

## Children's Advil® Cold

### Ibuprofen and Pseudoephedrine Hydrochloride Suspension

This leaflet is part III of a three-part "Product Monograph" published when Children's Advil Cold 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. Contact your doctor or pharmacist if you have any questions about the drug.

#### ABOUT THIS MEDICATION

##### What the medication is used for:

The temporary relief of symptoms of colds, including stuffy nose, fever, body aches, sore throat pain, headache, and nasal and sinus congestion.

##### What it does:

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

##### When it should not be used:

Do not use Children's Advil Cold if your child has or is:

- allergic/hypersensitive to ibuprofen, acetylsalicylic acid (ASA), other salicylates, other nonsteroidal anti-inflammatory drugs (NSAIDs), pseudoephedrine or other sympathomimetic amines, or any of Children's Advil Cold's ingredients (Refer to the nonmedicinal ingredients section of this insert),
- active or recurrent stomach ulcer or gastrointestinal 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,
- 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 and pseudoephedrine hydrochloride.

##### What the important nonmedicinal ingredients are:

artificial grape flavour, carboxymethylcellulose sodium, citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, glycerin, microcrystalline cellulose, polysorbate 80, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum.

##### What dosage forms it comes in:

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

#### 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 talk to your doctor or pharmacist if your child has:

- 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, is under doctor's care for any serious condition, or is taking 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 or pain medication.

Drugs that may interact with Children's Advil Cold include:

- Acetaminophen

- Acetylsalicylic acid (ASA)
- Allergy medications
- Anticoagulants (blood thinning medications)
- Antidepressants
- 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

Tell your doctor or pharmacist what prescription or non-prescription drugs your child is taking or is 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 6 hours while symptoms persist, up to 4 doses a day, or as directed by a doctor. If possible, use weight to dose; otherwise use age.

Age	Weight (approx.)	Single Dose	
		mL	teaspoons
Under 6 years		DO NOT USE	
6-12 yrs.	21.4-43.0 kg/48.95 lbs	10 mL	2 tsp.

Do not exceed the recommended dose unless directed by a doctor. Do not use longer than 3 days for a fever or 5 days for cold symptoms.

**Overdose:**

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

**Missed Dose:**

Give your child the missed dose as soon as you remember. Do not give twice the recommended dose following a missed dose.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Children’s Advil Cold may occasionally produce unwanted side effects, such as heartburn, constipation, nausea, bloating, nervousness or sleeplessness.

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

Talk to your doctor if:

- § Your child does not get any relief within 24 hours.
- § Redness or swelling is present in the painful area.
- § Sore throat is severe, last for more than 2 days or occurs with fever or headache.
- § Cold symptoms do not improve within 3 days.
- § Symptoms worsen or are accompanied by a high fever (>38°C) or the production of thick yellow/green phlegm.

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, contact your doctor or pharmacist.*

**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.*

**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.

**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 L4Z 3M6, at: 1-888- 275-9938 or [www.advil.ca](http://www.advil.ca).

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

Product monograph available to doctors and pharmacists upon request.

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