

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

**Advil® Arthritis Pain
Ibuprofen Capsules, 400 mg
(as free acid and potassium salt)**

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

ABOUT THIS MEDICATION

What the medication is used for:

Arthritis Pain: Temporary relief of pain of inflammation associated with conditions of arthritis.

Also used for fast and effective temporary relief of mild to moderate migraine headaches, muscle aches and pain, joint and body pain, backache, muscle sprains and strains, pain of inflammation associated with physical or athletic overexertion (e.g. sprains or strains), headache including tension headache, dental pain, menstrual pain, aches and pain due to the common cold and flu and for reduction of fever.

Clinical studies show long lasting pain relief for up to 8 hours.

What it does:

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

When it should not be used:

Do not take Advil Arthritis Pain 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 NSAIDs including any other ibuprofen product,
- allergic/hypersensitive to ASA, ibuprofen, other salicylates, other NSAIDs or any of Advil Arthritis Pain 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,
- high potassium in the blood,
- Systemic Lupus Erythematosus,
- or if you are in your third trimester of pregnancy.

Advil Arthritis Pain 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 ingredients are:

Ibuprofen (present as free acid and potassium salt).

What the important nonmedicinal ingredients are:

D&C Yellow No. 10, FD&C Green No. 3, FD&C Red No. 40, gelatin, lecithin (soy), medium chain triglycerides, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan, sorbitol.

What dosage forms it comes in:

Each liquid filled capsule contains ibuprofen 400mg (present as free acid and potassium salt).

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 prone to 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.
- Advil Arthritis Pain should not be used during third trimester of pregnancy.
- Talk to your doctor if you are trying to conceive, in your first or second trimester of pregnancy or if breastfeeding.

BEFORE you use Advil Arthritis Pain 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, pregnant or breastfeeding 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.

The use of NSAIDs, like Advil Arthritis Pain in the second trimester of pregnancy should be restricted to the lowest dose necessary for the shortest possible duration.

At 20 weeks or later in pregnancy, your use of NSAIDs may need to be monitored by a doctor due to the rare risk of kidney problems in the unborn baby which may result in decreased amniotic fluid volume and other complications.

Stop use and ask a doctor if • you show signs of stomach bleeding • pain worsens or lasts more than 5 days • fever worsens or lasts more than 3 days • any new symptoms appear

INTERACTIONS WITH THIS MEDICATION

Do not use Advil Arthritis Pain 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 Liqui-gel every 6-8 hours as needed. Do not exceed 3 Liqui-gels® in 24 hours, unless directed by a doctor.

Do not use longer than 3 days for a fever or 5 days for pain relief. Do not give to children under 12.

Overdose:

In case of overdose, call 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 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 reddening, 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 Arthritis Pain, discontinue use immediately and contact a doctor.

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 Arthritis Pain, 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/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- 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). Protect from light.

Keep out of reach of children. This package contains enough medicine to seriously harm a child. Advil Arthritis Pain is not child-resistant.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Haleon Canada ULC, Mississauga, ON L5R 4B2, at: 1-888-788-8181 or www.advil.ca.

This leaflet was prepared by Haleon Canada ULC.

Product monograph available to doctors and pharmacists upon request.

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