacode Reads This Way
First Bar
Last Bar

RB Artwork and Print Specification

Trident Reference No:	RB49081
ZEN Ref:	TR2285082
Action:	H
Brand:	Nurofen
Category:	Adult
Segment Group:	Stronger Pain
Segment:	300mg Slow Release Capsule
Pack Size:	24/Pack
Market/Country:	Ireland
Date:	11/02/22

RBH Contact: Bridget Barcoe

Artwork Type: BW Commercial

Component Code (if applicable):	3191703
2 nd Component Code (if applicable):	N/A
Parent Technical Packaging Specification:	DD69118
Finished Goods Code:	3167262
Supply Point:	RB Nottingham
3rd Party Code:	N/A
Pharmacode No/NE:	110000100(1795)
Edgemark Position:	NA

CAD Cam Ref: N-LR-FB-D069118-190x295mm LST Flat
Printer: Westrock MPS (Tewkesbury, UK)
Substrate: Paper White

Technical & Non Printing Items

Cutter	Cutter 2 (if applicable)
Guides	Guides 2 (if applicable)

Colours (Leaflet)

Process Black	100%
White	100%

BARCODE INFO

Barcode Type:	N/A
Barcode Number:	N/A
Magnification:	N/A
Truncated By:	N/A
Full Height:	N/A
Bar Height (Smallest Bar):	N/A
BWR:	N/A
Encoded Data:	N/A



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CUSTOMER INFO:
Minimum Point Size = 9.50pt

190mm



Production line		
Manufacturing site		
Pack Tech approver	1st	2nd
Date		
Check Criteria	Details & Comments	Checks
Approvals		1st 2nd
Market Approval		
Regulatory Approval		
3rd Party Approval		
Technical Drawing/ Cutter ref no. & PPI component code		
PPI component code number/s correct on artwork?		
PPI component code number/s in correct position on artwork?		
Correct drawing for the production line?		
Profile shape & dimensions		
Graphics layout/orientation		
Unwind diagram (PPTD1022/1-20)		
Printable areas/bleed		
Varnish free areas		
Variable coding position & dimensions		
Varnish and print requirements		
Pre-printed headers (alignment and suitability)		
Embossing, Braille & Foil Blocking		
Separations on artwork		
Alignment within cutter		
Braille structure		
Verification Code Type; Pharma Code / 2D / OCV		
Bar sequence and/or number correct on artwork		
Bar sequence and/or number in correct position on artwork?		
Size (height, width, spacing, font)		
Direction of read		
Light margins and print free areas		
Colour		
Repeat distance (reeled material)		
Cross check related docs ie BOM		
Bar code Type; EAN, ITF, Code39, etc		
Magnification / width and height		
Colour (e.g. black print on white background)		
Light margins & indicators		
Bearer bars & H gauges (if required)		
Symbol grade (Pass = A,B,C; Action = D,F)		
Bar code number (human readable)		
Bar code number (encoded & hidden data)		
Confirm bar code number from source		
Cross check related docs (JDE/PID)		
Photo-electric cell mark / edge marks		
Present & per Tech drawing?		
Correct pitch?		
Additional markings		
e-mark, recycle logo etc		
Legend box (RB specification)		
Correct component code		
Correct D spec / has cutter changed?		
Correct printer / has printer changed?		
Correct Substrate		
A/W is set up appropriately for this substrate		
Edge mark details		
Pharmacode details		
Colours & print process		
Varnish		
Barcode information		
General details are correct		
Pass / Fail comments and Signature		
By approving the artwork referenced within this form I authorise it for release to the print supplier		
Additional Comments		

RB Artwork and Print Specification

Trident Reference No: RB490081
 ZEN Ref: **TR2285082**
 Action: **H**
 Brand: Nurofen
 Category: Adult
 Segment Group: Stronger Pain
 Segment: 300mg Slow Release Capsule
 Pack Size: 24Pack
 Market/Country: Ireland
 Date: 11/02/22

RBH Contact: Bridget Barcoe

Artwork Type: BW Commercial

Component Code (if applicable): **3191703**
 2nd Component Code (if applicable): **N/A**
 Parent Technical Packaging Specification: D0369118
 Finished Goods Code: **3167262**
 Supply Point: RB Nottingham
 3rd Party Code: N/A
 Pharmacode No/NE: 1100000100(1795)
 Edgemark Position: NA

CAD Cam Ref: N-LR-FB-D0069118-190x295mm LST Flat
 Printer: Westrock MFS (Tewkesbury, UK)
 Substrate: Paper White

Technical & Non Printing Items

■ Cutter ■ Cutter 2 (if applicable)
 ■ Guides ■ Guides 2 (if applicable)

Colours (Leaflet)

Process Black

BARCODE INFO

Barcode Type: N/A
 Barcode Number: N/A
 Magnification: N/A
 Truncated By: N/A
 Full Height: N/A
 Bar Height (Smallest Bar): N/A
 BWR: N/A
 Encoded Data: N/A



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 Sm*Art check results: G=0; O=2; R=2; - AV - 11/02/22 13:01:27

