

## Information for the user



# Cold & Flu Relief with Ibuprofen (Ibuprofen, Pseudoephedrine Hydrochloride)

**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription to treat minor conditions. However, you still need to take it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice

## What this medicine is for

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

**Ibuprofen** belong 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 adults, the elderly and children older than 12 years and works in the following ways to relieve the symptoms of cold and flu:

- clears a blocked nose and sinuses
- relieves aches, pains, headache, and high temperature (fever)
- eases the discomfort of a sore throat.

## What you need to know before you take this medicine

### **X Do not take this medicine:**

- If you have a stomach ulcer, perforation or bleeding, or have had one twice or more in the past
- If you have had perforation or a bleeding stomach after taking a non-steroidal anti-inflammatory medicine (you may have been sick and it contained blood or dark particles that look like coffee grounds, passed blood in your stools or passed black tarry stools)
- If you are allergic to ibuprofen, pseudoephedrine or any other ingredients of this medicine, or to aspirin or other non-steroidal anti-inflammatory medicines
- If you have had a worsening of asthma, runny nose, itchy skin or facial swelling after taking aspirin or similar medicines
- If you are taking aspirin with a daily dose above 75 mg, or other non-steroidal anti-inflammatory (NSAID) medicines
- If you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure
- If you have severe liver, heart or blood vessel disease, including fast heart rate (tachycardia), angina
- If you have very high blood pressure (hypertension) or hypertension not controlled by your medication
- If you have glaucoma, an overactive thyroid, diabetes, or a tumour near your kidney (phaeochromocytoma)
- If you are taking monoamine oxidase inhibitors (for depression and known as MAOIs) or

have taken them within the last 14 days

- If you are taking beta-blockers
- If you are using other sympathomimetic decongestants (including nasal sprays)
- If you are pregnant or breast-feeding (see section 'Pregnancy, breast-feeding and fertility')
- If you are under 12 years of age

## **Warnings and precautions**

### **! Talk to your pharmacist or doctor before taking this medicine:**

- If you are taking any other painkillers or receiving regular treatment from your doctor
- If you are elderly – you may get more side effects
- If you are between 12 and 18 years old and you are dehydrated, you may get kidney problems
- If you have kidney problems (these can be made worse if you are dehydrated, especially if you are elderly, or between 12 and 18 years old)
- If you have asthma, a history of asthma or other allergic disease, bowel problems (such as ulcerative colitis, Crohn's disease)
- If you have heart or liver problems
- If you have a connective tissue disorder such as SLE (Systemic Lupus Erythematosus)
- If you have had 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" – see 'Risk of heart attack or stroke' under "Other important information")
- If you have high blood pressure, high cholesterol, have a family history of heart disease or stroke, prostate problems, or if you are a smoker
- If you have an infection – please see heading "Infections" below

### **Allergic reactions**

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 Boots Cold & Flu Relief with Ibuprofen tablets and immediately contact your doctor or medical emergency department if you notice any of these signs.

### **Infections**

Ibuprofen may hide signs of infections such as fever and pain. It is therefore possible that ibuprofen 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 generalized exanthematous pustulosis (AGEP) have been reported in association with Ibuprofen treatment. Stop using Boots Cold & Flu Relief with ibuprofen and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in 'Possible side effects'.

### **Other important information**

If you are taking this medicine for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 'Possible side effects').

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 'Possible side effects' section.

Reduction of blood flow to your optic nerve may occur with pseudoephedrine. If you develop sudden loss of vision, stop taking this medicine and contact your doctor or seek medical attention immediately. See 'Possible side effects' section.

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).

Risk of heart attack or stroke: Anti-inflammatory/painkiller 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.

