**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.

**Drug Information**

**What is this medicine?**
- Ibuprofen and diphenhydramine hydrochloride.

**What the medicinal ingredients are:**
- Ibuprofen and diphenhydramine hydrochloride.

**What the non-medicinal ingredients are:**
- Coconut oil, B&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
- Gastritis
- 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
- Diogen
- Diuretics (e.g., for bleeding or heart conditions)
- Insulin
- Lithium
- Medications for high blood pressure or depression, including monoamine oxidase inhibitors (MAOIs)
- Methotrexate
- Oral antidiabetic agents
- Other pain relievers, sleep-aids or cold medications

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

**PROPER USE OF THIS MEDICATION**

**Usual dose:**
- **Adults ≥ 18-65 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.

**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**

If heartburn, nausea or vomiting, bleeding, 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**

**STOP USE** and consult your physician immediately if you experience: abdominal pain, allergic reaction (itching, blisters, rashes, skin redening, 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
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-4789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, ON K1A 0K9

Postpaid 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 medication 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: 1-888-275-9938 www.advil.ca.

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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