

NUROFEN®

200mg Coated Tablets

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 200mg Coated Tablets 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 200mg COATED TABLETS ARE AND WHAT THEY ARE USED FOR?

Nurofen 200mg Coated Tablets 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. Each tablet contains 200mg ibuprofen.

Nurofen 200mg Coated Tablets provide fast and effective relief from **headaches, dental pain, period pain, backache, muscular pain, for the symptomatic treatment of osteoarthritis, cold and flu symptoms and fever.**

2. BEFORE YOU TAKE NUROFEN 200mg COATED TABLETS:

Do not take Nurofen 200mg Coated Tablets if you:

- are allergic to ibuprofen, or any of the ingredients of Nurofen 200mg Coated Tablets 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, liver or heart problems
- are in the last 3 months of pregnancy
- are under 12 years of age

Consult your doctor or pharmacist before taking Nurofen 200mg Coated Tablets if you

- have asthma or have suffered from asthma
- have kidney, liver or heart problems
- have stomach or intestinal problems (such as Crohn's disease or ulcerative colitis)
- have ever had high blood pressure or heart failure
- 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)
- are taking painkiller medication & find that you still have frequent or daily headaches despite taking medication, please speak to your doctor

Adolescents

There is a risk of renal impairment in dehydrated adolescents.

Other warnings

Medicines such as Nurofen 200mg Coated Tablets may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment [3 days].

If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with 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, do **NOT** take this product 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
- anti-hypertensives and diuretics: since NSAIDs may diminish the effect of these drugs
- medicines for thinning the blood (such as warfarin) since NSAIDs may enhance the effects of these medicines.
- anti-platelet agents (such as aspirin) and selective serotonin-reuptake inhibitors (a medicine for depression) since these may increase the risk of gastrointestinal side effects
- medicines for high blood pressure and water tablets 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 (a medicine to treat HIV)
- Quinolone antibiotics since patients taking NSAIDs and quinolone antibiotics may have an increased risk of developing convulsions
- Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/ acetylsalicylic acid, warfarin, ticlopidine), some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta blockers such as atenolol or angiotensin-II receptor antagonists such as losartan) and other medicines may affect or be affected by treatment with ibuprofen. You should therefore always seek the advice of a healthcare professional before you use ibuprofen with other medicines.
- mifepristone (now or in the last 12 days)

Pregnancy and breastfeeding.

Nurofen 200mg Coated Tablets 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.

Consult your doctor before use if you are in the first 6 months of pregnancy. Do not use Nurofen 200mg Coated Tablets in the last 3 months of pregnancy.

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

Important information about some of the ingredients of Nurofen 200mg Coated Tablets

This medicinal product contains 1.1 mmol (25.3mg) sodium per 2 tablets. To be taken into consideration by patients on a controlled sodium diet. This product also contains sucrose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Driving and using machines

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

3. HOW TO TAKE NUROFEN 200mg COATED TABLETS:

Adults and children over 12 years:

Swallow 2 tablets with water, then if necessary, 1-2 tablets every 4 hours. Do not exceed 6 tablets in 24 hours. Do not use in children under 12 years of age. 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 200mg Coated Tablets than you should:

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

If you forget to take Nurofen 200mg Coated Tablets

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

4. POSSIBLE SIDE EFFECTS:

Like all medicines, Nurofen 200mg Coated Tablets 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 any of the side effects gets serious, or if you notice any side effects not listed in the leaflet, tell your doctor or pharmacist.

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

Signs of intestinal bleeding such as: bright red faeces (stools/motions), black tarry stools, vomiting blood or dark particles that look like coffee grounds.

Signs of serious allergic reactions such as:

- difficulties in breathing or unexplained wheezing
- dizziness or faster heartbeat
- severe forms of skin reactions such as itchiness, skin rash with redness, peeling, flaking or blistering (eg, Steven Johnson syndrome)
- swelling of your face, tongue or throat

Signs of kidney problems such as:

- Passing less or more urine
- Cloudy urine or blood in urine
- Pain in the back and/or swelling (particularly in the legs)

Signs of aseptic meningitis with neck stiffness, headache, feeling sick, being sick, fever or consciousness. Patients with autoimmune disorders (lupus, mixed connective-tissue disease) may be more likely to be affected.

STOP TAKING the medicine and tell your doctor if you experience the following uncommon side effects which affect 1 to 10 users in 1000:

- Indigestion, heartburn or feeling sick

- Pains in your stomach (abdomen) or other abnormal stomach problems.

TELL YOUR DOCTOR if you have any of the following side effects, they become worse or you notice any effects not listed:

Uncommon side effects which affect 1 to 10 users in 1000:

- Allergic reactions, such as skin rashes (urticaria), itching, peeling
- Headaches

Rare side effects which affect 1 to 10 users in 10,000:

- Flatulence (wind), diarrhoea, constipation and vomiting

Very rare side effects which affect less than 1 user in 10,000:

- Blood disorder resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion
- Drop in blood pressure or irregular heart beat
- Stomach or intestinal ulcers, sometimes with bleeding and perforation, inflammation of the lining of the mouth with ulceration (ulcerative stomatitis), inflammation of the stomach (gastritis)
- Liver problems

Side effects for which the frequency cannot be estimated from available data:

- Worsening of asthma or bronchospasm
- Swelling (oedema), high blood pressure, heart failure or attack
- Worsening of colitis and Crohn's disease

Medicines such as Nurofen 200mg Coated Tablets may be associated with a small risk of heart attack ("myocardial infarction") or stroke. See section 2 'Other Warnings'

Reporting of side effects

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;

E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE NUROFEN 200mg COATED TABLETS?

KEEP OUT OF REACH AND SIGHT OF CHILDREN

This medicinal product does not require any special storage precautions. 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. 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.

6. FURTHER INFORMATION

What Nurofen 200mg Coated Tablets contain

The active substance is ibuprofen 200mg. The tablet core contains Croscarmellose Sodium, Sodium laurilsulfate, Sodium Citrate, Stearic Acid, Colloidal anhydrous silica. The tablet coat contains Carmellose sodium, Talc, Acacia Spray Dried, Sucrose, Titanium Dioxide (E171), Macrogol 6000.

The Printing ink is Black Printing Ink which contains iron oxide black (E172), propylene glycol (E1520) and shellac.

What Nurofen 200mg Coated Tablets look like and contents of the pack

Nurofen 200mg Coated Tablets are white round sugar-coated tablets with "NUROFEN" imprinted in black. Available in packs of 12, 24 or 48 tablets.

Marketing Authorization Holder and Manufacturer

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

For product enquiries, please telephone (01) 6305429

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