NUROFEN®
Cold & Flu

Contains Ibuprofen and Pseudoephedrine Hydrochloride

INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Nurofen Cold & Flu will be referred to as 'this medicine' throughout this leaflet.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you start to feel worse.

What is in this leaflet:

1. What this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

1. What this medicine is and what is it used for

This medicine contains two active ingredients (which make the medicine work). These are Ibuprofen and Pseudoephedrine Hydrochloride.

Ibuprofen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by reducing pain, swelling and high temperature. **Pseudoephedrine** belongs to a group of drugs called vasoconstrictors which act on the blood vessels in the nose to relieve nasal congestion.

This medicine can be used in children older than 12 years and works in the following ways:
- **clears a blocked nose and sinuses**
- **relieves aches, pains, headache and high temperature (fever)**
- **eases the discomfort of a sore throat.**

2. What you need to know before you take this medicine

Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Immediately stop taking this medicine and contact your doctor or medical emergencies if you notice any of these signs.

Do not take this medicine if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take this medicine during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, this medicine can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Do not take this medicine if you:
- are allergic to ibuprofen, pseudoephedrine or any of the other ingredients of this medicine (listed in section 6) or to aspirin or other non-steroidal anti-inflammatory drugs
- have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking aspirin or similar medicines
- have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding
- have had gastrointestinal bleeding or perforation when previously taking (non-steroidal anti-inflammatory drugs) (NSAIDs).
- are taking other NSAID painkillers or more than 75 mg aspirin a day
- have severe heart disease or very high blood pressure (severe hypertension) or hypertension not controlled by your medication
- have severe acute (sudden) or chronic (long term) kidney disease or kidney failure
- have severe heart or liver problems
- are under 12 years of age.
- are taking Monoamine Oxidase Inhibitors (for depression and known as MAOIs) or have taken these in the last 14 days.
- have a phaeochromocytoma.

Check with your pharmacist or doctor before taking Nurofen Cold & Flu if you:
- have asthma
- have Systemic Lupus Erythematosus (SLE)- an illness affecting the immune system causing joint pain, skin changes and other problems
- have liver or kidney problems, especially in dehydrated children and adolescents, as kidney problems can be made worse
- have high cholesterol or have previously had a heart attack or a stroke
- have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease)
- are a smoker
- have an over-active thyroid
- are diabetic, have glaucoma or prostate problems
- reduction of blood flow to your optic nerve may occur with this medicine. If you develop sudden loss of vision, stop taking this medicine and contact your doctor or seek medical attention immediately. See section 4.
- have an infection - please see heading 'Infections' below.

Infections
This medicine may hide signs of infections such as fever and pain. It is therefore possible that this medicine 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 chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

Skin reactions
Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalised exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using this medicine and seek medical attention immediately, if you notice any of the symptoms related to these serious skin reactions described in section 4.

Taking other medicines
This medicine may affect or be affected by some other medicines. For example:
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine) as their affects may be increased
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan) and diuretics as this medicine can reduce the effects of these drugs.
- Corticosteroids, anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs) as there is an increased risk of gastrointestinal bleeding
- Cardiac glycosides used to stimulate the heart.
- medicines for depression (lithium, selective serotonin uptake inhibitors may affect or be affected by treatment with pseudoephedrine
- Methotrexate as this medicine can increase plasma levels of these drugs
- Ciclosporin & tacrolimus as there is an increased risk of kidney problems
- This product should not be taken within 8-12 days of taking Mifepristone (for termination of pregnancy)
- Zidovudine (for HIV treatment)
- Quinolone antibiotics
- When using Monoamine oxidase inhibitors (MAOIs) (e.g. moclobemide) and/or Reversible inhibitors of monoamine oxidase A (RIMAs), or within 14 days of stopping treatment with these medicines
- Ergot alkaloids (ergotamine & methysergide)
- Other sympathomimetic agents such as decongestants, amphetamine-like psychostimulants and appetite suppressants, as their effect may be increased by the pseudoephedrine contained in this medicine
- Oxytocin as there is a risk of increase in blood pressure.
- Anticholinergics as they can affect the way that pseudoephedrine works.
- Linezolid (medicine used to treat bacterial infections) as this may increase blood pressure

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

Other warnings
- This medicine belongs to a group of medicines which **may impair fertility in women.** This is reversible on stopping the medicine. It is unlikely that this medicine, used occasionally, will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.
- Anti-inflammatory/pain-killer medicines such as 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.

