

PART III: CONSUMER INFORMATION

Advil Nighttime Ibuprofen and Diphenhydramine Hydrochloride

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

ABOUT THIS MEDICATION

- For fast and effective relief of occasional mild to moderate nighttime pain and accompanying sleeplessness, due to minor aches and pains associated with joints, muscles, backache, headache and toothache as well as pain of migraine and arthritis.
- For longer sleep, uninterrupted by temporary pain.

Only for temporary mild to moderate pain that causes sleeplessness. If this is not the case, do not use.

What it does:

Contains two drugs: ibuprofen (a pain reliever for short term use) and diphenhydramine hydrochloride (a sleep-aid for sleeplessness). Pain relief from ibuprofen helps to fall asleep, and diphenhydramine helps to stay asleep.

When it should not be used:

Do not use if:

- You have pain that does not keep you from sleeping.
- You have sleeplessness but are not in pain.
- You have active peptic ulcer, a history of recurrent ulceration or active inflammatory disease of the gastrointestinal system.
- Nasal polyps (swelling of the inside of the nose), asthma.
- Taking, acetylsalicylic acid (ASA), acetaminophen, or other NSAIDs, such as naproxen or other ibuprofen product.
- Known or suspected hypersensitivity or allergy to ibuprofen or other NSAIDs, ASA or other salicylates, diphenhydramine or to any ingredient in the formulation.
- Pregnant.

What the medicinal ingredients are:

Ibuprofen and diphenhydramine hydrochloride.

What the nonmedicinal ingredients are:

Coconut oil, D&C red no. 33, FD&C blue no. 1, gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan, and sorbitol.

What dosage forms it comes in:

Each Liqui-gel (gelatin capsule) contains ibuprofen 200 mg (as free acid and potassium salt) and diphenhydramine hydrochloride 25 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- Causes sedation or sleepiness. Not for daytime use.
- Caution in patients prone to gastrointestinal tract irritation.

BEFORE use, talk to your doctor or pharmacist if you have/are:

- Diabetes
- Chronic lung disease
- Glaucoma
- Difficulty in urination due to an enlarged prostate
- Autoimmune disease (e.g., lupus)
- High blood pressure
- Heart disease
- Kidney or liver disease
- Any other serious disease
- Taking any other prescription or over-the-counter drug
- Over 65 years of age
- Nursing a baby
- Sleeplessness due to mild to moderate pain persists continually for more than 5 days.

Insomnia may be a symptom of a serious underlying medical condition other than pain.

While taking this product, do not drive motor vehicle or operate machinery.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with Advil Nighttime include:

- Antihistamines, tranquilizers, alcohol or other sedating drugs
- Digoxin
- Diuretics (e.g., for bloating or heart conditions)
- Insulin
- Lithium
- Medications for high blood pressure or depression, including monamine oxidase inhibitors (MAOIs)
- Methotrexate
- Oral antidiabetic agents
- Other pain relievers, sleep-aids or cold medicines

Do not take this product at the same time as other medications containing pain relievers (e.g., ibuprofen, ASA, acetaminophen, naproxen, etc.) or diphenhydramine (e.g., allergy medications, sedating drugs, cough/cold/flu medications, antinausea drugs) etc.

PROPER USE OF THIS MEDICATION

Usual dose:

Adults ≥16 to 65 years: Take a single dose of 1 or 2 Liqui-Gels at night. Do not take more than the recommended dosage unless directed by a physician. Do not exceed 1200 mg of ibuprofen and

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 0701C

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.

300 mg of diphenhydramine (including the 200-400 mg ibuprofen and 25-50 mg diphenhydramine hydrochloride from Advil Nighttime dose) in 24 hours. Should be taken no sooner than 4-6 hours after the last daytime ibuprofen or diphenhydramine dose. See **Interactions with this Medication** for examples of other products which contain these ingredients. Do not take for more than 5 consecutive nights unless directed by a physician.

Do not give to children under 16 unless directed by a physician.

Overdose:

In case of accidental overdose: stop use and contact a physician or poison control centre immediately, even if there are no symptoms.

Missed Dose:

Take once at night before bedtime. Do not take twice the recommended dose after a missed dose.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

STOP USE and consult your physician immediately if you experience: abdominal pain, allergic reaction (itching, blisters, rashes, skin reddening, etc), any change in vision, blood in vomit, bloody or black stools, bladder pain, hallucinations, or difficulty speaking.

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

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.

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- 869-9384.

This leaflet was prepared by Pfizer Consumer Healthcare, a division of Pfizer Canada Inc.

Product monograph available to physicians and pharmacists upon request.

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SIDE EFFECTS AND WHAT TO DO ABOUT THEM

If heartburn, nausea or vomiting, bloating, diarrhea or constipation, ringing or buzzing in the ears, nervousness, dizziness, fluid retention, or any other side effect or unexplained symptoms develop while taking Advil Nighttime, discontinue use immediately and contact a physician.

Consult your physician if the symptoms of pain or sleeplessness persist for more than 5 days.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM