

Package leaflet: Information for the user

Advil Cold & Flu Relief Soft Capsules

Ibuprofen 200 mg / Pseudoephedrine hydrochloride 30 mg

Read all of this leaflet carefully before you start taking Advil Cold & Flu Relief because it contains important information for you.

Advil Cold & Flu Relief is available without prescription. Always take Advil Cold & Flu Relief exactly as described in this leaflet or as your doctor or pharmacist has 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 or pharmacist. 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 5 days.

What is in this leaflet

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

1. What Advil Cold & Flu Relief is and what it is used for

What Advil Cold & Flu Relief is

Advil Cold & Flu Relief contains two active substances, ibuprofen and pseudoephedrine.

- Ibuprofen belongs to a group of medicines called ‘non-steroidal anti-inflammatory drugs’ (NSAIDs). It helps to reduce pain and lower a high temperature (fever).
- Pseudoephedrine belongs to a group of medicines called ‘vasoconstrictors’. It helps to clear the nasal passages and eases nasal congestion.

What Advil Cold & Flu Relief is used for

Advil Cold & Flu Relief is used to treat symptoms of the common cold and flu, including headache, high temperature (fever), sore throat, aches and pains, blocked nose, in adults and young people aged 12 and over.

Only use this medicine if you have a blocked nose together with the symptoms listed above such as headache and high temperature. Do not use if you only have one of the symptoms listed above.

2. What you need to know before you take Advil Cold & Flu Relief

Do not take Advil Cold & Flu Relief if:

- you are allergic to ibuprofen or pseudoephedrine, or any of the other ingredients of this medicine listed in section 6, or you have had an allergic reaction to a similar medicine in the past such as aspirin/acetylsalicylic acid or other NSAIDs. Signs of an allergic reaction include skin rash, hives, itching, difficulty breathing, tightness in the chest, swelling of the mouth, face, lips or tongue
- you have ever had gastrointestinal problems after taking Advil Cold & Flu Relief, ibuprofen, aspirin/acetylsalicylic acid or other NSAIDs in the past, such as stomach ulcers, stomach bleeding or a perforation
- you currently have a stomach ulcer or stomach bleeding, or any other signs of bleeding
- you have severe liver or severe kidney problems

- you are pregnant or breast-feeding
- you are under 12 years of age
- you have severe problems with your heart including:
 - severe heart failure
 - high blood pressure
 - severe heart disease
 - angina (chest pain)
- you have ever had a stroke
- you are taking:
 - other medicines containing NSAIDs for pain relief such as ibuprofen or aspirin/acetylsalicylic acid
 - other medicines to clear the nasal passages either orally (by mouth) or nasally (through your nose) such as pseudoephedrine, phenylpropanolamine, phenylephrine or ephedrine
 - medicines to treat depression called non-selective monoamine oxidase inhibitors (MAOIs) such as iproniazid, or if you have taken them in the last 14 days
 - other medicines to treat depression called tricyclic anti-depressants such as amitriptyline
- you have diabetes, problems with your thyroid gland or a tumour on your adrenal gland (called pheochromocytoma)
- you have glaucoma (raised pressure in the eye)
- you have problems passing urine, due to prostate problems or other causes.

Do not take Advil Cold & Flu Relief if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Advil Cold & Flu Relief.

Advil Cold & Flu Relief contain soya lecithin. If you are allergic to peanut or soya, do not use this medicinal product.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Advil Cold & Flu Relief 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”).you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- you have asthma – this is because there is a risk of having an asthma attack
- you have liver or kidney problems
- you have problems with your prostate
- you have bleeding problems
- you have ever had gastrointestinal problems in the past such as stomach ulcers, stomach bleeding, ulcerative colitis or Crohn’s disease
- you have systemic lupus erythematosus (SLE) – an illness affecting the immune system causing joint pain, skin changes and other problems.
- you have an infection – please see heading “Infections” below.

Pseudoephedrine may cause a positive reaction in anti-doping checks. Do not take Advil Cold & Flu Relief if this may affect you.

Reduction of blood flow to your optic nerve may occur with Advil Cold & Flu Relief . If you develop sudden loss of vision or decreased vision, such as a blind spot or persistent blurring, stop taking Advil Cold & Flu Relief and contact your doctor or seek medical attention immediately- See section 4.

If you develop a feverish generalised erythema (redness of the skin) associated with pustules, stop taking Advil Cold & Flu Relief and contact your doctor or seek medical attention immediately. See section 4.

Sudden abdominal pain or rectal bleeding may occur with Advil Cold & Flu Relief, due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms, stop taking Advil Cold & Flu Relief and contact your doctor or seek medical attention immediately. See section 4.

Take special care with Advil Cold & Flu Relief,

Skin reactions

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

Infections

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

During chicken pox (varicella) it is advisable to avoid the use of ibuprofen.

If any of the above apply to you, or you are not sure, talk to your doctor or pharmacist before taking Advil Cold & Flu Relief.

