

**Nurofen Sinus Pressure & Headache Relief 200mg/30mg tablets**  
**Contains Ibuprofen and Pseudoephedrine Hydrochloride**

**PLEASE READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TO TAKE YOUR MEDICINE**

It gives you important information about Nurofen Sinus Pressure and Headache Relief 200mg/30mg Tablets.

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

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

**Nurofen Sinus Pressure and Headache Relief 200mg/30mg Tablets**

**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 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**

- 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**

**Do not take this medicine if you:**

- have (or have had two or more episodes of) 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 (non-steroidal anti-inflammatory drugs) (NSAIDs).
- are taking other NSAID painkillers or more than 75mg aspirin a day
- are taking Monoamine Oxidase Inhibitors (for depression and known as MAOIs) or have taken these in the last 14 days.
- have severe liver or kidney problems
- have heart problems, high blood pressure, prostate problems or an overactive thyroid
- have diabetes or glaucoma.
- are under 12 years of age
- are pregnant or breast feeding.

**Check with your pharmacist or doctor before taking this medicine if you:**

- have asthma

- have kidney or liver problems
- 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)
- have Systemic Lupus Erythematosus (SLE)- an illness affecting the immune system causing joint pain, skin changes and other problems
- are a smoker.
- 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 have been reported in association with this medicine. You should stop taking this medicine and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

### **Other medicines and this medicine**

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/acetysalicylic 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)
- medicines for depression (lithium, selective serotonin uptake inhibitors and monoamine oxidase inhibitors (known as MAOIs)) may affect or be affected by treatment with 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.

### **Other warnings**

- This medicine belong 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 this medicine 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 take longer than necessary to control your symptoms (10 days).
- Sudden abdominal pain or rectal bleeding may occur with Nurofen Sinus Pressure and Headache Relief 200mg/30mg Tablets, 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.
- develop a feverish generalised erythema associated with pustules, stop taking this medicine and contact your doctor or seek medical attention immediately. See section 4.

Important information about the ingredients in Nurofen Cold & Flu:

- 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**

This product 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 it for longer than 10 days unless your doctor tells you to.

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**

This medicine is generally well tolerated by most people. However, side effects may occur. 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 a serious allergic reaction such as severe skin rashes, peeling, flaking or blistering skin, facial swelling, unexplained wheeziness, shortness of breath, easy bruising.
- 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 Generalized Exanthematous Pustulosis - AGEP) that may occur within the first 2 days

of treatment with Nurofen Sinus Pressure & Headache Relief 200mg/30mg tablets. 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).

**Tell your doctor if you experience the below other possible side effects:**

**Uncommon:** may affect up to 1 in 100 people

- indigestion or heartburn
- stomach pain or other abnormal stomach symptoms
- rashes, itching
- headache

**Very rare:** may affect up to 1 in 10,000 people

- liver and kidney problems

**Not known:** frequency cannot be estimated from the available data:

- worsening of asthma
- sweating, thirst, muscle weakness or tremors, sleeplessness, chest pain or fast, irregular heart beat
- dizziness and hearing disturbance, difficulty in urinating, mood changes e.g. restlessness.
- 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](http://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 200mg and Pseudoephedrine Hydrochloride 30mg.

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). Nurofen Sinus Pressure and Headache Relief 200mg/30mg Tablets is available in packs of 12 and 24 tablets.

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