Package leaflet: Information for the user
Nurofen Rapid Pain Relief Max 400 mg Soft 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 or pharmacist 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 or pharmacist. This includes any possible side effects not listed in this leaflet. **See section 4.**
- In adolescents aged 12 years and over and adults, 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 Rapid Pain Relief Max 400 mg Soft Capsules is and what is it used for

Ibuprofen belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines provide relief by changing how the body responds to pain and fever.

Nurofen Rapid Pain Relief Max 400 mg Soft Capsules is for use in adults and adolescents from 40 kg body weight (12years of age and older).

Nurofen Rapid Pain Relief Max 400 mg Soft Capsules is used for the short-term symptomatic treatment of mild to moderate pain such as headache, toothache, period pain, and fever and pain associated with the common cold.

In adolescents aged 12 years and over and adults, you must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take Nurofen Rapid Pain Relief Max 400 mg Soft Capsules
Do not take Nurofen Rapid Pain Relief Max 400 mg Soft Capsules:
- if you are allergic to ibuprofen, ponceau 4R (E124), peanut or soya, or any of the other ingredients of this medicine (listed in section 6)
- if you have ever suffered from shortness of breath, asthma, a runny nose, swelling on your face and/or hands or hives after using ibuprofen, acetylsalicylic acid or other similar painkillers (NSAIDs)
- if you have (or have had two or more distinct episodes of) a stomach or duodenal ulcer (peptic ulcer) or bleeding
- if you have a history of gastrointestinal bleeding or perforation when previously taking NSAIDs (Non-steroidal anti-inflammatory drugs)
- if you have severe liver, kidney or heart failure
- if you suffer from unclarified blood-formation disturbances
- if you are in the last three months of pregnancy (see section ‘Pregnancy, breast-feeding and fertility’)
- if you suffer from severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake)

- if you suffer from bleeding on the brain (cerebrovascular bleeding) or other active bleeding.

Warnings and precautions
Talk to your doctor or pharmacist before using this product if you:
- have an infection - please see heading 'Infections' below
- have certain diseases of the skin (systemic lupus erythematosus (SLE)) or mixed connective tissue disease (conditions of the immune system causing joint pain, skin rashes and fever)
- have certain hereditary blood formation disorder (e.g. acute intermittent porphyria) or problems with your blood clotting
- have or have ever had bowel disease (ulcerative colitis or Crohn's disease)
- have reduced renal function
- have liver disorders. In prolonged administration of this medicine regular checking of the liver values, the kidney function, as well as of the blood count, is required
- have recently undergone major surgery
- are attempting to get pregnant
- have or have had asthma or allergic disease as shortness of breath may occur
- suffer from hayfever, 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)
- are taking other medicines which could increase the risk of ulceration or bleeding such as oral corticosteroids, medicines for thinning the blood (such as warfarin), selective serotonin-reuptake inhibitors (medicines for depression) or anti-platelet agents such as acetylsalicylic acid
- are taking other NSAIDs medicine, including cyclo-oygenaseoxygenase-2 specific inhibitors (COX-2), as these can increase the risk of side effects and should be avoided (see section 'Other medicines' below)
- have chicken pox (varicella). It is advisable to avoid use of this medicine.

Undesirable effects are minimised by using the minimum effective dose for the shortest period of time.

Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, you should stop taking this medicine and talk to your doctor. The diagnosis of medication overuse headache (MOH) should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications.

In general, the habitual use of (several sorts of) analgesics can lead to lasting severe kidney problems and should be avoided. This risk may be increased further by physical strain associated with loss of salt and dehydration. Therefore, it should be avoided.

There is a risk of kidney impairment in dehydrated adolescents.

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.

You should discuss your treatment with your doctor or pharmacist before taking this medicine if you:
- have heart problems including heart failure, angina pectoris (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.

<u>Infections</u>
This medicine may hide signs of infections such as fever and pain. It is therefore possible that this medicine 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.

