

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

Advil

Advil Caplets
Ibuprofen Tablets USP, 200 mg

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

ABOUT THIS MEDICATION

What the medication is used for:

For fast and effective temporary 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, migraine pain, dental pain, menstrual pain, aches and pain due to the common cold and flu and for reduction of fever.

What it does:

Advil Caplets (Ibuprofen) is a nonsteroidal anti-inflammatory drug (NSAID) that can reduce the chemicals produced by your body which cause pain and inflammation.

Advil Caplets can only relieve pain and reduce swelling as long as you continue to take it.

When it should not be used:

Do not take Advil Caplets if you have or are:

- active or recurrent stomach ulcer, gastrointestinal (GI) bleeding, or active inflammatory bowel disease (e.g. Crohn's, colitis),
- taking acetylsalicylic acid (ASA) or any other NSAIDs including any other ibuprofen product,
- allergic/hypersensitive to ASA, ibuprofen, other salicylates, other NSAIDs or any of Advil Caplets ingredients (Refer to the nonmedicinal ingredients on outer carton or composition section),
- 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,
- 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,
- right before or after heart surgery,
- serious liver or kidney disease,
- Systemic Lupus Erythematosus,
- or if you are in your third trimester of pregnancy.

Advil Caplets should NOT be used in patients under 12 years of age since the safety and effectiveness have NOT been established. Children under 12 should use Children's Advil.

What the medicinal ingredient is:

Ibuprofen

What the important nonmedicinal ingredients are:

acetylated monoglycerides, beeswax, carnauba wax, corn starch, croscarmellose sodium, iron oxides, lecithin (soy), microcrystalline cellulose, parabens, pharmaceutical ink, povidone, pregelatinized starch, shellac, silicon dioxide, sodium benzoate, sodium lauryl sulfate, stearic acid, sucrose, titanium dioxide.

What dosage forms it comes in:

Each caplet contains ibuprofen, 200 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- Caution in those with heart failure, high blood pressure or other conditions that may cause excess fluid collecting in tissues. • Caution in patients at risk of gastrointestinal tract irritation, including those with a history of peptic ulcer. 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. • Caution in patients at risk of kidney problems, including the elderly or those using diuretics. • Stop use immediately if you have difficulty or pain when urinating. • Use during pregnancy or nursing should be avoided.

BEFORE you use Advil Caplets talk to your doctor or pharmacist if:

- you have previous or current stomach ulcers, diabetes, high blood pressure, heart failure, heart disease or thyroid disease, asthma, kidney or liver disease, glaucoma, blood clotting disorder (such as hemophilia), any other serious disease, are under doctor's care for any serious condition, you are trying to conceive, in your first or second trimester of pregnancy or if you are breast-feeding or are taking any other drug including over the counter drugs.
- 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.
- ASA or other anti-inflammatory medication.

Talk to your doctor or pharmacist if you are taking other medication (prescription or non-prescription) such as any of the following (NOT a complete list): acetaminophen, anticoagulants (blood thinners), digoxin, oral antidiabetic agents and insulin, diuretics, methotrexate, lithium, protein-bound drugs including probenecid, thyroxine, antibiotics, cyclosporine, phenytoin, corticosteroids or benzodiazepines, other NSAIDs, or medications for high blood pressure. Tell your doctor or pharmacist what prescription drugs you are taking or plan to take.

PROPER USE OF THIS MEDICATION

Usual dose:

Adults and children 12 years and over: Take 1 (every 4 hours) or 2 (every 6 to 8 hours) caplets as needed. Do not exceed 6 caplets in 24 hours, unless directed by a physician. Do not use longer than 3 days for a fever or 5 days for pain relief. Children under 12 should use Children's Advil.

Overdose:

If in case of overdose, contact a Poison Control Centre or 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 two doses at the same time.

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, nervousness, sleeplessness, dizziness or any change in vision, itching, fluid retention, shortness of breath, wheezing, any trouble breathing or chest tightness, hives, swelling or itching, skin rashes, skin redness, hives, 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, discontinue use immediately and contact a physician.

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 Caplets, contact your doctor or pharmacist.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/thp-mps/modelf/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax;
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. 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: 1-888-275-9938 or www.advil.ca.

This leaflet was prepared by GlaxoSmithKline Consumer Healthcare ULC.

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Product monograph available to doctors and pharmacists upon request.

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