Heart attack and stroke

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.

Older people

If you are an older person taking Advil Cold & Flu Relief, you are more likely to get side effects such as stomach bleeding or a perforation (signs may include stomach pain and heartburn). This may be life threatening. See 'Possible side effects' in section 4 for more information.

Children and adolescents Do not give Advil Cold & Flu Relief to children under 12 years of age.

Talk to your doctor or pharmacist before taking Advil Cold & Flu Relief if you are 12 to 17 years of age and you have not been drinking fluids or you are dehydrated due to diarrhoea or being sick. This is because there is a higher risk of kidney problems with Advil Cold & Flu Relief when you are dehydrated.

Other medicines and Advil Cold & Flu Relief

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, and herbal medicines.

Do not take Advil Cold & Flu Relief if you are taking any of the following medicines:

- other medicines containing NSAIDs including cyclooxygenase-2 selective inhibitors for pain relief such as ibuprofen or aspirin/acetylsalicylic acid
- other medicines to clear the nasal passages either orally (by mouth) or nasally (through your nose) such as pseudoephedrine, phenylpropanolamine, phenylephrine or ephedrine

- medicines to treat depression called non-selective monoamine oxidase inhibitors (MAOIs) such as iproniazid, or if you have taken them in the last 14 days
- other medicines to treat depression called tricyclic anti-depressants such as amitriptyline.

Do not take Advil Cold & Flu Relief if any of the above apply to you. If you are not sure talk to your doctor or pharmacist before taking Advil Cold & Flu Relief.

Talk to your doctor or pharmacist before taking Advil Cold & Flu Relief if you are taking any of the following medicines:

- medicines to treat depression called reversible inhibitors of monoamine oxidase A (RIMAs) and selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine
- linezolid
- bromocriptine, pergolide, lisuride, cabergoline, ergotamine or dihydroergotamine
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- heparin when it is being used to treat or prevent a blood clot
- lithium when it is being used to treat severe mood problems
- methotrexate
- medicines that reduce high blood pressure (ACE inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin II receptor antagonists such as losartan or any water tablets (diuretics)
- digoxin or quinidine used to treat heart problems
- ciclosporin or tacrolimus used after a transplant
- potassium sparing diuretics such as amiloride or spironolactone
- phenytoin used to treat epilepsy
- probenecid and sulfinpyrazone used to treat gout
- zidovudine used to treat HIV
- sulphonylureas such as gliclazide or glimepiride used to treat diabetes
- quinolone antibiotics such as ciprofloxacin
- ginkgo biloba
- antacids
- mifepristone used in pregnancy terminations
- corticosteroids (a type of anti-inflammatory medicine) such as hydrocortisone
- aminoglycosides such as gentamicin or amikacin
- furazolidone, an anti-bacterial
- guanethidine, reserpine or methyldopa.

Tell your doctor you are taking Advil Cold & Flu Relief if you need to have an anaesthetic before an operation or procedure. Your doctor will ask you to stop taking Advil Cold & Flu Relief a few days before your anaesthetic. You should also tell your anaesthetist (the doctor giving you the anaesthetic) you have been taking Advil Cold & Flu Relief.

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

Advil Cold & Flu Relief with alcohol

Do not drink alcohol while you are taking Advil Cold & Flu Relief.

Pregnancy and breast-feeding

- Do not take Advil Cold & Flu Relief if you are pregnant or breast-feeding.
- 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.

Fertility

Ibuprofen may affect a woman's ability to become pregnant. This effect is reversed once treatment with ibuprofen is stopped.

It is unlikely that ibuprofen, if used occasionally, will affect your chances of becoming pregnant. Talk to your doctor before taking this medicine if you have had problems becoming pregnant in the past.

Driving and using machines

After taking Advil Cold & Flu Relief you may feel dizzy, have unusual headaches, or problems with your sight or hearing, including seeing or hearing things that are not there (hallucinations). If this happens, do not drive, cycle or use any tools or machines.

Advil Cold & Flu Relief contains sorbitol (E 420),

Advil Cold & Flu Relief contains 64.1 mg sorbitol (E 420) in each capsule which is equivalent to 69.7 mg/g.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine

3. How to take Advil Cold & Flu Relief

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children over 12 years of age:

How much to take

- The recommended dose is 1 capsule every 4 to 6 hours.
- If your symptoms are more severe you can take 2 capsules at the same time.
- Do not take more than 6 capsules in 24 hours.

Taking this medicine

Swallow the capsules whole with a large glass of water

How long to take this medicine for

Do not take this medicine for more than 5 days.

- This medicine is for short term use only, take the lowest dose for the shortest time necessary to relieve your symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).
- You must talk to a doctor if you do not feel better or if you feel worse or if you get any new symptoms. They will tell you if it is safe to carry on taking this medicine.

If you take more Advil Cold & Flu Relief 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.

Take the medicine pack with you.

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.

Do not continue to take Advil Cold & Flu Relief if you accidentally take more than you should (overdose).

