

PART III: CONSUMER INFORMATION

Advil® Cold & Sinus Plus Ibuprofen, Pseudoephedrine Hydrochloride and Chlorpheniramine Maleate Caplets

This leaflet is part III of a three-part "Product Monograph" published when Advil® Cold & Sinus Plus was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Advil® Cold & Sinus Plus. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Temporarily relieves the combined symptoms associated with colds including: stuffy nose, fever, minor body aches, sore throat, headache, runny nose, sneezing, itchy, watery eyes and sinus pain.

What it does:

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

When it should not be used:

Do not use Advil® Cold & Sinus Plus if you have or are:

- 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. drug for depression or Parkinson's disease) or for 14 days after stopping the MAOI drug, acetylsalicylic acid (ASA), or other non-steroidal anti-inflammatory drugs (NSAIDs) including any other ibuprofen product,
- allergic/hypersensitive to ASA, ibuprofen, other salicylates, other NSAIDs, pseudoephedrine or other sympathomimetic amines, chlorpheniramine maleate, or any of Advil® Cold & Sinus Plus's ingredients (Refer to the nonmedicinal ingredients section of this insert),
- 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,
- about to have or just had heart surgery,
- serious liver disease,
- severe kidney disease,
- thyroid disease,
- Raynaud's Syndrome (a disorder of the circulatory system),
- Systemic Lupus Erythematosus,
- Pregnant or nursing.

What the medicinal ingredients are:

Ibuprofen, pseudoephedrine hydrochloride and chlorpheniramine maleate.

What the important nonmedicinal ingredients are:

Carnauba wax, corn starch, croscarmellose sodium, FD&C red no. 40, FD&C yellow no. 6, glyceryl behenate, hypromellose, iron oxide black, microcrystalline cellulose, polydextrose, polyethylene glycol, pre-gelatinized starch, propylene glycol, silicon dioxide, and titanium dioxide.

What dosage forms it comes in:

Each caplet contains ibuprofen 200mg, pseudoephedrine hydrochloride 30mg and chlorpheniramine maleate 2mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- **Caution in patients at risk of gastrointestinal tract irritation.**
- **Patients at risk of kidney problems, including the elderly or those using diuretics.**
- **Use during pregnancy or nursing should be avoided.**
- **Stop use immediately if you have difficulty or pain when urinating.**

BEFORE you use Advil® Cold & Sinus Plus talk to your doctor or pharmacist 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, are under doctor's care for any serious condition
- taking sedatives or tranquilizers (as they may increase drowsiness), or any other drug including over the counter drugs.

INTERACTIONS WITH THIS MEDICATION

Do not use this product if you are taking:

- a MAOI or if you have stopped taking one within the past 2 weeks.
- Daily low dose ASA (81 – 325 mg), without talking to a doctor or pharmacist. Ibuprofen may interfere with the preventative benefits of ASA.
- other anti-inflammatory medication.

Drugs that may interact with Advil Cold & Sinus Plus include:

- Acetaminophen
- Acetylsalicylic acid (ASA)
- Allergy medications
- Anticoagulants (blood thinning medications)
- Anti-depressants
- Anti-hypertensives (blood pressure medications)
- Antibiotics (levofloxacin)
- Benzodiazapines
- 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
- Tranquilizers or other sedating drugs

Tell your doctor or pharmacist what prescription or non-prescription drugs you are taking or plan to take.

Do not smoke or drink alcohol while using this product. Alcohol may increase drowsiness.

PROPER USE OF THIS MEDICATION

Usual dose:

Adults and children over 12-65 years old: Take 1 or 2 caplets every 4 to 6 hours as needed. Do not exceed six caplets in 24 hours, unless directed by a physician.

Do not give to children under 12 unless directed by a physician. Do not use longer than 3 days for a fever or 5 days for pain relief or cold symptoms.

Overdose:

In case of accidental overdose, call a Poison Control Centre or a doctor 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Advil® Cold & Sinus Plus may cause drowsiness. Do not drive or engage in activities requiring alertness.

This product may occasionally produce unwanted side effects, such as heartburn, constipation, nausea, bloating, dry mouth, nervousness or sleeplessness.

Stop use and contact a doctor or pharmacist 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, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Seek immediate emergency medical assistance
		Only if severe	In all cases	
Uncommon	Symptoms of allergic reaction, including: rash, severe itching/ redness, blisters, swelling, or trouble breathing			T
	Blood in vomit, bloody or black stools			T
	Abdominal pain, vomiting, diarrhea		T	
	Ringing or buzzing in the ears / dizziness		T	
	Change in vision,		T	
	Fluid retention		T	

This is not a complete list of side effects. For any unexpected effects while taking Advil® Cold & Sinus Plus, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature (15°-30°C).

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

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>).

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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Pfizer Consumer Healthcare, a division of Pfizer Canada Inc., Mississauga, Ontario L5R 4B2 at: 1-888-275-9938.

This leaflet was prepared by Pfizer Consumer Healthcare Inc.

Product monograph available to physicians and pharmacists upon request.

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