

PART III: CONSUMER INFORMATION

**Children’s Advil® Cold & Flu Multi-symptom
Ibuprofen, Pseudoephedrine Hydrochloride and
Chlorpheniramine Maleate Suspension**

This leaflet is part III of a three-part "Product Monograph" published when Children’s Advil® Cold & Flu Multi-symptom was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Children’s Advil® Cold & Flu Multi-symptom. 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 cold and flu: stuffy nose, fever, 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 Children’s Advil® Cold & Flu Multi-symptom if your child has or is:

- 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 Children’s Advil® Cold & Flu Multi-symptom’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,

What the medicinal ingredients are:

Ibuprofen, pseudoephedrine hydrochloride and chlorpheniramine maleate.

What the important nonmedicinal ingredients are:

Carboxymethylcellulose sodium, citric acid, edetate disodium, FD&C red no. 40, flavour, glycerin, microcrystalline cellulose, polysorbate 80, purified water, sodium citrate, sodium benzoate, sorbitol, sucralose, xanthan gum. Children’s Advil Cold & Flu Multi-symptom berry flavour also contains FD&C blue no. 1.

What dosage forms it comes in:

Each 5 mL or 1 teaspoon of oral suspension contains ibuprofen 100 mg, pseudoephedrine hydrochloride 15 mg and chlorpheniramine maleate 1 mg.

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.**
- **Stop use immediately if child has difficulty or pain when urinating.**

BEFORE you use Children’s Advil® Cold & Flu Multi-symptom talk to your doctor or pharmacist if your child has or is:

- blood clotting disorder (such as hemophilia)
- breathing problems or chronic lung disease (such as chronic bronchitis)
- diabetes,
- difficulty in urination
- 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 your child is taking:

- a MAOI or if your child has stopped taking one within the past 2 weeks.
- ASA or other anti-inflammatory medication.

Drugs that may interact with Children's Advil® Cold & Flu Multi-symptom 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 other non-prescription drugs your child is taking or planning to take.

PROPER USE OF THIS MEDICATION

Usual dose:

Shake well before use. Use only the measuring device provided. Doses below may be repeated every 6 hours while symptoms persist, up to 4 doses per day, or as directed by a doctor. If possible use weight to dose,

Age	Weight (approx.)	Single Dose	
		mL	teaspoons
Under 6 years		DO NOT USE	
6-11 years	21.4-43.0 kg/48.95 lbs	10 mL	2 teaspoons

otherwise use age.

Do not exceed the recommended dose unless directed by a physician. Do not use longer than 3 days for a fever or 5 days for pain relief or cold/flu symptoms.

Overdose:

In case of accidental overdose, call a Poison Control Centre or a doctor immediately, even if there are no symptoms.

Missed Dose:

- Take the missed dose as soon as you remember.
- Do not take twice the recommended dose following a missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Children's Advil® Cold & Flu Multi-symptom may occasionally produce unwanted side effects, such as heartburn, constipation, nausea, bloating, dry mouth, nervousness or sleeplessness.

May cause drowsiness or excitability. Do not use when child is engaged in activities requiring mental alertness.

Stop use and contact a doctor or pharmacist if these symptoms worsen or persist.

Consult your physician if:

- Your child does not get any relief within 24 hours.
- Redness or swelling is present in the painful area.
- Cold or flu symptoms do not improve within 3 days.
- Symptoms worsen, last for more than a week or are accompanied by a high fever (>38°C) or the production of thick yellow/green

- phlegm.
- Sore throat is severe, lasts for more than 2 days or occurs with a fever or headache.

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 Children's Advil® Cold & Flu Multi-symptom, 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.

This package has a child resistant cap. Do not use if breakable ring is separated or missing.

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, ON L5R 4B2 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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