If you forget to take Advil Cold & Flu Relief

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

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

4. Possible side effects

Like all medicines, Advil Cold & Flu Relief can cause side effects, although not everybody gets them. The chance of getting side effects can be lowered by taking the lowest dose for the shortest time necessary to treat your symptoms.

The following side effects may happen with this medicine:

Stop taking Advil Cold & Flu Relief straight away and tell your doctor or pharmacist if you notice any of the following side effects:

Common: may affect up to 1 in 10 people

- feeling sick (nausea)
- bleeding from the stomach or bowel, signs include vomiting blood, blood in faeces, or black coloured faeces.

Uncommon: may affect up to 1 in 100 people

- severe headaches or headaches that are more painful than usual.

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

- heart attack
- fast heartbeat or palpitations
- allergic reaction to Advil Cold & Flu Relief, signs include skin rash, hives, itching, difficulty breathing, tightness in the chest, swelling of the mouth, face, lips or tongue
- blistering lesions on the skin or mucous membranes such as the inside of your mouth, signs include burning feeling, with redness, blisters and ulcers.

Not Known: it is not known how often these happen

- stroke
- behavioural problems such as feeling excited, agitated, anxious, restless or nervous
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 & Flu Relief, if you develop these symptoms and seek medical attention immediately. See also section 2
- Inflammation of the colon due to insufficient blood supply (ischemic colitis).
- Reduced blood flow to the optic nerve (ischaemic optic neuropathy).

Stop taking Advil Cold & Flu Relief straight away and tell your doctor or pharmacist if you notice any of the side effects listed above.

Other side effects

Tell your doctor or pharmacist if you get any of the following side effects:

Common: may affect up to 1 in 10 people

- indigestion, stomach ache, being sick (vomiting), diarrhoea, constipation, wind.

Uncommon: may affect up to 1 in 100 people

- stomach ulcer
- not being able to sleep

- feeling drowsy or tired
- feeling dizzy or irritable
- problems with your sight
- headaches that do not go away
- breakouts on the skin such as rash or itching
- inflamed stomach or bowel, worsening of existing inflammatory bowel disease
- hypersensitivity such as wheezing and difficulty breathing in patients who have ever had bronchial asthma or allergic disease.

Rare: may affect up to 1 in 1,000 people

- kidney problems
- ringing in your ears (tinnitus).

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

- depression
- heart failure
- kidney failure
- high blood pressure
- sore or inflamed mouth
- inflamed pancreas (pancreatitis)
- narrowing of the gut (intestinal stricture)
- aseptic meningitis, worsening of infectious inflammations
- problems with your blood cells – you may be more likely to bruise or get infections
- liver problems including abnormal liver function, hepatitis or jaundice (yellowing of the skin or eyes).

Not Known: it is not known how often these happen

- chest pain
- dry mouth, feeling thirsty
- abnormal spasm, seizures
- spinning sensation (vertigo)
- haematocrit levels decreased and haemoglobin decreased
- seeing or hearing things that are not there (hallucinations)
- skin rash, red or purple skin discolouration, fluid retention (oedema)
- skin becomes sensitive to light
- passing urine less often, blood or protein in your urine (shown in tests)
- 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).

Tell your doctor or pharmacist if you get any of the side effects listed above.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any 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; E-mail: 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 Relief

- 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 box and blister pack after EXP. The expiry date refers to the last day of that 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 Relief contains

- The active substances are ibuprofen 200 mg and pseudoephedrine hydrochloride 30 mg
- The other ingredients are:
 - Liquid fill: potassium hydroxide, macrogol 600, purified water
 - Gelatine capsule: sorbitol (E420), gelatine, black printing ink [Macrogol 400, polyvinyl acetate phthalate, propylene glycol, iron oxide black (E172)]
 - Processing aids: soya lecithin in triglycerides, medium chain.

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

Advil Cold & Flu Relief is a clear oval shaped, soft capsule. It is imprinted with 200/30 logo in black ink.

Advil Cold & Flu Relief is available from your pharmacist in white, opaque, PVC/PE/PVdC or PVC/PVdC heat sealed Glassine/Aluminium foil blister strips of 2, 4, 8, 10, 12, 16, 20 or 24 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

GlaxoSmithKline Consumer Healthcare (Ireland) Limited, 12 Riverwalk, CityWest Business Campus, Dublin 24, Ireland.

Manufacturer

Pfizer Consumer Manufacturing Italy Srl
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This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland: Advil Cold & Flu Relief Soft Capsules Ibuprofen 200 mg / Pseudoephedrine hydrochloride 30 mg

Romania: Advil Răceală și Gripă 200 mg/30 mg capsule moi

Slovakia: Robicold Rapid 200mg/30mg mäkké kapsuly

Malta: Advil Cold & Flu Relief Soft Capsules Ibuprofen 200 mg / Pseudoephedrine 30 mg

Hungary: Advil Cold Rapid 200 mg/30 mg lágy kapszula

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