

PATIENT MEDICATION INFORMATION

**Children's Advil Cold**

**Ibuprofen and Pseudoephedrine Hydrochloride Suspension**

Read this carefully before you start taking Children's Advil Cold 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 child's medical condition and treatment and ask if there is any new information about Children's Advil Cold.

**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.
- Children's Advil Cold should not be used during the third trimester of pregnancy.
- Use during the first and second trimesters of pregnancy or nursing should be avoided.
- Stop use immediately if you observe blood in the urine or your child develops urgent, frequent, painful or difficult urination.

**What is Children's Advil Cold used for?**

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

**How does Children's Advil Cold work?**

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

**What are the ingredients in Children's Advil Cold?**

Medicinal ingredients: ibuprofen and pseudoephedrine hydrochloride.  
Non-medicinal ingredients: 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.

**Children's Advil Cold comes in the following dosage forms:**

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

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

- allergic/hypersensitive to ibuprofen, acetylsalicylic acid (ASA), other salicylates, other NSAIDs, pseudoephedrine or other sympathomimetic amines, or any of the ingredients in Children's Advil Cold (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
- 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 the third trimester of pregnancy

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Children's Advil Cold. Talk about any health conditions or problems your child may have, including 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
- under doctor's care for any serious condition
- trying to conceive, in the first or second trimester of pregnancy or breastfeeding
- taking medication for weight control
- taking any other drug, including over the counter drugs

**Tell your healthcare professional about all the medicines your child takes, including any drugs, vitamins, minerals, natural supplements or alternative medicines. The following may interact with Children's Advil Cold:**

- acetaminophen
- acetylsalicylic acid (ASA)
- allergy medications
- anticoagulants (blood thinning medications)
- antidepressants
- 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
- throxine

**How to take Children's Advil Cold:**

**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 a day, or as directed by a doctor. If possible, use weight to dose; otherwise use age.

Weight	Age	Dosage
--	Under 6 years	DO NOT USE
21.4 – 43.0 kg / 48 – 95 lbs	6 – 12 years	10 mL = 2 teaspoons

- Do not exceed the recommended dose unless directed by a doctor.

**Overdose:**

If you think you, or a person you are caring for, have taken too much Children's Advil Cold, contact a healthcare professional, hospital emergency department, or regional poison control centre 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.

**What are possible side effects from using Children's Advil Cold?**

These are not all the possible side effects your child may have when taking Children's Advil Cold. If your child experiences any side effects not listed here, tell your healthcare professional.

Give with food or milk if upset stomach occurs.

Children's Advil Cold 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.

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, lasts for more than 2 days or occurs with a 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
- Your child shows signs of stomach bleeding
- Your child is nervous, dizzy or can't sleep
- Your child develops sudden severe headache accompanied by vomiting sensation, confusion, seizures or changes in vision. These may be signs of a serious condition.

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>			
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 your child has a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your child's 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. This package has a child-resistant cap. Do not use if breakable ring is separated or missing.

**If you want more information about Children's Advil Cold:**

- 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 1-888-275-9938.

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