

## Advil Cold & Flu Coated Tablets

Ibuprofen 200mg / Pseudoephedrine 30mg

### Package leaflet: Information for the user

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.

### 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 very high blood pressure (severe hypertension) or hypertension not controlled by your medication
- have severe kidney disease (kidney failure), severe liver disease, heart disease, severe heart failure, high blood pressure or circulatory problems (angina).
- if you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure
- 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, pain relievers, or decongestants.
- are under 12 years of age.
- are pregnant or breast-feeding.

### **Warnings and precautions**

Anti-inflammatory/pain-killer 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.

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. Stop immediately Advil Cold & Flu and contact immediately your doctor or medical emergencies if you notice any of these signs.

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

- 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”).
- high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker). 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).
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- 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.
- Dehydrated 12-17 years old as there is a risk of kidney problems. 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.
- an infection – please see heading “Infections” below.

Pseudoephedrine causes narrowing of blood vessels (vasoconstriction). This action may be associated with the occurrence of the following sudden medical conditions. These conditions require immediate medical attention:

- **Acute Coronary Syndrome (ACS):** This includes conditions such as a heart attack or unstable angina. Both are associated with a type of severe chest pain caused by blocked blood supply to parts of the heart. The sudden chest pain or discomfort (a feeling of pressure or tightness) can spread from your chest to your arms, jaw, neck, back or tummy. You may also feel lightheaded or dizzy, be sweating or experience shortness of breath while at rest. Stop using this product immediately and seek immediate medical assistance if you develop symptoms that may be signs of ACS.

- 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 product 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).
- Reduction of blood flow to your optic nerve may occur Advil Cold & Flu. If you develop sudden loss of vision or decreased vision, such as a blind spot or persistent blurring, stop taking Advil Cold & Flu and contact your doctor or seek medical attention immediately. See section 4.
- Sudden abdominal pain or rectal bleeding may occur with Advil Cold & Flu, due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms, stop taking Advil Cold & Flu and contact your doctor or seek medical attention immediately. See section 4.

Take special care with Advil Cold & Flu

#### Skin reactions

Serious skin reactions have been reported in association with Advil Cold & Flu treatment. You should stop taking Advil Cold & Flu 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.

Drinking alcohol should be avoided during treatment.

Pseudoephedrine hydrochloride may cause a positive reaction in tests conducted during anti-doping checks. During chicken pox (varicella) it is advisable to avoid the use of ibuprofen

#### Infections

Advil Cold & Flu may hide signs of infections such as fever and pain. It is therefore possible that Advil Cold & Flu 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.

#### 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.
- 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:
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting (e.g. warfarin, ticlopidine or aspirin/acetysalicylic acid).
- medicines to reduce high blood pressure (e.g. ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as 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 (used to treat symptoms of stomach ulcers e.g. heartburn).
- 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 sulfonylureas 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) (used to treat depression).
- aminoglycosides (e.g. gentamicin or amikacin) (used to treat infections).
- the antibacterial agent furazolidone (used to treat infections).
- zidovudine (used to treat HIV).
- guanethidine, reserpine or methyldopa (medicines for heart and circulation problems).
- sulfinpyrazone and probenecid (used to treat gout).
- potassium sparing diuretics (used to treat heart problems).
- ergot derivatives (medicines to treat migraines).
- dopamine receptor agonists (used to treat Parkinson's symptoms).
- heparins, Ginkgo biloba (treatment of blood clots).

If you are having an anaesthetic, stop treatment beforehand and inform the anaesthetist.

Some other medicines may also affect or be affected by the treatment of Advil Cold & Flu . You should therefore always seek the advice of your doctor or pharmacist before you use Advil Cold & Flu with other medicines.

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

This product should not be taken if you are pregnant or breast-feeding.

Taken in the last 3 months of pregnancy, the ibuprofen in this medicine 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. If taken for more than a few days from 20 weeks of pregnancy onward, Advil Cold & Flu 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 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.**

- This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say 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 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).**

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 or if children have taken the medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.** Bring the remaining tablets with you to show the doctor. 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.

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>• 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 Advil Cold &amp; Flu, 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>• serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)</li> </ul>

	<ul style="list-style-type: none"> <li>• Stop using this product 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</li> <li>• stroke</li> <li>• behavioural problems such as feeling excited, agitated, anxious, restless or nervous</li> <li>• A red, scaly widespread rash with bumps under the skin and blisters mainly localized in skin folds, trunk and upper extremities accompanied by fever at the initiation of treatment (acute generalized exanthematous pustulosis). Stop using Advil Cold &amp; Flu if you develop these symptoms and seek medical attention immediately. See also section 2.</li> <li>• Inflammation of the colon due to insufficient blood supply (ischemic colitis).</li> <li>• Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome</li> <li>• Reduced blood flow to the optic nerve (ischaemic optic neuropathy).</li> </ul>
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**In addition to the above, the following side effects may occur during treatment.**

Common	<ul style="list-style-type: none"> <li>• indigestion, stomach ache, feeling sick (nausea), vomiting, diarrhoea, constipation, wind</li> </ul>
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> </ul>

	<ul style="list-style-type: none"> <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>• skin becomes sensitive to light</li> <li>• passing urine less often, blood or protein in your urine (shown in tests)</li> <li>• 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).</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 HPRC Pharmacovigilance, Website: [www.hpra.ie](http://www.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 °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 to 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 (E 487), Stearic acid. The tablet coating contains: Sucrose, Microcrystalline cellulose, Carnauba wax, Shellac, Povidone, Acetylated monoglyceride, Industrial methylated spirits, Titanium dioxide (E171), Iron oxide yellow (E 172), Iron oxide red (E 172), Methyl Parahydroxybenzoate (E 218), Propyl Parahydroxybenzoate (E 216).

Black printing ink contains shellac, iron oxide black (E 172), propylene glycol (E1520) or shellac, iron oxide (E 172), propylene glycol (E 1520) 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: Haleon Ireland Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

Manufacturer: Haleon 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:

Czech Republic: Robicold

Hungary: Advil Cold

Ireland: Advil Cold & Flu

Poland: Advil Zatoki

Slovakia: Robicold

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PA0678/147/001