Package leaflet: Information for the user

ibuprofen

PACKAGE LEAFLET: INFORMATION FOR THE USER

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 or nurse 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 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.

In this leaflet:

1. WHAT NUROFEN RAPID RELIEF Maximum Strength 400 mg LIQUID CAPSULES ARE AND WHAT THEY ARE USED FOR?

Nurofen Rapid Relief Maximum Strength 400 mg 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 Maximum Strength 400 mg 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 Maximum Strength 400 mg LIQUID CAPSULES:

Do not take Nurofen Rapid Relief Maximum Strength 400 mg Liquid Capsules if you:

- are allergic (hypersensitive) 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
- are in the last 3 months of pregnancy
- are under 12 years of age

Consult your doctor or pharmacist before taking Nurofen Rapid Relief Maximum Strength 400 mg 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")
- 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 Rapid Relief Maximum Strength 400 mg Liquid Capsules.

Adolescents

There is a risk of renal impairment in dehydrated adolescents.

Other warnings

Nurofen Rapid Relief Maximum Strength 400 mg 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.

Tell your doctor if you notice any unusual symptoms - especially dark bowel motions, vomiting blood or stomach pains – particularly soon after you have taken this medicine. Shortness of breath can occur if you suffer from or have a history of allergic diseases

Serious skin reactions have been reported in association with Nurofen Rapid Relief Maximum Strength 400 mg Liquid Capsules treatment. You should stop taking Nurofen Rapid Relief Maximum Strength 400 mg Liquid Capsules and seek medical attention immediately, if you develop any skin rash, lesions of the mucosal 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 Maximum Strength 400 mg Liquid Capsules may hide signs of infections such as fever and pain. It is therefore possible that Nurofen Rapid Relief Maximum Strength 400 mg 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.

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.

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).

Do not exceed the recommended dose or duration of treatment [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.

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:

- 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
- cyclosporin (a medicine to suppress the immune reaction) since there is evidence of an increased risk of 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 Rapid Relief Maximum Strength 400 mg Liquid Capsules
- Oral hypoglycemic agents (tablets for diabetes) since the effects of these may be enhanced
- Zidovudine (a medicine for HIV) since there is evidence of an increased risk of bleeding in HIV+ hamophilliacs who take zidovudine and ibuprofen together
- Mifepristone (used in pregnancy terminations)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)

Some other medicines may also affect or be affected by the treatment of Nurofen Rapid Relief Maximum Strength 400 mg Liquid Capsules. You should therefore always seek the advice of your doctor or pharmacist before you use Nurofen Rapid Relief Maximum Strength 400 mg Liquid Capsules with other medicines.

Pregnancy and breast-feeding
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 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.

Nurofen Rapid Relief Maximum Strength 400mg 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 Maximum Strength 400 mg Liquid Capsules
This product contains sorbitol. 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.

3. HOW TO TAKE NUROFEN RAPID RELIEF Maximum Strength 400 mg 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). 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 Rapid Relief Maximum Strength 400 mg Liquid Capsules for longer than 3 days unless your doctor tells you to do so.

If you take more Nurofen Rapid Relief Maximum Strength 400 mg Liquid Capsules than you should:
If you have taken more Nurofen Rapid Relief Maximum Strength 400 mg 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 Maximum Strength 400 mg 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.

4. Possible side effects

Like all medicines, Nurofen Rapid Relief Maximum Strength 400 mg 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
- 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 Nurofen Rapid Relief Maximum Strength 400 mg Liquid Capsules if you develop these symptoms and seek medical attention immediately. See also section 2.
- Skin becomes sensitive to light.

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

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 via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE NUROFEN RAPID RELIEF MAXIMUM STRENGTH 400 mg LIQUID 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 ºC. Store in the original package.
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. FURTHER INFORMATION

What Nurofen Rapid Relief Maximum Strength 400 mg Liquid Capsules contain:
The active substance is ibuprofen. Each capsule contains 400 mg ibuprofen.
The other ingredients are:
Capsule contents; macrogol 600, potassium hydroxide, purified water, medium chain triglycerides, isopropyl alcohol, lecithin.
Capsule shell; gelatin, dehydrated sorbitol, purified water, ponceau 4R (E124).
Printing ink; opacode NS-78-18011 (contains titanium dioxide (E171), propylene glycol, hypromellose 2910/3).

What Nurofen Rapid Relief Maximum Strength 400 mg Liquid Capsules look like and contents of the pack
Nurofen Rapid Relief Maximum Strength 400 mg Liquid Capsules are oval shaped 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.

Manufacturer
Reckitt Benckiser Healthcare International Ltd, Nottingham, United Kingdom or RB NL Brands B.V., WTC Schiphol Airport, Schiphol Boulevard 207,1118 BH Schiphol, Netherlands.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:
PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

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