

PART III: CONSUMER INFORMATION

Children's Advil®

Ibuprofen Oral Suspension USP

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

ABOUT THIS MEDICATION

What the medication is used for:

Provides up to 8 hours relief of children's fever. Relieves pain and fever due to colds or flu, sore throat, immunization, and earache.

What it does:

Ibuprofen reduces pain and fever.

Ibuprofen belongs to the class of non-steroidal anti-inflammatory drugs (NSAIDs), which act by decreasing prostaglandin biosynthesis, which are natural occurring substances in the body involved in the production of pain and inflammation. Relief from pain may be expected in 0.5 hour.

When it should not be used:

- Do not use Children's Advil if your child has or is:
 - peptic ulcer disease or gastrointestinal bleeding,
 - taking acetylsalicylic acid (ASA), or any other non-steroidal anti-inflammatory medication including any other ibuprofen product,
 - allergic/hypersensitive to ASA, ibuprofen, other salicylates, other non-steroidal anti-inflammatory drugs (NSAIDs) or any of Children's Advil's ingredients (Refer to the non-medical ingredients on outer carton or composition section),
 - nasal polyps (swelling of the inside of the nose), or allergic manifestations such as asthma, 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 severe coronary artery disease,
 - serious liver or kidney disease,
 - Systemic Lupus Erythematosus,
 - pregnant or nursing.

What the medicinal ingredient is:

Ibuprofen.

What the important non-medicinal ingredients are:

See outer product carton or composition section of product monograph.

What dosage forms it comes in:

Each 5 mL or 1 teaspoon of oral suspension contains ibuprofen 100 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- Caution in patients prone to gastrointestinal tract irritation, including those with a history of peptic ulcer.

BEFORE you use Children's Advil talk to your doctor or pharmacist if:

- Child has peptic ulcers, diabetes, high blood pressure, heart failure or thyroid disease, asthma, kidney or liver disease, glaucoma, blood clotting disorder (such as hemophilia), any other serious disease, are under doctor's care for any serious condition, or are taking any other drug including over the counter drugs.
- Pregnant or nursing.

Use with caution in the elderly.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with Children's Advil include: acetaminophen, anticoagulants (blood thinners), digoxin, oral antidiabetic agents and insulin, diuretics, methotrexate, lithium, protein-bound drugs including probenecid, thyroxine, antibiotics (e.g. cyclosporine), phenytoin, corticosteroids or benzodiazepines, other NSAIDs, or medications for high blood pressure. Tell your doctor or pharmacist what prescription drugs you are taking or plan to take.

PROPER USE OF THIS MEDICATION

Usual dose:

Shake well before using. Doses below may be repeated every 6-8 hours while symptoms persist, up to 3 doses a day, or as directed by a doctor. If possible use weight to dose; otherwise use age. Do not use longer than 3 days for a fever or 5 days for pain relief.

Do not use more than the recommended amount. Give with food or milk if stomach upset occurs.

Age (yrs.)	Weight		Dosage
	kg	lbs	
< 2	Under 10.9	< 23.8	Use Advil Pediatric Drops
2-3	10.9 – 15.9	24 – 35	1¼ teaspoons = 6 mL
4-5	16.0 – 21.3	36 – 47	2 teaspoons = 10 mL
6-8	21.4 – 26.7	48 – 59	2½ teaspoons = 12.5 mL
9-10	26.8 – 32.5	60 – 71	3 teaspoons = 15 mL
11-12	32.6 – 43.0	72 – 95	3¾ teaspoons = 19 mL

Children over 12 years of age and adults who have difficulty swallowing tablets may take up to 2-4 teaspoons (200-400 mg) every 4 hours as needed. Do not exceed 12 teaspoons (1200 mg/day).

Overdose:

In case of 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.
- If it is almost time for your next dose, wait until then to take your medicine and skip the missed dose.
- Do not take two doses at the same time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

If abdominal pain, heartburn, nausea or vomiting, bloating, diarrhea or constipation, ringing or buzzing in the ears, nervousness, sleeplessness, dizziness or any change in vision, fluid retention, itching, skin rashes, skin reddening, blisters, blood in vomit, bloody or black stools, or any other unexplained symptoms develop while taking Children's Advil, discontinue use immediately and contact a doctor.

Talk to a doctor if:

- Child does not get any relief within 24 hours.
- The symptoms or fever persist for more than 3 days.
- Redness or swelling is present in the painful area.
- Sore throat is severe, lasts for more than 2 days or occurs with fever or headache.

This is not a complete list of side effects. For any unexpected effects while taking Children's Advil, contact your doctor or pharmacist.

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 0701E
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.

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 body sleeve is broken 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

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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