

Package leaflet: Information for the patient

NUROFEN®

Cold & Flu Film-Coated Tablets

ibuprofen 200 mg
pseudoephedrine hydrochloride 30 mg

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 and 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
- if you have very high blood pressure (hypertension) or hypertension not controlled by your medication
- if you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure
- 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 an infection – please see heading 'Infections' below
- 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")
- 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
- develop a feverish generalised erythema associated with pustules, stop taking Nurofen Cold and Flu and contact your doctor or seek medical attention immediately. See Section 4.

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).

Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema) and chest pain have been reported with ibuprofen. Stop Nurofen Cold & Flu Film Coated Tablets immediately and contact your doctor or medical emergencies if you notice any of these signs.

Sudden abdominal pain or rectal bleeding may occur with Nurofen Cold and Flu Film Coated Tablets, due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms stop taking this medicine and contact you doctor or seek medical attention immediately, see section 4.

Reduction of blood flow to your optic nerve may occur with Nurofen Cold and Flu Film Coated

Tablets. If you develop sudden loss of vision, stop taking Nurofen Cold and Flu Film Coated Tablets and contact your doctor or seek medical attention immediately. See section 4.

Take special care with Nurofen Cold & Flu Film Coated Tablets:

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using Nurofen Cold & Flu Film Coated Tablets and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions

described in Section 4.

Infections: Nurofen Cold & Flu Film Coated Tablets may hide signs of infections such as fever and pain. It is therefore possible that Nurofen Cold & Flu Film 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.

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using Nurofen Cold and Flu Tablets immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 "Possible side effects" for symptoms).

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 haemathroses 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 methyldopa (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 (erotamine & 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: : 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. 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:

- serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)

Stop using Nurofen Cold and Flu Tablets immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include:

- severe headache with a sudden onset
- feeling sick
- vomiting
- confusion
- seizures
- changes in vision

Other possible side effects:

- 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
- Inflammation of the colon due to insufficient blood supply (ischemic colitis)
- 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 (blood disorders).
- 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
- 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 which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- fast irregular heartbeat
- decreased appetite
- severe skin infections and soft tissue complications during chicken pox (varicella) infection.
- Reddish, non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of the mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis]
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome)
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis)
- Skin becomes sensitive to light
- A reduced blood flow to the optic nerve (Ischaemic optic neuropathy – frequency unknown).

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.

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 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., Website: www.hpra.ie.

5. How to store Nurofen Cold & Flu Film-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 °C.

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

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 Cold & Flu Film-Coated Tablets contain

The active substances are Ibuprofen 200 mg and Pseudoephedrine Hydrochloride 30 mg.

Product imported from Greece:

The tablet core contains tricalcium phosphate, microcrystalline cellulose, povidone, croscarmellose sodium and magnesium stearate.

The film coating contains hypromellose, talc, opaspray yellow M-1F-6168 or mastercoat yellow FA 0156.

The printing ink is black printing ink which contains iron oxide black (E172),

N-butyl alcohol, propylene glycol, dehydrated ethanol, isopropyl alcohol and shellac glaze.

Product imported from Poland:

The tablet core contains calcium phosphate, microcrystalline cellulose, povidone, croscarmellose sodium, magnesium stearate

The film-coating contains hypromellose, talc, opaspray yellow M-1F-6168 or Mastercoat Yellow FA 0156 (containing titanium dioxide (E171), sunset yellow (E110), quinoline yellow (E104)).

The printing ink contains iron oxide black (E172), propylene glycol, shellac.

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.

Available in packs of 12 or 24 tablets. Not all pack sizes may be marketed.

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.

Manufacturer

Reckitt Benckiser Healthcare International Ltd., Nottingham Site, Thane Road, Nottinghamshire NG90 2DB, United Kingdom or RB NL Brands B.V., WTC Schipol Airport, Schipol Boulevard 207, 1118 BH Schipol, The Netherlands.

Parallel Product Authorisation number:

Nurofen Cold & Flu Tablets – PPA0465/337/002

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