Package leaflet: Information for the patient

Nurofen Long Lasting 300 mg Prolonged-Release Tablets
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 or pharmacist have 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 or pharmacist. 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 4 days, with pain.**

What is in this leaflet

1. What Nurofen Long Lasting 300 mg Prolonged-Release Tablets are and what they are used for

The active substance (which makes this medicine work) is ibuprofen. Ibuprofen belongs to a group of medicines called 'nonsteroidal antiinflammatory drugs' (NSAIDs). These medicines work by reducing pain, fever and inflammation.

Nurofen Long Lasting 300 mg Prolonged-Release Tablets are used in adults aged 18 years and above for the short-term treatment of mild to moderate pain expected to last longer than 6-8 hours, such as backache, muscular pain, joint pain, period pain and dental pain.

This medicine is made to release its ibuprofen slowly over 12 hours– please see Section 3.

2. What you need to know before you take Nurofen Long Lasting 300 mg Prolonged-Release Tablets

Do not take Nurofen Long Lasting 300 mg Prolonged-Release Tablets if you:

- are allergic to ibuprofen or any of the other ingredients of this medicine (see section 6)
- have ever had an allergic reaction e.g. asthma, skin rash, itchy runny nose or facial swelling when previously taking acetylsalicylic acid or other related painkillers (NSAIDs).
- have or have ever had more than two episodes of an ulcer, perforation or bleeding of the stomach or intestines.

- have had gastrointestinal bleeding or perforation when previously taking NSAIDs (nonsteroidal antiinflammatory drugs).
- have problems with blood cell formation such as anaemia and low white blood cell count.
- if you have severe liver, kidney, or heart failure.
- suffer from severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake).
- suffer from bleeding on the brain (cerebrovascular bleeding) or other active bleeding.
- if you are a woman in the last three months of pregnancy.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nurofen Long Lasting 300 mg Prolonged-Release Tablets if you:
- have an infection - please see heading "Infections" below.
- have or have had asthma or other allergic diseases.
- have kidney, heart, liver or bowel problems.
- have bowel disease (Crohn's disease or ulcerative colitis) as these conditions may be made worse (see section 4 Possible side effects).
- have 'Systemic Lupus Erythematosus' (a condition of the immune system causing joint pain, skin changes and other organ problems).
- suffer from blood clotting disturbances.
- have just had major surgery.
- have chicken pox (varicella), as it is advisable to avoid use of ibuprofen during periods of infection.
- have an increased tendency to bleed or problems with abnormal bruising.
- have or have had 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 'ministroke' or transient ischaemic attack, TIA).
- have high blood pressure, diabetes, high cholesterol, a family history of heart disease or stroke, or if you are a smoker.
- suffer from hay fever, nasal polyps or chronic obstructive respiratory disorders, as an increased risk of allergic reactions exists. The allergic reactions may present as asthma attacks (so-called analgesic asthma), acute swellings (Quincke's oedema) or a skin rash (urticaria).

Other warnings:

- Anti-inflammatory / painkiller 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.
- The habitual use of painkillers can lead to permanent kidney damage with the risk of kidney failure especially when several painkillers are used at the same time.
- Prolonged use of any type of painkillers for headaches can make them worse or more frequent. This is called medication overuse headache (MOH). If this happens or is suspected, stop taking this medicine and seek medical advice.
- Serious skin reactions have been reported in association with ibuprofen treatment. **Stop taking this medicine and seek immediate medical attention**, if you develop any skin rashes, itching, swelling, blistering or other allergic symptoms as these may be the first signs of a very serious skin reaction. See section 4 Possible side effects.
- Aseptic meningitis has been observed on rare occasions in association with ibuprofen treatment. **Stop taking this medicine and seek immediate medical attention** if you develop signs of aseptic meningitis such as severe headache, high temperature, stiffness of the neck or intolerance to bright light.

This Prolonged Release formulation is intended for situations where more than a single lower dose of treatment (Immediate Release formulation) is expected to be necessary.

Side effects may be minimised by taking the lowest dose for the shortest time needed to relieve the

symptoms.

Gastrointestinal bleeding, ulceration or perforation

Bleeding, ulceration, or perforation in the stomach may occur at any time during treatment, with or without warning, symptoms or a previous history of serious gastrointestinal effects.

The risk of this is higher with:
- increasing ibuprofen doses.
- in patients with a history of gastrointestinal ulcer, particularly with bleeding and perforation (see section 2: Do not take this medicine).
- in the elderly.
- in patients taking certain other medicines at the same time as ibuprofen (see "Other medicines and Nurofen Long Lasting 300 mg Prolonged-Release Tablets").

These patients should commence treatment on the lowest dose available.

If any symptoms of gastrointestinal bleeding, ulceration, or perforation occur (such as severe pain in the abdomen, black tarry stools, vomiting blood or dark particles that look like coffee grounds), stop taking this medicine immediately and seek medical advice.

Infections

Nurofen Long Lasting 300 mg Prolonged-Release Tablets may hide signs of infections such as fever and pain. It is therefore possible that Nurofen Long Lasting 300 mg Prolonged-Release 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 have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

Elderly
The elderly have an increased risk of side effects when taking NSAIDs, particularly those relating to the stomach and bowel. See section 4 Possible side effects.

Children and adolescents
This medicine should not be used by children or adolescents under the age of 18 years.

Other medicines and Nurofen Long Lasting 300 mg Prolonged-Release Tablets

Tell your doctor or pharmacist before taking this medicine if you are taking, have recently taken or might take any other medicines especially:

Other ibuprofen medicines or other NSAIDs (including COX-2 inhibitors such as celecoxib or etoricoxib)	As this may increase the risk of side effects
Blood thinning or medicines that prevent clotting (warfarin, acetylsalicylic acid or clopidogrel)	As ibuprofen may enhance the effects of these medicines and increase the risk of bleeding
Medicines for high blood pressure and water tablets (e.g. ACE inhibitors such as captopril, beta-receptor blockers such as atenolol, angiotensin II antagonists such as losartan and diuretics)	As ibuprofen may reduce the effects of these medicines and there could be a possible increased risk of damage to the kidneys
Corticosteroids (medicinal products containing cortisone or cortisone-like substances)	As this may increase the risk of gastrointestinal ulcers and bleeding

Selective serotonin reuptake inhibitors called SSRIs (for depression)	As SSRIs may increase the risk of gastrointestinal bleeding
Cardiac glycosides e.g. digoxin (for heart problems)	As the effect of digoxin may be enhanced
Herbal extracts: from the Ginkgo biloba tree	As this may increase the risk of bleeding with NSAIDs
Lithium (for mania and depression)	As the effect of lithium may be enhanced
Phenytoin (for epilepsy)	As the effect of phenytoin may be enhanced
Methotrexate (for cancer or rheumatism)	As the effect of methotrexate may be enhanced
Cyclosporin and tacrolimus (to suppress the immune system)	As there is an increased risk of effects on the kidneys
Mifepristone (for pregnancy termination)	Since the effect of mifepristone can be reduced, NSAIDs should not be used for 8-12 days after mifepristone administration
Sulfonylureas (antidiabetic medicines)	As blood sugar levels can be affected
Potassium sparing diuretics	Since this may lead to high potassium levels in the blood
Zidovudine (for treating HIV/AIDS)	As use may result in an increased risk of bleeding into a joint or increased bleeding in HIV (+) haemophiliacs
Probenecid and sulfinpyrazones (for gout)	As the excretion of ibuprofen may be delayed
Aminoglycosides (such as tobramycin for certain bacterial infections and tuberculosis)	NSAIDs may decrease the excretion of aminoglycosides
Quinolone antibiotics (for infections)	As the risk of convulsions (fits) may be increased
Voriconazole and fluconazole (CYP2C9 inhibitors) used for fungal infections	As the effect of ibuprofen may be increased
Cholestyramine (used in the treatment of high cholesterol)	Absorption of ibuprofen is delayed and decreased when taking and cholestyramine at the same time. Therefore, each of these medicines should be administered with a few hours interval between.