Serious skin reactions
Serious skin reactions have been reported in association with this medicine treatment. You should stop taking this medicine 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.

Elderly
The elderly are at increased risk of side effects.

Other medicines and Nurofen Rapid Pain Relief Max 400 mg Soft Capsules
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. In particular, tell them if you are taking:

Other NSAIDs including cyclooxygenase-2 selective inhibitors	Since this may increase the risk of gastrointestinal ulcers or bleeding
Digoxin (for heart insufficiency)	Since the effect of digoxin may be enhanced
Glucocorticoids (medicinal products containing cortisone or cortisone-like substances)	Since this may increase the risk of gastrointestinal ulcers or bleeding
Anti-platelet agents	Since this may increase the risk of bleeding
Acetylsalicylic acid (low dose)	Since the blood-thinning effect may be impaired
Medicines for thinning the blood (such as warfarin)	Since ibuprofen may enhance the effects of these medicines
Phenytoin (for epilepsy)	Since the effect of phenytoin may be enhanced
Selective serotonin reuptake inhibitors (medicines used for depression)	As these may increase the risk of gastrointestinal bleeding
Lithium (a medicine for manic depressive illness and depression)	Since the effect of lithium may be enhanced
Probenecid and sulfinpyrazones (medicines for gout)	Since the excretion of ibuprofen may be delayed
Medicines for high blood pressure and water tablets	Since ibuprofens may diminish the effects of these medicines and there could be a possible increased risk for the kidney
Potassium sparing diuretics	Since this may lead to hyperkalaemia
Methotrexate (a medicine for cancer or rheumatism)	Since the effect of methotrexate may be enhanced
Tacrolimus and cyclosporine (immunosuppressive medicines)	Since kidney damage may occur
Zidovudine (a medicine for treating HIV/Aids)	Since the use of this medicine may result in an increased risk of bleeding into a joint or a bleeding that leads to swelling in HIV (+) haemophiliacs
Sulfonylureas (antidiabetic medicines)	Interactions may be possible

Quinolone antibiotics	Since the risk for convulsions may be increased
Mifepristone (used to terminate pregnancies)	Since the effect of mifepristone can be reduced. NSAIDs should not be used for 8-12 days after mifepristone administration
Voriconazole and fluconazole (CYP2C9 inhibitors) used for fungal infection	Since the effect of ibuprofen may increase. Reduction of the ibuprofen dose should be considered, particularly when high-dose ibuprofen is administered with either voriconazole or fluconazole

This medicine may affect or be affected by some other medicines. For example:
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. 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 this medicine. You should therefore always seek the advice of your doctor or pharmacist before you use this medicine with other medicines.

Nurofen Rapid Pain Relief Max 400 mg Soft Capsules with 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 this medicine.

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

Pregnancy
Tell your doctor if you become pregnant whilst taking Nurofen Rapid Pain Relief Max 400 mg Soft Capsules. Do not take this medicine in the last 3 months of pregnancy. 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. Avoid the use of this medicine in the first 6 months of pregnancy, unless the doctor advises otherwise. 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 metabolites pass into breast milk. This medicine may be taken 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 (NSAIDs) which may impair fertility in women. This effect is reversible on stopping the medicine.

Driving and using machines
For short-term use and at recommended dosage, this medicine has no or negligible influence on the ability to drive and use machines.
If side effects such as tiredness and dizziness, drowsiness, vertigo or visual disturbances occur while taking this medicine, do not drive or operate machines. These effects may be worse when taken in combination with alcohol.

Nurofen Rapid Pain Relief Max 400 mg Soft Capsules contains sorbitol
This medicine contains 72.59 mg sorbitol in each capsule.
Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Nurofen Rapid Pain Relief Max 400 mg Soft Capsules contains the colour ponceau 4R (E124).
It may cause allergic reactions.

Nurofen Rapid Pain Relief Max 400 mg Soft Capsules contains soya lecithin.
If you are allergic to peanut or soya, do not use this medicine.

