

NUROFEN®

Cold & Flu Relief
200mg/5mg Tablets

Contain ibuprofen and
phenylephrine hydrochloride

INFORMATION FOR THE USER

Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription. However, you still need to use Nurofen Cold & Flu Relief carefully to get the best results from it.

Keep this leaflet. You may want to read it again.

If you have any further questions after you have read it, ask your doctor or pharmacist.

You must contact a doctor if your symptoms worsen or do not improve after 10 days.

If any side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

Nurofen Cold & Flu Relief contains ibuprofen and phenylephrine hydrochloride, which are effective in relieving the symptoms associated with colds and flu, including relief of aches and pains, sore throats, headache, nasal congestion (blocked nose) and lowering of temperature.

Ibuprofen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs) and is effective against aches and pains (including headache), swelling and can also reduce a fever. Phenylephrine hydrochloride (nasal decongestant) reduces swelling in the passages of the nose, relieving nasal congestion and reducing the pressure which may cause a headache.

2. Before taking this medicine

Do not take this medicine if you:

- are allergic to ibuprofen, phenylephrine hydrochloride or any other ingredients of this medicine (see section 6) or to aspirin or other painkillers
- have ever had a stomach ulcer, perforation or bleeding
- have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking ibuprofen, aspirin or similar medicines
- have had gastrointestinal bleeding or perforation when previously taking NSAIDs (Non-Steroidal Anti-Inflammatory Drugs)
- are taking other NSAID painkillers
- are taking more than 75mg of aspirin a day. If you are on low-dose aspirin (up to 75mg daily) speak to your doctor or pharmacist before you take this medicine
- have severe liver or kidney problems
- have heart problems, high blood pressure or blood coagulation disorder
- have breathing difficulties
- have an overactive thyroid
- are taking or have taken within the last 14 days a medicine called monoamine oxidase inhibitor (usually used to treat depression)
- are in the last 3 months of pregnancy
- are under 12 years old

CHECK WITH YOUR PHARMACIST OR YOUR DOCTOR BEFORE TAKING THIS PRODUCT IF YOU

- have or have had asthma
- have kidney, heart, liver or bowel problems
- have high cholesterol or previously have had a heart attack or stroke
- have an history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease)
- have Systemic Lupus Erythematosus (a condition of the immune system causing joint pain, skin changes or other organ disorders)
- are a smoker
- are in the first 6 months of pregnancy.

Taking other medicines

To reduce the risk of side effects, do not take this product with other NSAID containing products (e.g. aspirin, ibuprofen). If you are on low-dose aspirin (up to 75mg daily) speak to your doctor or pharmacist before you take this medicine.

Some drugs may affect the way in which ibuprofen and phenylephrine hydrochloride work or may themselves be affected by this product. Avoid taking this product with corticosteroids tablets, quinolone antibiotics or drugs that are:

- to thin your blood or prevent clotting (e.g. warfarin)
- to stimulate your heart (e.g. glycosides including digoxin) or treat high blood pressure (beta-blockers and other hypertensives),
- to help you passing water (diuretics)
- for the temporary suppression of your immune system (e.g. methotrexate, cyclosporine, tacrolimus)
- for mania or depression (e.g. lithium, SSRIs or Monoamine Oxidase Inhibitors)
- for pregnancy termination (e.g. mifepristone)
- for HIV treatment (e.g. zidovudine)
- containing other sympathomimetic agents such as decongestants (e.g. pseudoephedrine)

Speak to your pharmacist or doctor before taking this product with other medicines.

Other warnings

- Medicines such as Nurofen Cold & Flu Relief may be associated with a **small increased risk of heart attack or stroke**. Any risk is more likely with high doses or prolonged treatment.
- **Do not exceed the recommended dose.**
- **If you have heart problems, previous stroke or think that you might be at risk of these conditions** (for example if you have high blood pressure, diabetes, high cholesterol or are a smoker), you should discuss your treatment with your doctor or pharmacist.

Fertility, pregnancy and breast-feeding

Nurofen Cold & Flu Relief belongs to a group of medicines which may affect fertility in women. Fertility goes back to normal when you stop taking the medicine. It is unlikely that if you only take Nurofen Cold & Flu Relief occasionally it will affect your chances of becoming pregnant. If you have problems becoming pregnant, talk to your doctor before taking this medicine.

Tell your doctor if you become pregnant whilst taking Nurofen Cold & Flu Relief. Do not take this medicine in the last 3 months of pregnancy. Avoid the use of this medicine in the first 6 months of pregnancy unless the doctor advises otherwise.

Speak to your doctor or pharmacist before taking this medicine if you are breast-feeding.

3. How to take this medicine

Tablets must be taken with water and swallowed whole.

It is important to drink plenty of fluids when suffering from colds and flu.

Adults, the elderly and children over 12 years:

This medicine is for short-term use only. Take the lowest dose for the shortest time necessary. **Do not take Nurofen Cold & Flu Relief for longer than 10 days.** If you do not get better, or get worse, talk to your doctor. They will tell you if it is safe to carry on taking the medicine.

Take 2 tablets every 8 hours. Leave at least 4 hours between doses and do not exceed 6 tablets in any 24 hour period.

Do not give to children under 12 years.

If you take more Nurofen Cold & Flu Relief than you should

You may feel drowsy or nauseous. You should seek immediate medical advice in the event of an overdose, even if you feel well.

If you forgot to take Nurofen Cold & Flu Relief

Simply refer to the directions above on how to take the medicine and do not take more than is advised.

4. Possible side-effects

Like all medicines, Nurofen Cold & Flu Relief 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 this leaflet, tell your doctor or pharmacist.

If you get any of the following at any time during your treatment **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 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 1,000:

- indigestion, heartburn or feeling sick
- pains 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 1,000:

- allergic reactions, such as skin rashes (urticaria), itching, peeling
- headaches, dizziness, tinnitus (ringing in the ears)

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
- liver problems

Side effects for which the frequency can not 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
- difficulties in passing urine (in men only).

Medicines such as Nurofen Cold & Flu Relief may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. See section 2 "Other warnings".

Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at www.mhra.gov.uk/yellowcard. Alternatively you can call Freephone 0808 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy.

5. How to store

Keep all medicines out of the reach and sight of children.

Do not use after the end of the month of the expiry date (EXP month/year) shown on the pack.

Do not store above 25°C (77°F). Store in a dry place. Store in the original package.

6. Further information

Each tablet contains the active ingredients ibuprofen (200mg) and phenylephrine hydrochloride (5mg). The other ingredients are cellulose, sodium starch glycoate, hypromellose, magnesium stearate, talc, Mastercote yellow (contains Hydroxypropylmethyl Cellulose (E464), Titanium Dioxide (E171), Quinoline Aluminium Lake (E104) and Sunset Yellow Aluminium Lake (E110)) and black printing ink (contains shellac, iron oxide black (E172) and propylene glycol).

The product is available in cartons of 4, 6, 8, 10, 12, 14 and 16 tablets. Not all packs may be marketed.

Alternative format patient information for the visually impaired is available on request from the Marketing Authorisation Holder.

Licence Holder: Reckitt Benckiser Healthcare (UK) Ltd, Hull, HU8 7DS.

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