



200mg Coated Tablets (ibuprofen)

Your medicine is available as NUROFEN 200mg Coated Tablets but will be referred to as Nurofen Coated Tablets throughout the leaflet.

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 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 effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- What Nurofen Coated Tablets are and what they are used for
- Before you take Nurofen Coated Tablets
- How to take Nurofen Coated Tablets
- Possible side effects
- How to store Nurofen Coated Tablets
- Contents of the pack and other information

1. What Nurofen Coated Tablets are and what they are used for

Nurofen 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 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 Coated Tablets

Do not take Nurofen Coated Tablets if you:

- are allergic to ibuprofen, or any of the ingredients of Nurofen 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 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 Coated Tablets if you

- 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)
- are taking painkiller medication and find that you still have frequent or daily headaches despite taking medication, please speak to your doctor
- have chicken pox as it is advisable to avoid the use of Nurofen Coated Tablets.

Adolescents

There is a risk of renal impairment in dehydrated adolescents.

Other warnings

Anti-inflammatory/painkiller 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).

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 this may increase the risk of gastrointestinal side effects
- water tablets (diuretics) since NSAIDs may diminish their effects
- 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
- 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 (now or in the last 12 days)

Some other medicines may also affect or be affected by the treatment of Nurofen Coated Tablets. You should therefore always seek the advice of your doctor or pharmacist before you use Nurofen Coated Tablets with other medicines.

Pregnancy and breast-feeding

Nurofen 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 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 breast-feeding for short term treatment at the recommended dose.

Important information about some of the ingredients of Nurofen Coated Tablets

This medicinal product contains 1.1mmol (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 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 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 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 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 (e.g. 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
- Pain 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
- Severe skin infections and soft tissue complications during chicken pox (varicella) infection

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 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 Coated Tablets

- **Keep this medicine out of the sight and reach of children.**
- Do not store above 25°C. Store in the original pack.
- Do not use this medicine after the expiry date (EXP) which is marked on the carton and blister strips. This refers to the last day of that month.
- If your doctor decides to stop treatment, return any leftover tablets to the pharmacist. Only keep them if the doctor tells you to.
- Do not use this medicine if you notice discoloration, damage or any other signs of deterioration.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nurofen Coated Tablets contain

The active substance is ibuprofen.
Each tablet contains 200mg ibuprofen.

The tablet core contains: croscarmellose sodium, sodium laurilsulphate, sodium citrate, stearic acid and silicon dioxide.
The tablet coat contains: carmellose sodium, talc, acacia, sucrose, titanium dioxide (E171) and macrogol.
The printing ink is black printing ink which contains shellac, iron oxide black (E172) and propylene glycol.

What Nurofen Coated Tablets look like and contents of the pack

Nurofen Coated Tablets are white round sugar-coated tablet with 'NUROFEN' imprinted in black.

Nurofen Coated Tablets are available in packs of 12 or 24 tablets.

Not all pack sizes may be marketed.

Manufacturer

Manufactured by:
Reckitt Benckiser Healthcare International Ltd,
NG90 2DB, UK.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd.,
Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

PPA holder: Imbat Ltd.,
Unit L2, North Ring Business Park, Santry, Dublin 9.

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read?**

**Call +44 (0) 1302 365000
(Regulatory)**

**Please be ready to give the
following information:**

Product name: NUROFEN

200mg Coated Tablets

Reference No:

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