

PART III: CONSUMER INFORMATION

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

This leaflet is part III of a three-part "Product Monograph" published when Advil® Cold & Sinus Nighttime 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 Nighttime. 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: runny nose, sneezing, itchy watery eyes, headache, nasal congestion, minor aches and pains, sore throat, 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 Nighttime if you have or are:

- allergic/hypersensitive to acetylsalicylic acid (ASA), ibuprofen, other salicylates, other non-steroidal anti-inflammatory drugs (NSAIDs), pseudoephedrine or other sympathomimetic amines, chlorpheniramine maleate, or any of Advil® Cold & Sinus Nighttime's ingredients (Refer to the nonmedicinal ingredients section of this insert),
- peptic ulcer disease or gastrointestinal bleeding,
- taking a monoamine oxidase inhibitor (MAOI) 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,
- 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

- **If you have diabetes, glaucoma or difficulty in urination due to an enlarged prostate, do not take this drug unless directed by a physician.**
- **Caution in those with heart failure, high blood pressure or other conditions predisposing to fluid retention.**
- **Caution in those prone to gastrointestinal tract irritation, diverticulosis, or other inflammatory disease of the gastrointestinal tract such as ulcerative colitis or Crohn's disease.**
- **Caution in those at risk of kidney or liver problems, those taking diuretics and the elderly.**
- § **Stop use immediately if you have difficulty or pain when urinating.**

BEFORE you use Advil® Cold & Sinus Nighttime 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,
- 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.
- ASA or other anti-inflammatory medication.

Drugs that may interact with Advil® Cold & Sinus Nighttime 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 overdose, contact a doctor, 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 to 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 Nighttime 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 product may cause drowsiness. Be careful when driving motor vehicles or operating heavy machinery.

This is not a complete list of side effects. For any unexpected effects while taking Advil® Cold & Sinus Nighttime, 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 SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

Note: Should you require information related to the management of side effects, contact your health professional.

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 L4Z 3M6 at: 1-888-275-9938.

This leaflet was prepared by Pfizer Consumer Healthcare, a division of Pfizer Canada Inc.

Product monograph available to physicians and pharmacists upon request.

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