

**Package Leaflet: Information for the user**

***Advil\* Cold & Flu Coated Tablets***

**Ibuprofen 200 mg / Pseudoephedrine hydrochloride 30 mg**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

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. 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 feel worse after 3 days.

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

**What is in this leaflet:**

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

**1. WHAT ADVIL COLD & FLU IS AND WHAT IT IS USED FOR**

*Advil Cold & Flu* is used for the relief of nasal/sinus congestion with headache, fever and pain associated with the common cold and flu.

This medicine contains ibuprofen, a Non-Steroidal Anti-Inflammatory Drug (NSAID) which works by relieving pain and reducing high temperature and fever. The tablets also contain pseudoephedrine hydrochloride, a decongestant, which helps clear the nasal passages and ease nasal congestion.

Only use this product if you have a blocked nose together with headache, pain and/or fever. Do not use it if you have only one of the symptoms.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ADVIL COLD & FLU**

**Do not take *Advil Cold & Flu* if you:**

- are allergic to or have previously experienced skin rash, hives, itching, difficulty breathing, tightness in the chest, swelling of the mouth, face, lips or tongue on taking ibuprofen, aspirin, other NSAIDs, or any ingredients contained in this product. See section 6.
- suffer from, or have suffered from stomach ulcers, stomach bleeding or perforation in the past.
- suffer from diabetes, prostate problems, thyroid disease, glaucoma or phaeochromocytoma (i.e. tumour on the adrenal gland).
- have severe kidney disease (kidney failure), severe liver disease, heart disease, severe heart failure, high blood pressure or circulatory problems (angina).
- are taking medicine for the treatment of depression called mono-amine oxidase inhibitors or tricyclic anti-depressants (or if you have taken them in the past 14 days).
- have any other bleeding problems
- have a history of stroke

- are taking other NSAIDs, aspirin, pain relievers, or decongestants.
- are under 12 years of age
- are pregnant or breast feeding.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Advil Cold & Flu if you have or are:

- suffering from heart problems, have had a previous stroke or think that you may be at risk of these conditions (for example, if you have high blood pressure, diabetes or high cholesterol, or you are a smoker) Medicines containing ibuprofen may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.
- suffering from bleeding disorders.
- suffering from stomach ulcers or inflammatory bowel disease (e.g. ulcerative colitis or Crohn's disease).
- asthmatic, suffer from allergies.
- disease of the heart, kidney, liver or prostate.
- elderly – elderly people are more likely to experience unwanted side effects such as stomach bleeding and perforation which may be fatal.
- Systemic Lupus Erythematosus (SLE) – an illness affecting the immune system causing joint pain, skin changes and other problems.
- trying to become pregnant.
- 12-17 years old as there is a risk of renal impairment. Therefore ask a doctor before use if a 12-17 year old has not been drinking fluids or has lost fluids due to continuous vomiting or diarrhoea.
- Consumption of alcohol should be avoided during treatment.
- Pseudoephedrine hydrochloride may cause a positive reaction in tests conducted during anti-doping checks.

### **Children and adolescents**

*Advil Cold & Flu* is for use by adults and adolescents over 12 years of age. *Advil Cold & Flu* is not for use in children younger than 12 years.

### **Other medicines and Advil Cold & Flu**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

### **Do not use this medicine if you are:**

- taking other NSAID painkillers, or more than 75 mg aspirin a day.
- taking decongestants (nasal or oral)
- taking or have taken in the last two weeks drugs for depression known as Monoamine Oxidase inhibitors (MAOIs)
- taking tricyclic antidepressants (used to treat depression).

