NUROFEN®
Cold & Flu Relief
200 mg/5 mg Tablets

contains 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. Nurofen Cold & Flu Relief will be referred to as 'this medicine' throughout this leaflet.
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
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 is this medicine and what is it used for

This medicine 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. 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 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 75 mg of aspirin a day. If you are on low-dose aspirin (up to 75 mg 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
- have an enlarged prostate
- have phaeochromocytoma

Warnings and Precautions
Talk to your doctor or pharmacist before taking this product if you:
- have or have had asthma
- have kidney, heart, liver or bowel problems or are dehydrated
- 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.
- have diabetes
- have glaucoma
- have a blood vessel disease such as Raynaud's phenomenon
- 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.

Other warnings
- 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.
- 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 or 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 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).

Other medicines and this medicine
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 75 mg daily) speak to your doctor or pharmacist before you take this medicine.
This medicine may affect or be affected by some other medicines.
For example: Avoid taking this product with corticosteroids tablets, quinnolone antibiotics or medicines that are:
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- to stimulate your heart (e.g. glycosides including digoxin),
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- to help you passing water (diuretics)
- for the temporary suppression of your immune system (e.g. methotrexate, ciclosporin, 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)

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.

Fertility, pregnancy and breast-feeding
This medicine 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 this medicine 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 this medicine. 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. 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.

This medicine contains Sunset Yellow E 110.

The product contains an azo colouring agent Sunset Yellow E 110 which may cause allergic reactions.

This medicine contains less than 1 mmol sodium (23 mg) per 2 tablets, that is to say essentially `sodium-free'.

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. 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). **Do not take this medicine 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 two tablets up to 3 times a day. Leave at least four hours between doses and do not take more than 6 tablets in any 24 hour period.

Do not give to children under 12 years.

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, tinnitus (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 forgot to take this medicine
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, this medicine 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
  - 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 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 disorientation. Patients with autoimmune disorders (lupus, mixed connective-tissue disease) may be more likely to be affected.
- **signs of blood disorder** resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and sever exhaustion
- **signs of liver problems** such as stomach pain, nausea, jaundice (yellowing of the skin and the whites of the eyes) or passing dark brown urine.
- **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).See also section 2.

STOP TAKING the medicine and tell your doctor if you experience the following uncommon side effects which may affect up to 1 in 100 people:
- indigestion, heartburn or feeling sick
- pains in your stomach (abdomen) or other abnormal stomach problems.

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

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:
- drop in blood pressure or irregular heart beat
- liver problems

Not known: frequency cannot be estimated from the available data:
- worsening of asthma or bronchospasm
- swelling (oedema), high blood pressure, heart failure or attack
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- worsening of colitis and Crohn's disease
- difficulties in passing urine (in men only)
- skin becomes sensitive to light

Medicines such as this medicine may be associated with a small increased 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 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 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. Contents of the pack and other information

Each tablet contains the active ingredients ibuprofen (200 mg) and phenylephrine hydrochloride (5 mg). 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.

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