

PATIENT MEDICATION INFORMATION

# Advil Cold and Sinus

## Ibuprofen and Pseudoephedrine Hydrochloride Tablets USP

Read this carefully before you start taking **Advil Cold and Sinus** 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 and Sinus**.

### Serious Warnings and Precautions

- If you have 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. 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 and Sinus should not be used during the third trimester of pregnancy.
- Use during the first and second trimesters of pregnancy or nursing should be avoided unless directed by your health care professional.
- Stop use immediately if you observe blood in the urine or you develop urgent, frequent, painful or difficult urination.

### What is Advil Cold and Sinus used for?

- Fast, temporary relief of the symptoms of colds including sore throat pain, sinus pain, nasal congestion, headache, fever, body aches and pains.

### How does Advil Cold and Sinus work?

Ibuprofen reduces pain and fever. Pseudoephedrine hydrochloride is a nasal decongestant.

### What are the ingredients in Advil Cold and Sinus?

Medicinal ingredients: Ibuprofen and pseudoephedrine hydrochloride.

Non-medicinal ingredients: acetylated monoglycerides, carnauba wax, corn starch, croscarmellose sodium, iron oxides, microcrystalline cellulose, parabens, pharmaceutical ink, povidone, pregelatinized starch, shellac, silicon dioxide, sodium benzoate, sodium lauryl sulfate, stearic acid, sucrose, titanium dioxide.

### Advil Cold and Sinus comes in the following dosage forms:

Each caplet contains ibuprofen 200 mg and pseudoephedrine hydrochloride 30 mg.

### Do not use Advil Cold and Sinus if you have or are:

- allergic/hypersensitive to acetylsalicylic acid (ASA), ibuprofen, other salicylates, other NSAIDs, pseudoephedrine or other sympathomimetic amines or any of the ingredients in Advil Cold and Sinus (Refer to the nonmedicinal 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
- 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 and Sinus. 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 chronic bronchitis)
- diabetes
- difficulty in urination due to prostate enlargement
- 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, in your first or second trimester of pregnancy or if you are breastfeeding
- in the second trimester of pregnancy, your use of NSAIDs, like Advil products, may need to be monitored by a health care practitioner due to the rare risk of kidney problems in the unborn baby which may result in decreased amniotic fluid volume and other complications
- taking medication for weight control
- taking any other drug including over the counter drugs

### Other warnings you should know about:

Do not smoke or drink alcohol while using this product.

### 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 and Sinus:

- acetaminophen
- acetylsalicylic acid (ASA)
- allergy medications
- anticoagulants (blood thinning medications)
- selective serotonin reuptake inhibitors (SSRIs) used to treat depression
- anti-hypertensives (blood pressure medications)
- antibiotics (levofloxacin)
- benzodiazepines
- cold medications
- corticosteroids
- cyclosporine
- 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

### How to take Advil Cold and Sinus:

#### Usual dose:

- Adults and children 12 to 65 years: Take 1 or 2 caplets every 4- 6 hours as needed. Do not exceed 6 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 and Sinus, 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 or 2 caplets 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 and Sinus?

#### 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 and Sinus. If you experience any side effects not listed here, tell your healthcare professional.

Take with food or milk if upset stomach occurs.

Advil Cold and Sinus may occasionally produce unwanted side effects, such as heartburn, constipation, nausea, bloating, nervousness or sleeplessness. Stop use and contact a healthcare professional if these symptoms worsen or persist. 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	
<b>UNCOMMON</b>			
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;
- 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 and Sinus:

- 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](http://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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