

IMPORTANT: PLEASE READ

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

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.

For fast and effective temporary 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 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 Nighttime ingredients (refer to the nonmedicinal ingredients on outer carton or composition section).
- You have pain that does not keep you from sleeping.
- You have sleeplessness but are not in pain.
- You have active or recurrent stomach ulcer, gastrointestinal (GI) bleeding, or active inflammatory bowel disease (e.g. Crohn's, colitis).
- You have nasal polyps (swelling of the inside of the nose), or allergic manifestations such as asthma, anaphylaxis (sudden severe life threatening allergic reaction), urticaria/hives, hives (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 ASA, acetaminophen, or other NSAIDs, such as naproxen or other ibuprofen product, antihistamines and/or diphenhydramine containing products (e.g. for cough & cold, sleep aids, etc.), monoamine oxidase inhibitors (MAOIs).
- You are dehydrated (significant fluid loss) due to vomiting, diarrhea or lack of fluid intake.
- You have heart problems, such as high blood pressure or severe coronary artery disease.
- Right before or after heart surgery.
- You have Systemic Lupus Erythematosus.
- In your third trimester of pregnancy.

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, including those with a history of peptic ulcers. 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 acetylsalicylic acid (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.

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

- 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.
- Autoimmune disease (e.g. lupus).
- High blood pressure.
- Over 65 years of age.
- You are trying to conceive, in your first or second trimester of pregnancy or if you are breastfeeding.
- 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. Use with caution in the elderly. Long-term continuous use may increase the risk of heart attack or stroke.

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 Nighttime include: Acetaminophen, anti-coagulants (blood thinners), apomorphine, alcohol, digoxin, antibiotic agents (oral and inject), 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), tranquilizers, alcohol or other sedating drugs, NSAIDs (including naproxen and ibuprofen), sleep-aid, cold medications.

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, anti-nausea drugs) etc.

PROPER USE OF THIS MEDICATION

Usual dose: Adults and children 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 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. Do not use longer than 3 days for a fever or 5 days for pain or cold symptoms.

Overdose: In case of accidental overdose, stop use and contact a health care practitioner, hospital emergency department, 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.

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, fluid retention, 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 redness, 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 Nighttime, discontinue use immediately and contact a physician. Side effects may be minimized by using the smallest dose for the shortest duration of time. 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: 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.

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

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.

MORE INFORMATION

This document (plus the full product monograph, prepared for health professionals) can be found by contacting the sponsor, GlaxoSmithKline Consumer Healthcare ULC, Mississauga, ON L5R 4B2 at 1-888-275-9538.

This leaflet was prepared by GlaxoSmithKline Consumer Healthcare ULC. Product monograph available to physicians and pharmacists upon request.

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