

Package Leaflet: Information for the user

NUROFEN® **Cold & Flu Film-Coated Tablets** Ibuprofen 200mg Pseudoephedrine Hydrochloride 30mg

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 Cold & Flu Film-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 Cold & Flu Film-Coated Tablets are and what they are used for?

Nurofen Cold & Flu Film-Coated Tablets contain two active ingredients which work together to relieve the major symptoms of cold & flu: ibuprofen relieves pain, reduces inflammation and lowers temperature, whilst Pseudoephedrine Hydrochloride is an effective decongestant to ease nasal and sinus congestion. Nurofen Cold & Flu Film-Coated Tablets rapidly relieves the headaches, aches and the pain and fever commonly associated with colds and flu and eases blocked noses, sinuses and the pain of sore throats.

2. Before you take Nurofen Cold & Flu Film-Coated Tablets

Do not take Nurofen Cold & Flu Film-Coated Tablets if You:

- are allergic to ibuprofen, pseudoephedrine hydrochloride, or any of the ingredients of Nurofen Cold & Flu Film-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)
- are taking beta blockers (atenolol, metoprolol) or other sympathomimetic drugs (epinephrine, dopamine)
- are already taking monoamine oxidase inhibitors (MAOIs and/or RIMAs)
- are already taking tricyclic antidepressants
- have ever had stomach bleeding or perforation after taking ibuprofen, aspirin or other similar medicines
- suffer from severe kidney, liver or heart problems
- are pregnant or breastfeeding
- are under 12 years of age
- suffer from heart disease or circulatory problems
- suffer from high blood pressure, particularly if it is due to a tumour
- suffer from diabetes
- suffer from glaucoma
- suffer from thyroid or prostate problems
- suffer from pheochromocytoma (tumour on the adrenal glands)
- have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding.

Consult your doctor or pharmacist before taking Nurofen Cold & Flu Film-Coated Tablets if you

- have asthma or have suffered from asthma
- 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")
- caution in moderate to severe renal impairment
- have stomach or intestinal problems (such as Crohn's disease or ulcerative colitis)
- have low blood pressure
- 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 or raised intracranial pressure
- suffer from a connective tissue disease such as Systemic Lupus Erythematosus (SLE) (Lupus), peeling of the skin, e.g. Stevens-Johnson syndrome, or any similar disease
- are elderly: elderly people are more likely to experience side effects to NSAIDs, particularly stomach bleeding and perforation which can be fatal
- you previously experienced stomach bleeding or perforation after taking ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs). When stomach ulcer or bleeding occurs in patients receiving Nurofen Cold & Flu Film-Coated Tablets the treatment should be withdrawn
- are receiving regular treatment from your doctor
- are taking corticosteroids
- are taking anticoagulants (medicine for thinning the blood) such as warfarin
- are taking serotonin-reuptake inhibitors (a medicine for depression)
- are taking anti-platelet agents (such as aspirin)
- use with caution in occlusive vascular disease
- are taking antihypertensive agents (medicines for high blood pressure)
- have chicken pox as it is advisable to avoid the use of Nurofen Cold & Flu Film-Coated Tablets.

If any of the following occur; hallucinations, restlessness or sleep disturbances, pseudoephedrine should be stopped.

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).

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
- anti-hypertensives and diuretics: since NSAIDs may diminish the effect of these drugs
- 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
- 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
- Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone
- probenecid (to treat gout)
- aminoglycosides (a type of antibiotic)
- oral hypoglycaemic agents (oral medicines to treat diabetes)
- ciclosporin or tacrolimus (a medicine to suppress the immune reaction) since there is limited evidence of an increased risk for kidney toxicity
- Zidovudine: there is evidence of an increased risk of haemorrhoses and haematoma in HIV (+) haemophiles receiving concurrent treatment with Zidovudine and ibuprofen
- monoamine oxidase inhibitors and/or RIMAs, e.g. Selegiline, as depression or excitation may occur or have taken these within the last 14 days as very high blood pressure can be experienced

- decongestants or appetite suppressants as the effects of these may be enhanced
- Guanethidine, reserpine and methyl dopa (medicines used to treat high blood pressure) since these medicines may reduce the effects of pseudoephedrine
- Quinidine (medicine to help your heart beat normally) as pseudoephedrine may effect this medicine
- medicines for depression known as tricyclic antidepressants as these may enhance or reduce the effects of pseudoephedrine
- 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).