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Pharmacode Reads This Way
Start of pharmacode must be 45mm from edge
First Bar
Last Bar
295mm

- Sudden abdominal pain or rectal bleeding may occur with this medicine, due to inflammation of the colon (ischaemic colitis). If you develop these gastro-intestinal symptoms, stop taking this medicine and contact your doctor or seek medical attention immediately. See section 4.
- You should discuss your treatment with your doctor or pharmacist before taking this medicine if you:
  - 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 of feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack 'TIA').
  - have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- If you develop a feverish generalised erythema associated with pustules, stop taking this medicine and contact your doctor or seek medical attention immediately. See section 4.
- 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 this medicine 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).
- If you are taking this medicine for longer than the recommended time or at higher than recommended doses you are at risk of serious harm. These include serious harm to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Important information about the ingredients in this medicine:
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take this medicine

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure. **Do not take it for longer than 10 days** unless your doctor tells you to. 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).
The recommended dose is:

Adults, the elderly and children of 12 years and older:
Take 1 or 2 tablets with water, up to three times a day as required.
Leave at least 4 hours between doses.
Do not take more than 6 tablets in 24 hours.

Not suitable for children under 12 years.

Whilst taking this medicine:
If symptoms persist or pain or fever worsen, or if any new symptoms occur, consult your doctor or pharmacist.

If you have taken more of this medicine 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 advice 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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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 reaction** such as:
  - Difficulties in breathing
  - Dizziness or faster heartbeat
  - Signs of hypersensitivity and skin reactions such as reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of 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).
  - Swelling of your face, tongue or throat
- **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.
- **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).
- **sudden onset of fever, reddening of the skin, or many small pustules** (possible symptoms of Acute Generalised Exanthematous Pustulosis - AGEP) that may occur within the first 2 days of treatment with this medicine. See section 2.
- 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). See also section 2.
- **inflammation of the colon** due to insufficient blood supply (ischaemic colitis) (frequency not known).

STOP TAKING the medicine and tell your doctor if you experience the following uncommon side effects:
- indigestion, heartburn or feeling sick
- pains in your stomach (abdomen) or other abnormal stomach problems
- hallucinations, restlessness or sleep disturbance

Like all medicines, this medicine can cause side-effects, although not everybody gets them. Tell your doctor or pharmacist if you notice any of the following:
- Liver, kidney problems or difficulty urinating

This medicine, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

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

Uncommon: may affect up to 1 in 100 people:
- allergic reactions, such as skin rashes (urticaria), itching, peeling
- headaches, tremors

Rare: may affect up to 1 in 1,000 people:
- flatulence (wind), diarrhoea, constipation and vomiting

Very rare: may affect up to 1 in 10,000 people:
- 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 and kidney problems, characterised by yellowing of the skin or eyes; swollen hands, legs, ankles or feet; dark-coloured or bloody urine; pale, bloody or tar like stools; fatigue; shortness of breath; decreased appetite; or tendency to bruise easily.

Not known: frequency cannot be estimated from the available data:
- serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)

Stop using this medicine 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
- worsening of asthma or bronchospasm
- swelling (oedema), high blood pressure, heart failure or attack, chest pain (which can be a sign of a potential allergic reaction called Kounis Syndrome)
- worsening of colitis and Crohn's disease or dry mouth
- decreased appetite, anxiety
- excessive sweating, muscle weakness, difficulty in urinating, thirst
- Reduced blood flow to the optic nerve (Ischaemic optic neuropathy).
- skin becomes sensitive to light

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store this medicine

Keep all medicines out of the sight and reach of children. Do not use after the expiry date shown on the pack.
Store in a dry place.

6. Contents of the pack and other information

Each tablet contains the active ingredients Ibuprofen 200 mg and Pseudoephedrine Hydrochloride 30 mg.
Also contains: Calcium Phosphate, Microcrystalline Cellulose, Polyvinyl Pyrrolidone, Sodium Carboxymethyl Cellulose, Magnesium Stearate, Hydroxypropylmethyl Cellulose, Talc, Titanium Dioxide, Quinoline Yellow and Sunset Yellow (contains Aluminium and E110), black printing ink (contains shellac, Iron Oxide Black (E172) and propylene glycol).
This medicine is available in packs of 12 and 24 tablets.

Licence Holder: Reckitt Benckiser Healthcare (UK) Ltd, Slough, SL1 4AQ.
Manufacturer: Reckitt Benckiser Healthcare International Ltd, NG90 2DB.
Product Licence No. PL 00063/0375
Date of revision September 2024

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Start of pharmacode must be 45mm from edge
Pharmacode Reads This Way
First Bar
Last Bar
190mm