



**Read all of this leaflet carefully before you start taking this medicine because it contains important information for 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to your doctor if you do not feel better or if you feel worse after 3 days.

1. What Nurofen 400mg Liquid Capsules are and what they are used for
2. Before you take Nurofen 400mg Liquid Capsules
3. How to take Nurofen 400mg Liquid Capsules
4. Possible side-effects
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6. Further Information

Nurofen 400mg Liquid Capsules 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. Nurofen 400mg 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.**

- 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
- are in the last 3 months of pregnancy
- are under 12 years of age

- 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 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

- have been told by your doctor that you have an intolerance to some sugars
- are elderly
- have a history of inflammatory bowel disease such as ulcerative colitis or Crohn's disease.
- are receiving regular treatment from your doctor (see section "Taking other medicines" below)
- have chicken pox as it is advisable to avoid the use of Nurofen 400mg Liquid capsules

Nurofen 400mg Liquid Capsules may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Serious skin reactions (such as Steven-Johnson syndrome) have been reported very rarely in association with the use of NSAIDs. The use of Nurofen 400mg 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 GI bleeding, ulceration or 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.

**[3 days].**  
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.

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:

- other pain relievers or anti-inflammatory medicines such as aspirin, ibuprofen or other NSAIDs
- corticosteroids (such as prednisolone) since these may increase the risk of gastrointestinal ulceration or bleeding
- water tablets (diuretics) since NSAIDs may diminish the effect of this drug
- selective serotonin-reuptake inhibitors (SSRIs, medicine for depression) since these 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

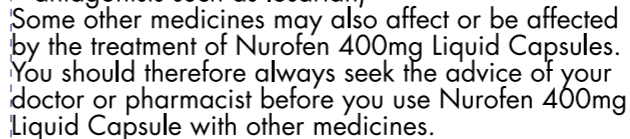


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Consult your doctor before use if you are in the first 6 months of pregnancy. Do not use Nurofen 400mg Liquid Capsules during the last 3 months of pregnancy.

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.

This product contains 69.2mg of sorbitol 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. This product also contains Ponceau 4R (E124) which may cause allergic reactions.

**Adults and children over 12 years:**  
Take 1 capsule with water and subsequently,  
if necessary, one capsule every 4 hours.

Do not take more than 3 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.

**Elderly:** NSAIDs should be used with particular caution in elderly patients who are more prone to side-effects.

This product is intended for short term use only. You should take the lowest dose for the shortest time necessary to relieve your symptoms. You should not take Nurofen 400mg Liquid Capsules for longer than 3 days unless your doctor tells you to do so.

Consult your doctor immediately. The following signs may occur; nausea, vomiting, stomach pain, headache, dizziness, drowsiness, blurred vision or ringing in the ears.

### **If you forget to take Nurofen 400mg Liquid Capsules**

Take your tablets as usual. Do not take a double dose to make up for forgotten tablets.

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

**Like all medicines, Nurofen 400mg Liquid Capsules can cause side-effects, although not everyone gets them.**

If you experience any of the following or any other unusual symptoms, stop taking the capsules and tell your doctor or pharmacist:

- stomach problems such as unexplained stomach pain, indigestion, feeling sick and/or vomiting, diarrhoea or constipation, flatulence.
- worsening of colitis or Crohn's disease
- Stomach ulcers or any sign of bleeding from the stomach or bowels (vomiting blood and/or passing black stools). These symptoms may not necessarily be preceded by warning signals, may occur in people who have not experienced stomach problems before and in rare cases can be fatal. When bleeding occurs, the treatment should be stopped immediately.
- 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.
- swelling, increased blood pressure or heart failure
- severe skin infections and soft tissue complications during chicken pox (varicella) infection

Medicines such as Nurofen 400mg Liquid Capsules may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;  
Tel: +353 1 6764971; Fax: +353 1 6762517.  
Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).  
By reporting side effects you can help provide more information on the safety of this medicine.

Do not use Nurofen 400mg Liquid Capsules 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 or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

The active substance is ibuprofen 400mg.

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 HPMC 2910 / Hypromellose 3CP.

Nurofen 400mg 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 20 capsules.

PA Holder: Reckitt Benckiser Ireland Ltd., 7 Riverwalk,  
Citywest Business Campus, Dublin 24. Manufacturer:  
Reckitt Benckiser Healthcare International Ltd.,  
Nottinghamshire NG90 2DB. UK

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Citywest Business Campus, Dublin 24.

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