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 pains
- Sore throat pain
- Fever
- Headache
- Runny nose
- Itchy, watery eyes
- Sore throat

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 to ibuprofen or other NSAsIDs, ASA or other salicylates, diphenhydramine or any ingredient in the formulation or component of the container (Refer to the non-medicinal ingredients on outer carton or composition section)
- peptic ulcer, gastrointestinal disease or gastrointestinal bleeding
- severe 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
  - non-stereoidal 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
  - Systemic Lupus Erythematosus
  - pregnant or nursing

The medicinal ingredients are:
- Ibuprofen and diphenhydramine citrate

What the non-medicinal ingredients are:
- Carbomer, carnauba wax, cellulose gel, citric acid, cornstarch, croscarmellose sodium, FD&C No. 2, 2 g, glycerin/behenate, hypromellose, lactose monohydrate, microcrystalline cellulose, pharmaceutical ink, polydextrose, polyethylene glycol, pregelatinized starch, sodium lauryl sulfate, sodium starch glycinate, stearic acid, titanium dioxide

What dosage form 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.

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:
- 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
- or are taking any other prescription or over-the-counter drug, including any other anti-inflamatory medication

Avoid alcoholic beverages while taking this product. Do not drive a motor vehicle or operate machinery. Use with caution in the elderly.

Talk to a doctor if fever lasts for more than 3 days or if pain or cold/flu symptoms last for 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:
- acetylsalicylic
- aspirin
- protons inhibitors
- blood thinners
- anticoagulants (blood thinners)
- aspirin
- other anti-inflammatory medication
- monoamine oxidase inhibitors (MAOIs)
- benzodiazepines
- antihistamines (such as allergy medications)
- tranquilizers or other sedating drugs
- NSAIDs (including naproxen and ibuprofen)
- 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

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

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

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Adverse effects: Headache, drowsiness, nausea, vomiting, tremors or flushing, dizziness, drowsiness, 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 doctor.

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 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°C–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, ON, Canada L4Z 3M6 at 1-888-275-9938.

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