

PATIENT MEDICATION INFORMATION

Advil

Cold, Sinus & Flu Extra Strength

Ibuprofen, Pseudoephedrine Hydrochloride and Chlorpheniramine Maleate Caplets

HALEON

Read this carefully before you start taking Advil Cold, Sinus & Flu Extra Strength and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Advil Cold, Sinus & Flu Extra Strength.

Serious Warnings and Precautions

- If you have diabetes, glaucoma or difficulty in urination due to an enlarged prostate, do not take this drug unless directed by a doctor.
- Use with caution in those with heart failure, high blood pressure or other conditions that may cause excess fluid collecting in tissues.
- Use with caution in patients at risk of gastrointestinal tract irritation, including those with a history of peptic ulcer, diverticulosis, or other inflammatory disease of the gastrointestinal tract such as ulcerative colitis or Crohn's disease. Symptoms may include feeling faint, vomiting blood, bloody or black stools. The chance of stomach bleeding is higher if you are: age 60 or older, have had stomach ulcers or bleeding problems, take a blood thinner or steroid drug, take with other drugs containing an NSAID like acetylsalicylic acid (ASA), ibuprofen, naproxen, or prescription anti-inflammatory drugs, or have 3 or more alcoholic drinks every day while using this product.
- Use with caution in patients at risk of kidney problems, such as those with heart failure, liver disease, the elderly or those using diuretics.
- Advil Cold, Sinus & Flu Extra Strength should not be used during the third trimester of pregnancy.
- Talk to your doctor if you are trying to conceive, in your first or second trimester of pregnancy or if breastfeeding.
- Stop use immediately if you observe blood in the urine or you develop urgent, frequent, painful or difficult urination.

What is Advil Cold, Sinus & Flu Extra Strength used for?

• Fast, temporary relief of the combined symptoms associated with colds and flu including: stuffy nose, fever, minor body aches, sore throat, headache, runny nose, sneezing, itchy, watery eyes and sinus pain.

How does Advil Cold, Sinus & Flu Extra Strength work?

Ibuprofen reduces pain and fever. Pseudoephedrine hydrochloride is a nasal decongestant. Chlorpheniramine maleate is an antihistamine.

What are the ingredients in Advil Cold, Sinus & Flu Extra Strength?

Medicinal ingredients: ibuprofen, pseudoephedrine hydrochloride and chlorpheniramine maleate.

Non-medicinal ingredients: Carnauba wax, corn starch, croscarmellose sodium, glyceryl behenate, hypromellose, iron oxide black, iron oxide yellow, microcrystalline cellulose, polydextrose, pre-gelatinized starch, propylene glycol, silicon dioxide, and titanium dioxide.

Advil Cold, Sinus & Flu Extra Strength comes in the following dosage forms:

Each caplet contains ibuprofen 400 mg, pseudoephedrine hydrochloride 60 mg and chlorpheniramine maleate 4 mg.

Do not use Advil Cold, Sinus & Flu Extra Strength if you have or are:

- allergic/hypersensitive to acetylsalicylic acid (ASA), ibuprofen, other salicylates, other NSAIDs, pseudoephedrine or other sympathomimetic amines, chlorpheniramine maleate or any of the ingredients in Advil Cold, Sinus & Flu Extra Strength (Refer to the non-medicinal ingredients section of this insert)
- active or recurrent stomach ulcer or gastrointestinal (GI) bleeding or active inflammatory bowel disease (e.g. Crohn's, colitis)
- taking a monoamine oxidase inhibitor (MAOI); e.g. drugs for depression or Parkinson's disease) or for 14 days after stopping the MAOI drug, ASA or other NSAIDs including any other ibuprofen product
- nasal polyps (swelling of the inside of the nose)
- asthma
- allergic manifestations such as anaphylaxis (sudden severe life-threatening allergic reaction) urticaria/hives, rhinitis (stuffed or runny nose that may be due to allergies), skin rash or other allergic symptoms
- dehydrated (significant fluid loss) due to vomiting, diarrhea or lack of fluid intake
- been diagnosed with severe high blood pressure or have heart disease
- right before or after heart surgery
- serious liver disease
- severe kidney disease
- high potassium in the blood
- thyroid disease
- Raynaud's Syndrome (a disorder of the circulatory system)
- Systemic Lupus Erythematosus
- in your third trimester of pregnancy.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Advil Cold, Sinus & Flu Extra Strength. Talk about any health conditions or problems you may have, including if you have or are:

