



IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

Advil Cold & Flu
Ibuprofen and Diphenhydramine Citrate Caplets

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

ABOUT THIS MEDICATION

What the medication is used for:

Advil Cold & Flu is used for the temporary relief of the symptoms associated with colds and influenza (the "flu"):

- Body aches and pain
- Sore throat pain
- Fever
- Headache
- Runny nose
- Itchy watery eyes
- Sneezing

What it does:

Ibuprofen relieves pain and reduces fever. Diphenhydramine citrate, an antihistamine, relieves the cold and flu symptoms.

When it should not be used:

Do not use Advil Cold & Flu if you have or are:

- allergic/hypersensitive to ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs), acetylsalicylic acid (ASA) or other salicylates, diphenhydramine or to any ingredient in the formulation or component of the container, or any of Advil Cold & Flu ingredients (Refer to the nonmedicinal ingredients on outer carton or composition section), • active or recurrent stomach ulcer, gastrointestinal (GI) bleeding, or active inflammatory bowel disease (e.g. Crohn's, colitis), • 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, • serious liver or kidney disease, • high potassium in the blood
- taking any of the following medications:
 - acetaminophen
 - ASA
 - antihistamines and/or diphenhydramine containing products, (e.g. for cough & cold, sleep aids, etc.)
 - monoamine oxidase inhibitors (MAOIs)
 - NSAIDs such as naproxen and ibuprofen,
- dehydrated (significant fluid loss), due to vomiting, diarrhea or lack of fluid intake • heart problems, such as high blood pressure or severe coronary artery disease, • right before or after heart surgery, • System Lupus Erythematosus, • in your third trimester of pregnancy.

What the medicinal ingredients are:

Ibuprofen and diphenhydramine citrate

What the nonmedicinal ingredients are:

calcium stearate, carnauba wax, colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C blue #2, glyceryl behenate, hypromellose, lactose monohydrate, microcrystalline cellulose, polydextrose, pregelatinized starch, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide.

What dosage forms it comes in:

Each caplet contains ibuprofen 200 mg and diphenhydramine citrate 38 mg

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Caution in patients prone to gastrointestinal tract irritation including those with a history of peptic ulcer. 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 ASA, ibuprofen, naproxen, or prescription anti-inflammatory drugs, have 3 or more alcoholic drinks every day while using this product.

Patients at risk of kidney problems, including the elderly or those using diuretics.

Use during pregnancy or nursing should be avoided.

Stop use immediately if you have difficulty or pain when urinating.

May cause marked drowsiness.

BEFORE you use Advil Cold & Flu talk to your doctor or pharmacist if you have/have had or if you:

- previous or current stomach ulcers, diabetes, thyroid disease, mild to moderate kidney disease, mild to moderate liver disease, heart disease, glaucoma, breathing problems or chronic lung disease (such as asthma, emphysema or chronic bronchitis), blood clotting disorder (such as hemophilia), difficulty in urination due to prostate enlargement or bladder neck obstruction, any other serious condition, are taking any other prescription or over-the-counter drug, including any other anti-inflammatory medication
- are trying to conceive, are in your first or second trimester of pregnancy, are breastfeeding

Use with caution in the elderly.

Long-term continuous use may increase the risk of heart attack or stroke.

Avoid alcoholic beverages while taking this product.

Do not drive motor vehicle or operate machinery.

Consult a doctor if pain/fever lasts more than 3 days or if flu symptoms last more than 5 days.

INTERACTIONS WITH THIS MEDICATION

Do not use this product if you are taking:

- Daily low dose ASA (81 – 325 mg), without talking to a doctor or pharmacist. Ibuprofen may interfere with the preventive benefits of ASA.

Drugs that may interact with Advil Cold & Flu include:

- acetaminophen, anticoagulants (blood thinners), apomorphine, alcohol, digoxin, antidiabetic agents (oral) and insulin, diuretics, methotrexate, lithium, probenecid, thyroxine, antibiotics (e.g. cyclosporine), phenytoin, corticosteroids, benzodiazepines, blood pressure medications, depression medications, monoamine oxidase inhibitors (MAOIs), antihistamines (such as allergy medications), tranquilisers or other sedating drugs, NSAIDs (including naproxen and ibuprofen), sleep-aids, cold medications

Do not use a topically-applied diphenhydramine product at the same time as Advil Cold & Flu.

Tell your doctor or pharmacist what prescription drugs you are taking or plan to take.

PROPER USE OF THIS MEDICATION

Usual dose:

Children and Adults 16 to 65 years: Take 1 or 2 caplets every 6 hours as needed to a maximum of 6 caplets per day. Do not exceed the single or maximum recommended daily dosage.

Do not give to children under 16 or adults over 65 years old unless directed by a physician.

Do not use longer than 3 days for a fever or 5 days for pain or cold symptoms.

Overdose

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

Missed Dose:

Continue to take 1 or 2 caplets every 6 hours. Do not take twice the recommended dose following a missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Take with food or milk if upset stomach occurs.

If abdominal pain, heartburn, nausea or vomiting, bloating, diarrhea or constipation, ringing or buzzing in the ears, nervousness, sleeplessness, dizziness, any change in vision, fluid retention, shortness of breath, wheezing, any trouble breathing or chest tightness, hives, swelling or itching, skin rashes, skin reddening, blisters, blood in vomit, bloody or black stools, jaundice (yellowing of the eyes or skin due to liver problem), or any other side effect or unexplained symptoms develop while taking Advil Cold & Flu discontinue use immediately and contact a physician.

Side effects may be minimized by using the smallest dose for the shortest duration of time.

This is not a complete list of side effects. For any unexpected effects while taking Advil Cold & Flu, contact your doctor or pharmacist.

REPORTING SUSPECTED 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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- 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.

HOW TO STORE IT

Store at room temperature (15°-30°C) in a tightly closed container.

Keep out of reach of children. This package contains enough medicine to seriously harm a child.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, GlaxoSmithKline Consumer Healthcare ULC, Mississauga, ON L5R 4B2, at: 1-888-869-9384

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When it should not be used:

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- are trying to conceive, are in your first or second trimester of pregnancy, are breastfeeding

Use with caution in the elderly.

Long-term continuous use may increase the risk of heart attack or stroke.

Avoid alcoholic beverages while taking this product.

Do not drive motor vehicle or operate machinery.

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Do not use a topically-applied diphenhydramine product at the same time as Advil Cold & Flu.

Tell your doctor or pharmacist what prescription drugs you are taking or plan to take.

PROPER USE OF THIS MEDICATION

Usual dose:

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Overdose

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Missed Dose:

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SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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