3. How to take Nurofen Rapid Pain Relief Max 400 mg Soft Capsules

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is:

Dosage
Adults and adolescents from 40 kg bodyweight (12 years and older):

Initial dose: Take 1 capsule (400 mg ibuprofen) with water. If necessary, take additional doses of 1 capsule (400 mg ibuprofen) but do not exceed a total dose of 3 capsules (1200 mg ibuprofen) in any 24 hour period. The dosing interval should not be below 6 hours.

This medicine is not intended for use in adolescents weighing under 40 kg or children under 12 years of age.

Method of administration
For oral use. Swallow the capsule whole with water. Do not chew.

It is recommended that patients with a sensitive stomach take this medicine with food. If taken shortly after eating, the onset of action of this medicine may be delayed. If this happens, do not take more of this medicine than recommended within this section or until the correct re-dosing interval has passed.

Duration of treatment
This medicine is intended for short term use only. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, talk to a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

If in adolescents and adults this medicine is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

If you take more Nurofen Rapid Pain Relief Max 400 mg Soft Capsules than you should
If you have taken more 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. The symptoms can include: nausea (feeling sick), stomach pain, vomiting (being sick – may be blood streaked), blood in stools (gastrointestinal bleeding), headache, ringing in the ears, diarrhoea and confusion, shaky eye movements. At high doses, weakness and dizziness, vertigo, blurred vision, low blood pressure, excitation, disorientation, coma, hyperkalaemia (raised blood potassium levels), increased prothrombin time/INR, acute renal failure, liver damage, respiratory depression, cyanosis and exacerbation of asthma in asthmatics, drowsiness, disorientation, cold body feeling, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), blood in urine, cool body feeling, and breathing problems have been reported.

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

4. Possible side effects

Like all medicines, this medicine 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 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: severe pain in the abdomen, black tarry stools, vomiting blood or dark particles that look like coffee grounds
- **signs of very 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
- **severe skin reactions** such as rashes covering the whole body, peeling, blistering or flaking skin.

Tell your doctor if you experience any of the following side effects, if they become worse or if you notice any effects not listed.

Common (may affect up to 1 in 10 people):

- stomach complaints, such as heart burn, stomach pain, feeling sick and nausea, indigestion, diarrhoea, vomiting, wind (flatulence), diarrhoea and constipation, and slight blood losses in stomach and/or bowel that may cause anaemia in exceptional cases.

Uncommon (may affect up to 1 in 100 people):

- gastrointestinal ulcers, sometimes with bleeding and perforation, inflammation of the mucous membrane of the mouth with ulceration (ulcerative stomatitis), inflammation of the stomach (gastritis), worsening of colitis and Crohn's disease
- central nervous system disturbances such as headache, dizziness, sleeplessness, agitation, irritability or tiredness
- visual disturbances
- allergic reactions, such as skin rashes, itching and asthma attacks. You must stop taking this medicine and inform your doctor at once
- various skin rashes

Rare (may affect up to 1 in 1,000 people):

- tinnitus (ringing in the ears)
- kidney increased urea concentrations in blood, pain in the flanks and/or the abdomen, blood in the urine and a fever may be signs of damage to kidneys (papillary necrosis)
- increased uric acid concentrations in the blood
- hearing impaired
- decreased haemoglobin levels

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)
- severe infections of the skin and soft-tissue complications have occurred during chicken pox (varicella) infection