### **Talk to your doctor or pharmacist if you are taking:**

- blood clotting agents (anti-platelet agents) generally used to thin the blood to help prevent stroke or heart problems (e.g. warfarin, ticlopidine or aspirin).
- tablets to reduce blood pressure (e.g. ACE inhibitors - captopril, beta-blockers – atenolol or losartan) or any water tablets (diuretics)
- cardiac glycosides such as digoxin (digitalis) or quinidine for a heart condition
- phenytoin (a medicine for epilepsy)
- lithium (used to treat mood disorders)

- methotrexate (used to treat arthritis)
- antacids
- cyclosporins (used to suppress the body's immune system e.g. following a transplant)
- mifepristone (used in pregnancy terminations)
- quinolone antibiotics (used to treat a wide range of infections)
- tacrolimus (a transplant drug)
- medicines known as sulphonylureas such as glibenclamide (used to treat diabetes)
- corticosteroids (a type of anti-inflammatory drug e.g. hydrocortisone)
- selective serotonin reuptake inhibitors (SSRIs e.g. fluoxetine)
- aminoglycosides (e.g. gentamicin or amikacin)
- the antibacterial agent furazolidone
- zidovudine (used to treat HIV)
- guanethidine, reserpine or methyldopa.
- sulfinpyrazone and probenecid
- potassium sparing diuretics
- ergot derivatives
- dopamine receptor agonists
- having an anaesthetic, stop treatment beforehand and inform the anaesthetist
- heparins, Ginkgo biloba

**Please tell your pharmacist or doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.**

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

This product should not be taken if you are pregnant or breastfeeding.

If you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Ibuprofen belongs to a group of medicines, NSAIDs, which may impair fertility in women. This effect is reversible upon stopping the medicine. It is unlikely that Ibuprofen, used occasionally, will affect your chances of becoming pregnant, however tell your doctor before taking this medicine if you have problems becoming pregnant.

#### **Driving and using machines**

There are no known effects on driving or on use of machines. *Advil Cold & Flu* may cause side effects such as dizziness, hallucinations, unusual headaches and visual or hearing disturbances in some people. If you are affected by any of these side effects it is best not to drive or use machinery.

#### ***Advil Cold & Flu* contains sodium, sucrose, methyl parahydroxybenzoate and propyl parahydroxybenzoate**

- each coated tablet contains less than 23 mg sodium per dose, and so is essentially sodium free
- if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product, as it contains sucrose
- this product contains methyl parahydroxybenzoate (E 218) and propyl parahydroxybenzoate (E 216) which may cause allergic reaction (possibly delayed).

### **3. HOW TO TAKE ADVIL COLD & FLU**

**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.**

**For oral administration and short term use only.**

**Adults, the elderly and children over 12 years of age: The minimum effective dose should be used for the shortest time necessary to relieve symptoms.**

The recommended dose is: 1 or 2 tablets every 4 to 6 hours as required. The tablets should be taken with water. Take only as much as you need and leave at least 4 to 6 hours between each dose. Do not take more than 6 tablets in any 24 hour period. If symptoms persist for more than 3 days, contact your doctor.

**Do not give to children under 12 years of age.  
Do not exceed the stated dose.**

**If you take more *Advil Cold & Flu* than you should:**

If you take too many tablets, contact your doctor or hospital immediately. Bring the remaining tablets with you to show the doctor.

Discontinue use in the case of accidental overdose.

**If you forget to take *Advil Cold & Flu***

Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

**Like all medicines, this medicine can cause side effects, although not everybody gets them. You can reduce the chances of experiencing side effects by using the minimum dose required.**

**If you experience any of the following side effects then STOP taking this medicine immediately and contact your doctor or pharmacist:**

Common	<ul style="list-style-type: none"><li>• feeling sick (nausea)</li><li>• bleeding of the stomach or bowel (vomiting blood or blood in faeces, black discolouration of faeces)</li></ul>
Uncommon	<ul style="list-style-type: none"><li>• severe headaches or headaches that are worse than usual</li></ul>
Very Rare	<ul style="list-style-type: none"><li>• heart attack</li><li>• fast heartbeat or palpitations</li><li>• allergic reaction to &lt;Trade name&gt;, signs include skin rash, hives, itching, difficulty breathing, tightness in the chest, swelling of the mouth, face, lips or tongue.</li><li>• blistering lesions on the skin or mucous membranes such as the inside of your mouth, signs include burning feeling, with redness, blisters and ulcers.</li></ul>
Not Known	<ul style="list-style-type: none"><li>• stroke</li><li>• behavioural problems such as feeling excited, agitated, anxious, restless or nervous</li></ul>