Seek the advice of your doctor or pharmacist if any of the above apply. If you are not sure what types of medicine you are taking, show the medicine to the doctor or pharmacist.

Nurofen Long Lasting 300 mg Prolonged-Release Tablets and alcohol
You should not drink alcohol while using this medicine. Some side effects, such as those affecting the gastrointestinal tract or the central nervous system can be more likely when alcohol is taken at the same time as ibuprofen.

Pregnancy, breast feeding and fertility
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
Do not use this medicine 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 baby. 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 this medicine in 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, ibuprofen 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.

Breast feeding
Only small amounts of ibuprofen and its decomposition products pass into breast milk.
This medicine may be used during breast-feeding, if it is used at the recommended dose and for the shortest possible time.

Fertility
This medicine belongs to a group of medicines, which may impair fertility in women. This effect is reversible on stopping the medicine. Tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

This medicine has no or little effect on the ability to drive and use machines when taken at the recommended doses or duration of treatment.

However, at higher doses, undesirable effects such as tiredness and dizziness may occur. If you experience these side effects whilst taking this medicine, do not drive or operate machines. These effects may be worse when taken in combination with alcohol.

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

3. How to take Nurofen Long Lasting 300 mg Prolonged-Release Tablets

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Dosage:

Adults over 18 years and the elderly:

Initial dose: take two tablets (2 x 300mg ibuprofen).
If necessary, another dose of two tablets (2 x 300mg ibuprofen) can be taken after 12 hours.
Leave at least 12 hours between doses.
Do not take more than 4 tablets of this medicine in any 24 hour period.

Do not use this medicine in children and adolescents below 18 years.

Method of administration

For oral short term use.

Swallow the tablets whole with water. **Do not chew, break, crush or suck the tablets.**

Duration of treatment

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 pain) persist or worsen (see section 2).

You must talk to a doctor if you do not feel better or if you feel worse after 4 days.

Do not exceed the recommended dose or duration of treatment.

If you take more of Nurofen Long Lasting 300 mg Prolonged-Release Tablets than you should
If you have taken more of this medicine 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.

Signs of overdose include nausea, stomach pain, vomiting (may be blood streaked), or more rarely diarrhoea. In addition, headache, gastrointestinal bleeding, blurred vision, ringing in the ear, confusion and shaky eye movement, worsening of asthma in asthmatics. At high doses, drowsiness, excitation, disorientation, chest pain, palpitations, loss of consciousness, coma, convulsions (mainly in children), vertigo, weakness and dizziness, blood in urine, low blood pressure, increased potassium levels in the blood, too much acid in the body (metabolic acidosis), increased clotting times, acute kidney failure, liver damage, cold body feeling and breathing problems causing blueish skin.

If you forget to take this medicine

Do not use a double dose to make up for a forgotten dose.

If you have any questions on the use of this product, please ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
You can reduce the chance of side effects by taking the lowest dose for the shortest time needed to relieve the symptoms.

STOP TAKING the medicine and seek immediate medical help if you develop:

- **signs of gastrointestinal bleeding** such as: severe pain in the abdomen, black tarry stools, vomiting blood or dark particles that look like coffee grounds (very rare).
- **signs of rare but serious allergic reaction** such as worsening of asthma, unexplained wheezing or shortness of breath, swelling of the face, tongue or throat, difficulty breathing, racing heart, drop in blood pressure leading to shock. These can happen even on first use of this medicine. If any of these symptoms occur, call a doctor at once (very rare).
- **severe skin reactions** such as widespread body rashes, peeling, blistering or flaking skin (e.g. Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis/Lyell's syndrome), hair loss (alopecia) (very rare).
- **problems with blood cell production**. First signs of this include: fever, sore throat, superficial mouth ulcers, flulike symptoms, severe exhaustion, nose and skin bleeding and unexplained bruising (very rare).
- **symptoms of aseptic meningitis** with stiff neck, headache, nausea, vomiting, fever or clouding of consciousness. Patients with autoimmune disorders (SLE, mixed connective tissue disease) may be more likely to be affected (very rare).
- **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 start of treatment (acute generalized exanthematous pustulosis) (very rare).