- high blood pressure, palpitations, heart failure, heart attack, inflammation of the blood vessels (vasculitis) and swelling (oedema)
- passing less urine than normal and swelling (especially in patients with high blood pressure or reduced kidney function), swelling (oedema) and cloudy urine (nephrotic syndrome); inflammatory kidney disease (interstitial nephritis) that may lead to acute kidney failure. If one of the abovementioned symptoms occur or if you have a general miserable feeling, stop taking this medicine and consult your doctor immediately as these could be first signs of a kidney damage or kidney failure
- liver dysfunction, damage to the liver (first signs could be discolouration of the skin), especially during long-term treatment, liver failure, acute inflammation of the liver (hepatitis)
- problems in blood cell production - first signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, nose and skin bleeding and unexplained bruising. In these cases, you must stop the therapy immediately and consult a doctor. You must not treat these symptoms with pain killers or medicinal products that reduce fever (antipyretic medicinal products)
- psychotic reactions and depression
- worsening of infection-related inflammations (e.g. necrotizing fasciitis) associated with the use of certain painkillers (NSAIDs) has been described. If signs of an infection occur or get worse during use of this medicine, you must go to the doctor without delay to investigate whether there is a need for an anti-infective/antibiotic therapy
- symptoms of aseptic meningitis with neck stiffness, headache, feeling sick, nausea, vomiting, fever or consciousness clouding have been observed when using ibuprofen. Patients with autoimmune disorders (SLE, mixed connective-tissue disease) may be more likely to be affected. Contact a doctor at once if these occur
- severe forms of skin reactions such as skin rash with redness and blistering (e.g. Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis/Lyell's syndrome), hair loss (alopecia)
- severe general hypersensitivity reactions
- worsening of asthma and bronchospasm

Not known (frequency cannot be estimated from the available data):
- respiratory tract reactivity comprising asthma, bronchospasm or dyspnoea
- 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 this medicine if you develop these symptoms and seek medical attention immediately. See also section 2
- skin becomes sensitive to light

This medicine contains Ponceau 4R (E124) which may cause allergic reactions.

Medicines such as this medicine may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke.

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 Rapid Pain Relief Max 400 mg Soft Capsules

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.

Do not store above 25°C. Store in the original package 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 Rapid Pain Relief Max 400 mg Soft Capsules contains:

The active substance is ibuprofen.
- Each soft capsule contains 400 mg ibuprofen.

The other ingredients are:

- Fill:
- Macrogol (E1521)
- Potassium hydroxide (minimum 85% purity) (E525)
- Purified water

- Soft capsule shell:
- Sorbitol liquid (E420), partially dehydrated
- Gelatin (E441)
- Ponceau 4R (E124)

- Printing ink:
- Opacode WB white NSP-78-180002 (consisting of Titanium Dioxide (E171), Propylene Glycol (E1520), SDA 35A Alcohol (Ethanol & Ethyl acetate), Isopropyl alcohol, Polyvinyl acetate phthalate, Purified water, Macrogol/PEG MW400 (E1521) and Ammonium hydroxide 28% (E527)

Processing aids:
- Soya Lecithin (E322)

What Nurofen Rapid Pain Relief Max 400 mg Soft Capsules looks like and contents of the pack
Nurofen Rapid Pain Relief Max 400 mg Soft Capsules are red, oval-shaped soft capsules with NURO400 printed in white ink. Each capsule is approximately 10 mm in width and approximately 15.5 mm in length. Nurofen Rapid Pain Relief Max 400 mg Soft Capsules are available in blisters containing 10, 20, 24, 30 or 40 soft capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Reckitt Benckiser Ireland Limited
7 Riverwalk
Citywest Business Campus
Dublin 24

Manufacturer

RB NL Brands B.V., Schiphol Boulevard 207, 1118 BH Schiphol, The Netherlands

This medicine is authorised in the Member States of the European Economic Area under the following names:
Austria - <To be completed nationally>
Belgium - <To be completed nationally>
Bulgaria - <To be completed nationally>
Croatia - <To be completed nationally>
Cyprus - <To be completed nationally>
Czechia - <To be completed nationally>
France - <To be completed nationally>
Germany - <To be completed nationally>
Greece - <To be completed nationally>
Hungary - <To be completed nationally>
Ireland - <To be completed nationally>
Italy - <To be completed nationally>
Luxembourg - <To be completed nationally>
Malta - <To be completed nationally>
Netherlands - <To be completed nationally>
Poland - <To be completed nationally>
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Romania - <To be completed nationally>
Slovakia - <To be completed nationally>
Spain - <To be completed nationally>

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