**In addition to the above, the following side effects may occur during treatment.**

Common	<ul style="list-style-type: none"><li>• Indigestion, stomach ache, vomiting, diarrhoea, constipation, wind</li></ul>
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Uncommon	<ul style="list-style-type: none"> <li>• stomach ulcer</li> <li>• not being able to sleep</li> <li>• feeling drowsy or tired</li> <li>• feeling dizzy or irritable</li> <li>• problems with your sight</li> <li>• headaches that do not go away</li> <li>• breakouts on the skin (rash, itching)</li> <li>• inflamed stomach or bowel, worsening of existing inflammatory bowel disease</li> <li>• hypersensitivity such as wheezing and difficulty breathing in patients who have ever had bronchial asthma or allergic disease.</li> </ul>
Rare	<ul style="list-style-type: none"> <li>• kidney problems</li> <li>• hearing disturbances (tinnitus)</li> </ul>
Very Rare	<ul style="list-style-type: none"> <li>• depression</li> <li>• heart failure</li> <li>• kidney failure</li> <li>• high blood pressure</li> <li>• sore or inflamed mouth</li> <li>• inflamed pancreas (pancreatitis)</li> <li>• narrowing of the gut (intestinal stricture)</li> <li>• aseptic meningitis, worsening of infectious inflammations</li> <li>• problems with your blood cells – you may be more likely to bruise or get infections</li> <li>• liver problems including abnormal liver function, hepatitis or jaundice (yellowing of the skin or eyes).</li> </ul>
Not Known	<ul style="list-style-type: none"> <li>• chest pain</li> <li>• dry mouth, feeling thirsty</li> <li>• abnormal spasm, seizures</li> <li>• spinning sensation (vertigo)</li> <li>• Haematocrit decreased and haemoglobin decreased</li> <li>• seeing or hearing things that are not there (hallucinations)</li> <li>• skin rash, red or purple skin discolouration, fluid retention (oedema)</li> <li>• passing urine less often, blood or protein in your urine (shown in tests)</li> </ul>

### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### 5. HOW TO STORE ADVIL COLD & FLU

Keep this medicine out of the sight and reach of children.  
 Do not use this medicine after the expiry date which is stated on the blister and carton.  
 The expiry date refers to the last day of the month.  
 Do not store above 25<sup>0</sup>C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What *Advil Cold & Flu* contains**

The active substances are:

Each coated tablet contains 200 mg Ibuprofen and 30 mg Pseudoephedrine hydrochloride.

The other ingredients are:

Maize starch, Pregelatinised starch (maize), Croscarmellose sodium, Colloidal anhydrous silica, Sodium laurilsulfate, Stearic acid. The tablet coating contains: Sucrose, Microcrystalline cellulose, Carnauba wax, Shellac, Povidone, Acetylated monoglyceride, Industrial methylated spirits, Titanium dioxide (E 171), Iron oxide (E 172), Methyl Parahydroxybenzoate (E 218), Propyl Parahydroxybenzoate (E 216). Black printing ink contains shellac, iron oxide (E 172), propylene glycol or shellac, iron oxide (E 172), propylene glycol and ammonium hydroxide.

### **What *Advil Cold & Flu* looks like and contents of the pack**

The tablet is oval shaped, butterscotch coloured, sugar coated and imprinted with '200/30' in black ink on one face. The medicine is available only from your pharmacist in a pack size of 2, 4, 10, 12, 20 and 24. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder: Pfizer Healthcare Ireland, Citywest, Dublin 24.

#### Manufacturer

Pfizer Consumer Manufacturing Italy S.r.l, Via Nettunense 90, Aprilia, Italy.

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: Ibuprofen/Pseudoephedrine HCl Pfizer

Czech Republic: Robicold

Hungary: Advil Cold

Ireland: Advil Cold & Flu

Luxembourg: Ibuprofen/Pseudoephedrine HCl Pfizer

Poland: Advil Zatoki

Slovakia: Robicold

UK: RobiCold Sinus Relief

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