

NUROFEN Rapid Relief 200mg Liquid Capsules

Ibuprofen

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 Rapid Relief 200mg Liquid Capsules 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 RAPID RELIEF 200mg LIQUID CAPSULES ARE AND WHAT THEY ARE USED FOR?

Nurofen Rapid Relief 200mg Liquid Capsules contain 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. Nurofen Rapid Relief 200mg Liquid Capsules are for the relief of **headaches, migraine, backache, period pain, dental pain, neuralgia, muscular pain, rheumatic pain, cold and flu symptoms and fever.**

2. BEFORE YOU TAKE NUROFEN RAPID RELIEF 200mg LIQUID CAPSULES:

Do not take Nurofen Rapid Relief 200mg Liquid Capsules if you:

- are allergic to ibuprofen or any of the ingredients of Nurofen Rapid Relief 200mg Liquid Capsules 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, codeine, aspirin or other similar medicines
- are already taking non-steroidal anti-inflammatory medication (NSAIDs)
- 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.
- suffer from severe kidney or liver problems
- have severe heart failure
- are in the last 3 months of pregnancy
- are under 12 years of age

Consult your doctor or pharmacist before taking Nurofen Rapid Relief 200mg Liquid Capsules 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, have a family history of heart disease or stroke, or if you are a smoker
- have a head injury, unexplained bleeding or raised intracranial pressure
- 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 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 Rapid Relief 200mg Liquid Capsules.

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).

Serious skin reactions have been reported in association with Nurofen 200mg Rapid Relief Liquid Capsules. You should stop taking Nurofen 200mg Rapid Relief Liquid Capsules 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 Rapid Relief 200mg Liquid Capsules may hide signs of infections such as fever and pain. It is therefore possible that Nurofen Rapid Relief 200mg Liquid Capsules 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 chicken pox. If you take this medicine while you have an infection and the symptoms of the infection persist or worsen, consult a doctor without delay.

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 (e.g. COX-2 inhibitors).
- corticosteroids (such as prednisolone) since this may increase the risk of gastrointestinal ulceration or bleeding
- drugs for heart failure such as digoxin
- selective serotonin-reuptake inhibitors (a medicine for depression) since these may increase the risk of gastrointestinal side effects
- water tablets (diuretics) since NSAIDs may diminish the effects of these
- 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 (a medicine to suppress the immune reaction) since there is limited evidence of an increased risk for kidney toxicity
- Zidovudine: there is evidence of an increased risk of haematomas and haematoma in HIV (+) haemophiles receiving concurrent treatment with Zidovudine and ibuprofen
- Quinolone antibiotics since patients taking NSAIDs and quinolone antibiotics may have an increased risk of developing convulsions
- 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 (used in pregnancy terminations)

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

Pregnancy and breastfeeding.

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.

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

Nurofen Rapid Relief 200mg Liquid 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.

Important information about some of the ingredients of Nurofen Rapid Relief 200mg Liquid Capsules

This medicine contains 22.26mg of sorbitol per capsule. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this medicinal product.

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

Driving and using machines

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

3. HOW TO TAKE NUROFEN RAPID RELIEF 200mg LIQUID CAPSULES:

Adults and children over 12 years: 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). Swallow 2 capsules with water, then if necessary 1-2 capsules every 4 hours. Do not take any more than 6 capsules in any 24 hour period. Do not chew the capsules. If in adolescents, this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

If you take more Nurofen Rapid Relief 200mg Liquid Capsules than you should:

If you have taken more Nurofen Rapid Relief 200mg Liquid Capsules 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 advise 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 Rapid Relief 200mg Liquid Capsules. Take your tablets as usual. Do not take a double dose to make up for forgotten capsules.

4. POSSIBLE SIDE EFFECTS:

Like all medicines, Nurofen Rapid Relief 200mg Liquid Capsules 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 e.g. Stevens-Johnson syndrome.
- 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
- blood disorders, swelling, high blood pressure, heart failure, blurred vision
- bruising easily, or bleeding (thrombocytopenia)
- 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 Rapid Relief 200mg Liquid Capsules if you develop these symptoms and seek medical attention immediately. See also section 2.
- Skin becomes sensitive to light.

Side effects may be minimized by using the minimum effective dose for the shortest duration. Medicines such as Nurofen Rapid Relief 200mg Liquid Capsules may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. 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. Tell your doctor if you notice any unusual symptoms – especially dark bowel motions, vomiting blood or stomach pains. Serious skin reactions (such as Stevens-Johnson syndrome) have been reported very rarely in association with the use of NSAIDs. The use of

Nurofen Rapid Relief 200mg Liquid Capsules should be stopped immediately at the first appearance of skin rash, mouth ulcers or any other signs of allergic reactions. There is increased risk of bleeding of 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. **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 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 RELIEF 200mg LIQUID CAPSULES?

KEEP OUT OF REACH AND SIGHT OF CHILDREN

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 that month. Do not store above 25°C and keep in the original package. Medicines should not be disposed of via waste water 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 Rapid Relief 200mg Liquid Capsules contain:

Each liquid capsule contains 200mg ibuprofen. The other ingredients are Polyethylene Glycol 600, Potassium Hydroxide, Sorbitol Liquid, partially dehydrated, Gelatin, Purified Water, Ponceau 4R (E124), Lecithin, Medium Chain Triglycerides, Titanium Dioxide, Propylene Glycol, isopropyl alcohol and HMPC 2910/hypromellose 3cP.

Nurofen Rapid Relief 200mg Liquid Capsules are clear capsules with a translucent red gelatin shell, containing a clear liquid, printed with "NUROFEN" in white. They are available in packs of 16, 24 or 40 capsules, not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturers.

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

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

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