

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 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 NSAIDs, 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)
- peptic ulcer, gastrointestinal disease or gastrointestinal bleeding
- serious liver or kidney disease
- nasal polyps (swelling of the inside of nose)
- asthma
- emphysema
- Allergic rhinitis (stuffed or runny nose that may be due to allergies)
- taking any of the following medications:
 - acetaminophen
 - acetylsalicylic acid (ASA)
 - antihistamines and or diphenhydramine containing products, (e.g. for cough & cold, sleep aids, etc.)
 - monoamine oxidase inhibitors (MAOIs)
 - non-steroidal anti-inflammatory drugs (NSAIDs), such as naproxen and ibuprofen
- dehydrated (significant fluid loss)
- heart problems, such as high blood pressure or severe

- coronary artery disease
- System Lupus Erythematosus
- pregnant or nursing

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

Patients prone to gastrointestinal tract irritation.
 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:

- diabetes
- thyroid disease
- mild to moderate kidney disease
- mild to moderate liver disease
- breathing problems or chronic lung disease (such as chronic bronchitis)
- blood clotting disorder (such as hemophilia)
- difficulty in urination due to prostate enlargement
- are taking any other prescription or over-the-counter drug, including any other anti-inflammatory medication

Avoid alcoholic beverages while taking this product.

Do not drive motor vehicle or operate machinery. Use with caution in the elderly.

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 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
- monamine 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:

Adults and children ≥16-≤65: Take 1 or 2 caplets every 6 hours 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

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, itching, skin rashes, skin reddening, blisters, blood in vomit, bloody or black stools, 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 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 0701D
Ottawa, Ontario
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) 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, Pfizer Consumer Healthcare, a division of Pfizer Canada Inc., Mississauga, Ontario L4Z 3M6, at: 1-888-TO-869-9384

This leaflet was prepared by Pfizer Consumer Healthcare, a

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