

PART III: CONSUMER INFORMATION

Advil® 12 Hour
Ibuprofen Extended Release Tablets BP, 600 mg

This leaflet is part III of a three-part "Product Monograph" published when Advil® 12 Hour 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® 12 Hour. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Advil 12 Hour provides fast & effective relief of pain lasting longer than 6 hours.

Advil 12 Hour relieves pain from inflammation associated with arthritis or physical overexertion, headaches including tension headache and mild to moderate migraine pain, minor aches and pain associated with muscles, joints, backache, aches and pain due to the common cold, relief of toothache and pain of dental extractions and menstrual pain, in addition to reducing fevers lasting for more than 6 hours.

Clinical studies show fast and long lasting pain relief for up to 12 hours.

What it does:

Advil 12 Hour (Ibuprofen) is a non-steroidal anti-inflammatory drug (NSAID) that can reduce the chemicals produced by your body which cause pain and inflammation.

Advil 12 Hour 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® 12 Hour if you have or are:

- active or recurrent stomach ulcer, gastrointestinal (GI) bleeding, or active inflammatory bowel disease (e.e. 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® 12 Hour ingredients (Refer to the non-medicinal 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,
- serious liver or kidney disease,
- Systemic Lupus Erythematosus,
- or if you are pregnant or nursing.

Advil 12 Hour should NOT be used in patients under 18 years of age since the safety and effectiveness have NOT been established.

What the medicinal ingredient is:

Ibuprofen

What the important nonmedicinal ingredients are:

Carnauba wax, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, microcrystalline cellulose, pharmaceutical ink, polydextrose, polyethylene glycol, pregelatinized starch, sodium lauryl sulfate, stearic acid, titanium dioxide.

What dosage forms it comes in:

Each bi-layer tablet contains ibuprofen, 600 mg (200 mg Immediate Release/400 mg Extended Release).

The first layer dissolves quickly to relieve pain fast. The second layer is time-released to give relief that lasts up to 12 hours. One Advil 12 Hour tablet provides the same amount of medication as 200 mg of standard (immediate release) ibuprofen given every 4 hours.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- Caution in patients prone to gastrointestinal tract irritation, including those with a history of peptic ulcer.

BEFORE you use Advil® 12 Hour 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, are pregnant or nursing 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.

PROPER USE OF THIS MEDICATION

Usual dose:

Adults \geq 18 years: Take 1 tablet every 12 hours as needed. Do not exceed 2 tablets 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 take more than directed or more than 1 tablet at a time.

Do not crush, chew or dissolve the tablet.

Overdose:

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

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[®] 12 Hour, 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[®] 12 Hour, 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).

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, Pfizer Consumer Healthcare, a division of Pfizer Canada Inc. Mississauga, ON L5R 4B2 at: 1-888-275-9938 or www.advil.ca.

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

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