- blood clotting disorder (such as hemophilia)
- breathing problems or chronic lung disease (such as asthma, emphysema or chronic bronchitis)
- diabetes
- difficulty in urination due to prostate enlargement or bladder neck obstruction
- glaucoma
- high blood pressure
- mild to moderate kidney disease
- mild to moderate liver disease
- any other serious disease
- under doctor's care for any serious condition
- Trying to conceive, pregnant or breastfeeding
- At 20 weeks or later in pregnancy, your use of NSAIDs may need to be monitored by a doctor due to the rare risk of kidney problems in the unborn baby which may result in decreased amniotic fluid volume and other complications
- taking sedatives or tranquilizers (as they may increase drowsiness), or any other drug including over the counter drugs
- Use with caution in the elderly
- Long-term continuous use may increase the risk of heart attack or stroke.

Other warnings you should know about:

- The use of NSAIDs, like Advil Cold, Sinus & Flu Extra Strength, in the second trimester of pregnancy should be restricted to the lowest dose necessary for the shortest possible duration
- Do not smoke or drink alcohol while using this product. Alcohol may increase drowsiness.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Advil Cold, Sinus & Flu Extra Strength:

- acetaminophen
- acetylsalicylic acid (ASA)
- allergy medications
- anticoagulants (blood thinning medications)
- antidepressants
- anti-hypertensives (blood pressure medications)
- antibiotics (levofloxacin and quinolone)
- benzodiazepines
- cold medications
- corticosteroids
- cyclosporine
- CYP2C9 inhibitors (fluconazole and voriconazole)
- diabetes medication (including insulin and oral antidiabetic agents)
- digoxin
- diuretics (water pills)
- lithium
- methotrexate
- monoamine oxidase inhibitors
- nonsteroidal anti-inflammatory drugs (NSAIDs); including naproxen and ibuprofen
- phenytoin
- probenecid
- thyroxine
- tranquilizers or other sedating drugs
- zidovudine.

How to take Advil Cold, Sinus & Flu Extra Strength:

Usual dose:

- Adults and children 12 to 65 years: Take 1 caplet every 4- 6 hours as needed. Do not exceed 3 caplets in 24 hours, unless directed by a doctor.
- Do not give to children under 12.

Overdose:

If you think you, or a person you are caring for, have taken too much Advil Cold, Sinus & Flu Extra Strength, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Continue to take 1 caplet every 4-6 hours as needed after a missed dose. Do not take twice the recommended dose following a missed dose.

What are possible side effects from using Advil Cold, Sinus & Flu Extra Strength?

Stop use and ask a doctor if

- you show signs of stomach bleeding
- sore throat pain lasts more than 2 days
- symptoms worsen or last more than 5 days
- fever lasts more than 3 days
- you are nervous, dizzy or can't sleep
- any new symptoms appear.

These are not all the possible side effects you may have when taking Advil Cold, Sinus & Flu Extra Strength. If you experience any side effects not listed here, tell your healthcare professional.

Take with food or milk if upset stomach occurs.

Advil Cold, Sinus & Flu Extra Strength may occasionally produce unwanted side effects, such as heartburn, constipation, nausea, bloating, dry mouth, nervousness or sleeplessness. Stop use and contact a healthcare professional if these symptoms worsen or persist.

This product may cause drowsiness. Be careful when driving motor vehicles or operating heavy machinery.

The risk of having side effects may be decreased by using the smallest dose for the shortest duration of time.

| Serious side effects and what to do about them | | | |
|--|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| UNCOMMON | | | |
| Sudden severe headache accompanied by confusion, seizures, vomiting sensation or changes in vision. These may be signs of a serious condition. | | | ✓ |
| Symptoms of allergic reaction, including rash, severe itching/redness, blisters, swelling, or trouble breathing | | | ✓ |
| Blood in vomit, bloody or black stools | | | ✓ |
| Abdominal pain, vomiting, diarrhea | | ✓ | |
| Ringing or buzzing in the ears / dizziness | | ✓ | |
| Change in vision | | ✓ | |
| Fluid retention | | ✓ | |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature (15 to 30°C).

Keep out of reach and sight of children. This package contains enough medicine to seriously harm a child.

If you want more information about Advil Cold, Sinus & Flu Extra Strength:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); or by contacting the sponsor at www.advil.ca or by calling 1-888-788-8181.

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This leaflet was prepared by Haleon Canada ULC.

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