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

Pseudoephedrine should not be used in combination with:

- Moclobemide: risk of hypertensive crisis.
- Antihypertensives (including adrenergic neurone blockers & betablockers): pseudoephedrine may block the hypotensive effects.
- Cardiac glycosides: increased risk of dysrhythmias.
- Ergot alkaloids (ergotamine & methysergide): increased risk of ergotism.
- Oxytocin: risk of hypertension.
- Anticholinergics: enhances effects of anticholinergic drugs (such as TCAs).

Pregnancy and breastfeeding and fertility

Do not use Nurofen Cold & Flu Film-Coated Tablets if you are pregnant or breastfeeding.

Nurofen Cold & Flu Film-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.

Driving and using machines

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

Important information about some of the ingredients of Nurofen Cold & Flu Film-Coated Tablets

This product contains Sunset Yellow (E110) which may cause allergic reactions.

3. How to take Nurofen Cold & Flu Film-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.

Consult your doctor if symptoms persist or worsen, or if the product is required for more than 3 days.

If you take more Nurofen Cold & Flu Film-Coated Tablets than you should:

Consult your doctor immediately. The following signs may occur; nausea, vomiting, headache, drowsiness, thirst, anxiety, fever, palpitations, sweating and blurred vision.

If you forget to take Nurofen Cold & Flu Film-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 Cold & Flu Film-Coated Tablets can cause side-effects, although not everyone gets them. Tell your doctor or pharmacist if you notice any of the following:

- stomach problems such as unexplained stomach pain, indigestion, feeling sick and/or vomiting, diarrhoea or constipation, flatulence
- any sign of bleeding from the stomach or bowels (vomiting blood and/or passing black stools) or worsening of colitis or Crohn's disease
- stomach ulcers
- 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 e.g. Stevens-Johnson syndrome
- 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
- blood disorders, swelling, high blood pressure, heart failure, blurred vision
- delusions, mood changes, anxiety, excitability, sleeplessness, sweating, restlessness, thirst, hallucinations, dizziness, shaking, disturbed hearing, headache, blurred vision, muscle weakness, difficulty urinating
- chest pain or fast irregular heartbeat
- decreased appetite
- severe skin infections and soft tissue complications during chicken pox (varicella) infection.

Undesirable effects may be minimized by using the minimum effective dose for the shortest duration.

The elderly are at an increased risk of side effects.

Shortness of breath may occur if you suffer from or have a history of allergic disease.

Tell your doctor if you notice any unusual symptoms – especially dark bowel motions, vomiting blood or stomach pains.

Serious skin reactions (such as Stevens-Johnson syndrome) have been reported very rarely in association with the use of NSAIDs.

The use of Nurofen Cold & Flu Film-Coated Tablets 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, 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. Medicines such as Nurofen Cold & Flu Film-Coated Tablets may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

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.

Reporting of side effect

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

5. How to store Nurofen Cold & Flu Film-Coated Tablets

KEEP THIS MEDICINE OUT OF SIGHT AND REACH OF CHILDREN

Do not use after the expiry date printed on the carton and the blister packaging after 'EXP'. This refers to the last day of that month.

Do not store above 25°C.

Store in the original packaging in order to protect from moisture.

Do not use this medicine if you notice discolouration, 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 Cold & Flu Film-Coated Tablets contain

The active substances are Ibuprofen and Pseudoephedrine Hydrochloride. Each tablet contains 200mg ibuprofen and 30mg pseudoephedrine hydrochloride.

Core: calcium phosphate, microcrystalline cellulose, povidone, croscarmellose sodium, magnesium stearate

Film Coating: hypromellose, talc, titanium dioxide, quinoline yellow, sunset yellow (contains Aluminium and E110)

Black printing Ink: shellac, black iron oxide (E172), propylene glycol.

What Nurofen Cold & Flu Film-Coated Tablets look like and contents of the pack

Nurofen Cold & Flu Film-Coated Tablets are Yellow, circular, biconvex, tablets printed in black with an identifying motif.

Your medicine is available in packs of 12 or 24 tablets.

Manufacturer

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

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

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

Distributed by: Eurodrug Ltd., Unit L2, North Ring Business
Park, Santry, Dublin 9.

Nurofen® is a registered trademark of Reckitt & Colman
(Overseas) Limited.

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Blind or partially sighted?
Is this leaflet hard to see or read?

Call +44 (0) 1302 365000
(Regulatory)

Please be ready to give the following information:

Product name:

Nurofen Cold & Flu
Film-Coated Tablets

Reference No: 1151/261/1