STOP TAKING the medicine and tell your doctor if you experience:

- stomach pain, feeling sick (nausea), indigestion, diarrhoea, flatulence (wind), constipation and vomiting (being sick or any other abnormal stomach symptoms) (common).
- skin rashes and other skin reactions such as itching (uncommon).
- signs of kidney damage or failure such as passing less urine than normal, swelling (especially in patients with high blood pressure or reduced kidney function) and cloudy urine (very rare).

Other side effects that may occur:

Uncommon (may affect up to 1 in 100 people)

- Headache and dizziness
- Visual disturbances.
- Various skin rashes.

- Worsening of existing bowel disease (ulcerative colitis or Crohn's disease).

Rare (may affect up to 1 in 1000 people)
- Hearing impaired.
- Kidney increased urea concentrations in blood, pain in the flanks and/or abdomen, blood in the urine and a fever may be signs of damage to kidneys (papillary necrosis).
- Decreased haemoglobin levels causing anaemia.

Very rare (may affect up to 1 in 10,000 people)
- Inflammation of the oesophagus (oesophagitis) or pancreas (pancreatitis), and formation of membrane-like narrowing in the small and large intestines (intestinal diaphragm-like strictures).
- Liver problems, damage to the liver (first signs could be discoloration of the skin), especially during longterm treatment, liver failure, acute inflammation of the liver (hepatitis).
- Worsening of infection-related inflammations. If signs of an infection occur or get worse, you must go to the doctor without delay as you may need antibiotics or other treatment.
- Hypertension, heart failure, heart attack and swelling in the face or hands (oedema).
- Psychotic reactions, depression.

Frequency not known:
- respiratory tract reactions such as asthma, difficulty breathing or laboured breathing.
- kidney problems.
- sensitivity of skin to light.
- reversible eye disorders such as toxic amblyopia, blurred vision and changes in colour perception
- 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 a type of white blood cells.

NSAID medicines such as this may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. See section 2 Warnings and precautions.

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 Long Lasting 300 mg Prolonged-Release Tablets

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 after EXP. The expiry date refers to the last day of that month.

Store below 30°C. Store in the original pack in order to protect from moisture.

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 300 mg Prolonged-Release Tablets contain

The active substance is ibuprofen. One prolonged release tablet contains 300 mg ibuprofen.

The other ingredients are: silica, colloidal hydrated (E551), hypromellose (E464), microcrystalline cellulose (E460), croscarmellose sodium (E468), glycine (E640), stearic acid (E570), coating (consisting of hypromellose (E464), titanium dioxide (E171), macrogol and polysorbate 80 (E433)), and polishing (containing carnauba wax (E903)).

What Nurofen Long Lasting 300 mg Prolonged-Release Tablets looks like and contents of the pack
Each capsule-shaped tablet is white to off white and debossed with 'N12' on one side and plain on the other. Dimensions: 17.5 mm length, 7.5 mm width and 4.9 mm thickness.

Blister packs comprised of PVC, aluminium and polyamide with aluminium foil lidding in an outer carton containing 6, 8, 10, 12, 16, 20 and 24 tablets.

Not all pack sizes will be marketed.

Marketing Authorisation Holder and Manufacturer

PA Holder: Reckitt Benckiser Ireland Limited, 7 Riverwalk, Citywest Business Campus, Dublin 24. Manufacturer: RB NL Brands B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL. For product enquiries, please telephone (01) 6305429

This medicinal product is authorised in the Member States of the EEA under the following names:

TBC

This leaflet was last revised in <{MM/YYYY}> <{month YYYY}>.

Upon Approval