### **If you take other medicines**

Before you take these tablets, make sure that you tell your doctor or pharmacist about ANY other medicines you might be using at the same time. Boots Cold and Flu Relief with Ibuprofen 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 effects 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 (water tablets) 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 (e.g. digoxin)
- methotrexate as this medicine can increase plasma levels of these drugs
- zidovudine (for HIV treatment)
- quinolone antibiotics
- medicines for depression (lithium, selective serotonin uptake inhibitors may affect or be affected by treatment with pseudoephedrine)
- ciclosporin or 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)
- when using Monoamine oxidase inhibitors (MAOIs) and/or Reversible inhibitors of monoamine oxidase A (RIMAs) (e.g. moclobemide), or within 14 days of stopping treatment with these medicines
- 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
- ergot alkaloids (ergotamine and methysergide)
- oxytocin as there is a risk of increase in blood pressure
- anticholinergic drugs (such as tricyclic antidepressants (TCAs)) as this medicine can enhance the effects of anticholinergic drugs
- methyl dopa as it may reduce the effectiveness of this medicine
- 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 with Boots Cold and Flu Relief with Ibuprofen.** You should therefore always seek advice of your doctor or pharmacist before you can use this medicine with any other medicines, including herbal and homeopathic remedies.

### **Pregnancy, breast-feeding and fertility**

#### **Pregnancy**

Do not take this medicine if you are pregnant (see section 'Do not take this medicine'). **In the last 3 months of pregnancy ibuprofen** could harm your unborn child or cause problems at delivery. **Ibuprofen** can cause kidney and heart problems in your unborn baby. It may affect you and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take ibuprofen 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, ibuprofen 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 ibuprofen for longer than a few days, your doctor may recommend additional monitoring.

Use of pseudoephedrine in the first 3 months of pregnancy has been associated with an increased frequency of some developmental abnormalities.

#### **Breast-feeding**

This medicine should not be used during breast-feeding (see section 'Do not take this medicine').

#### **Women of childbearing age**

If you take this medicine, it may reduce your ability to become pregnant. This effect will be reversed when you stop the medicine.

#### **Important information about some of the ingredients**

This medicine contains sunset yellow FCF (E110) which may cause allergic reactions.

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

### **✓ How to take this medicine**

Check the foil is not broken before use. If it is, do not take that tablet.

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 7 days. If your symptoms worsen or do not improve within 7 days, talk to your doctor or pharmacist. 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 'Infections').

Age	How many	How often
Adults, the elderly and children of 12 years and over.	Take 1 or 2 tablets with water	Up to three times a day. Leave at least 4 hours between doses. <b>Do not take more than 6 tablets in 24 hours.</b>
Take the lowest amount for the shortest possible time to relieve your symptoms.		

Do not give to children under 12 years.

Do not take more than the amount recommended above.

### 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 on 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, shaky eye movement, anxiety, irritability, restlessness, inability to urinate (urinary retention), fever, sinus tachycardia (a type of fast heart rate), abnormal heart rhythm (cardiac arrhythmias), sweating, insomnia, dilated pupils, blurred vision, delusions, hallucinations, muscular weakness, abnormalities with the process of urinating (difficulty in micturition), tremors and high blood pressure. 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.

### Possible side effects

Most people will not have problems, but some may get some.

**! If you get any of these serious side effects, stop taking the tablets. See a doctor at once 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:
  - difficulty 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 the face, tongue or throat
- **signs of aseptic meningitis** with stiff neck, 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 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 ‘What you need to know before you take this medicine’
- 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 may be AGEP. See also section ‘What you need to know before you take this medicine’.
- **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 ‘Other important information’). 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 (ulcerative colitis), 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, 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
  - dizziness
  - hearing problems.

### **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 on this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [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.

### **How to store this medicine**

Do not store above 25°C.

Store in the original package.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

Use by the date on the end flap of the carton or on the foil edge.

### **What is in this medicine**

Each tablet contains Ibuprofen 200 mg and Pseudoephedrine Hydrochloride 30 mg, which are the active ingredients.

As well as the active ingredients, the tablets also contain tricalcium phosphate, croscarmellose sodium, povidone, microcrystalline cellulose, hydroxypropylmethyl cellulose, magnesium stearate, talc and Mastercote orange FA1202A (solids) (which contains sunset yellow FCF (E110), quinoline yellow (E104) and titanium dioxide (E171)).

The pack contains 12 or 24 round orange tablets. They are marked with CF on one side.

### **Who makes this medicine**

Manufactured for the Marketing Authorisation holder The Boots Company PLC Nottingham NG2 3AA by Famar SA Anthoussa Attiki 15344 Greece.

### **Leaflet prepared: June 2025.**

If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA.