NUROFEN®
200 mg 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 200 mg 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.

In this leaflet:

1. WHAT NUROFEN 200 mg COATED TABLETS ARE AND WHAT THEY ARE USED FOR

Nurofen 200 mg 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 200 mg ibuprofen. Nurofen 200 mg 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 200 mg COATED TABLETS:

Do not take Nurofen 200 mg 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 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 200 mg Coated Tablets 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)
– are taking painkiller medication & 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 200 mg tablets

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 200 mg Tablets. You should stop taking Nurofen 200 mg Tablets 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 200 mg Coated Tablets may hide signs of infections such as fever and pain. It is therefore possible that Nurofen 200 mg Coated Tablets 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 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 200 mg Coated Tablets. You should therefore always seek the advice of your doctor or pharmacist before you use Nurofen 200 mg Coated Tablets with other medicines.

Pregnancy and breastfeeding
Nurofen 200 mg 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 200 mg 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 200 mg Coated Tablets
This medicine contains sodium (main component of cooking/table salt).
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 200 mg COATED TABLETS

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 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 200 mg Coated Tablets than you should:
If you have taken more Nurofen 200 mg Coated Tablets 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 200 mg 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 200 mg 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. Stevens 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 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
- 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 200 mg Tablets if you develop these symptoms and seek medical attention immediately. See also section 2.
- Skin becomes sensitive to light.

Medicines such as Nurofen 200 mg 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, 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 200 mg COATED TABLETS

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.
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 200 mg Coated Tablets contain
The active substance is Ibuprofen 200 mg.
The other ingredients are sodium citrate, croscarmellose sodium, stearic acid, colloidal anhydrous silica, sodium laurilsulphate, sucrose, talc, carmellose sodium, titanium dioxide, acacia spray dried, macrogol 6000, black printing Ink (iron oxide black (E172), propylene glycol (E1520), shellac)

What Nurofen 200 mg Coated Tablets look like and contents of the pack
Nurofen 200 mg Coated Tablets are white, biconvex, coated tablets with "NUROFEN" printed in black on one side.
Available in packs of 12, 24 or 48 tablets. Not all pack sizes may be marketed.

Manufacturer:
Reckitt Benckiser Healthcare International Ltd, Nottingham, UK or RB NL Brands B.V., WTC Schiphol Airport, Schiphol Boulevard 207, 1118 BH Schiphol, The 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

Parallel Product Authorisation Number: PPA 465/430/2

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