

**PART III: CONSUMER INFORMATION**

**ADVIL DAY/NIGHT CONVENIENCE PACK**

**Advil Liqui-Gels  
Ibuprofen Capsules**

**Advil Nighttime  
Ibuprofen and Diphenhydramine Hydrochloride Capsules**

**This leaflet is part III of a three-part "Product Monograph" published when Advil Day/Night Convenience Pack 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 Day/Night Convenience Pack. Talk to your doctor or pharmacist if you have any questions about the drug.**

**ABOUT THIS MEDICATION**

*Advil Liqui-Gels (Daytime)*

Temporary relief of mild to moderate migraine headaches including associated symptoms of nausea, and sensitivity to light and sound.

Fast and effective relief of muscle aches and pain, joint and body pain, backache, muscle sprains and strains, pain of inflammation associated with conditions including arthritis and physical or athletic overexertion (e.g. sprains or strains), headache including tension headache, dental pain and menstrual pain.

*Advil Nighttime*

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: ibuprofen (a pain reliever for short term use). Advil Nighttime contains one extra ingredient, diphenhydramine hydrochloride (a sleep-aid for sleeplessness).  
Liquid fast relief.

**When it should not be used:**

Do not use if:

- You have active peptic ulcer, a history of recurrent ulceration active inflammatory disease of the gastrointestinal system or gastrointestinal bleeding.
- Nasal polyps (swelling of the inside of the nose), or allergic manifestations such as asthma, anaphylaxis (sudden severe life threatening allergic reaction), urticaria/hives, rhinitis (stuffed or runny nose that may be due to allergies), skin rash or other allergic symptoms,

- Taking, acetylsalicylic acid (ASA), acetaminophen, or other Non-Steroidal Anti-inflammatory Drugs (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.
- Dehydrated (significant fluid loss) due to vomiting, diarrhea or lack of fluid intake.
- Diagnosed with severe high blood pressure or have severe coronary artery disease, serious liver or kidney disease, Systemic Lupus Erythematosus.
- Pregnant or nursing.

Do not use Advil Nighttime if:

- You have pain that does not keep you from sleeping.
- You have sleeplessness but are not in pain.

**What the medicinal ingredients are:**

*Advil Liqui-gels:* Ibuprofen (present as free acid and potassium salt)

*Advil Nighttime:* Ibuprofen (present as free acid and potassium salt) and diphenhydramine hydrochloride.

**What the nonmedicinal ingredients are:**

*Advil Liqui-gels:* FD&C green no. 3, gelatin, lecithin (soy), medium chain triglycerides, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan, sorbitol.

*Advil Nighttime:* 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:**

*Advil Liqui-gels:* Each liquid filled capsule contains ibuprofen 200 mg (present as free acid and potassium salt).

*Advil Nighttime:* 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**

- Caution in patients prone to gastrointestinal tract irritation, including those with a history of peptic ulcer.
- Advil Nighttime causes sedation or sleepiness. Not for daytime use.

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
- Heart failure or thyroid disease
- Peptic ulcers
- Asthma

- Blood clotting disorder (such as hemophilia)
- Kidney or liver disease
- Any other serious disease
- Taking prescription or over-the-counter drug
- Over 65 years of age
- Pregnant or 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 Advil Nighttime, do not drive motor vehicle or operate machinery.

### INTERACTIONS WITH THIS MEDICATION

Do not use Advil Liqui-Gels or Advil Nighttime 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.
- ASA or other anti-inflammatory medication.

Drugs that may interact with Advil Liqui-Gels or Advil Nighttime include:

- Anticoagulants (blood thinners)
- 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 mononamine oxidase inhibitors (MAOIs)
- Methotrexate
- Oral antidiabetic agents
- Other NSAIDs
- Other pain relievers, sleep-aids or cold medicines
- Protein-bound drugs including probenecid, thyroxine, antibiotics (e.g. cyclosporine), phenytoin, corticosteroids or benzodiazapenes

**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.

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

### PROPER USE OF THIS MEDICATION

**Usual dose:**

**Adults ≥16 to 65 years of age: Advil Liqui-Gels (Daytime):** Take 1 green Liqui-Gel every 4 hours or 2 green Liqui-Gels every 6-8 hours at the first sign of symptoms as needed. **Advil Nighttime :** Take 1 or 2 blue Liqui-Gels at night, 4-6 hours after the last daytime ibuprofen or diphenhydramine dose. Do not take for more than 5 consecutive days/nights unless directed by a

doctor. **Do not exceed a combined total of any 6 Advil Liqui-Gels or Advil Nighttime Liqui-Gels in 24 hours**, unless directed by a doctor.

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

### Overdose:

**In case of overdose: stop use and contact a Poison Control Centre or a doctor immediately, even if there are no symptoms.**

### Missed Dose:

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take your medicine and skip the missed dose. Do not take twice the recommended dose after a missed dose.

### 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 Liqui-Gels or Advil Nighttime, discontinue use immediately and contact a doctor.

Talk to your doctor if the symptoms of pain or sleeplessness persist for more than 5 days.

Side effects may be minimized by using the smallest dose for the shortest duration of time.

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

**STOP USE** and consult your doctor 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 Liqui-Gels or 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.

**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](http://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](http://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.*

**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 or [www.advil.ca](http://www.advil.ca).

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

Product monograph available to doctors and pharmacists upon request.

Last revised: April 5, 2018