

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE  
PATIENT MEDICATION INFORMATION

**Advil Plus Acetaminophen**  
Ibuprofen 125 mg/Acetaminophen 250 mg Tablets

Read this carefully before you start taking Advil Plus Acetaminophen. This leaflet is a summary and will not tell you everything about this drug, talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Advil Plus Acetaminophen.

**Serious Warnings and Precautions**

- If you have, or previously had, any of the following medical conditions, ask your doctor before taking Advil Plus Acetaminophen: • Heart Failure • High blood pressure • Kidney or liver disease • Pregnant or nursing.
- Advil Plus Acetaminophen should not be used during third trimester of pregnancy, use during the first and second trimesters of pregnancy or nursing should be avoided.
- **Stomach bleeding warning:** This product may cause stomach bleeding. Symptoms may include feeling full, vomiting blood, bloody or black stools, the change of stomach bleeding to higher frequency. • Age over 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 aspirin, ibuprofen, naproxen, or prescription anti-inflammatory drugs) • Have 3 or more alcoholic drinks every day while using this product.
- Liver warning: Advil Plus Acetaminophen contains acetaminophen, which has been associated with cases of acute liver failure. Severe or possibly fatal liver damage may occur if you take: • More than 6 tablets within 24 hours which is the maximum daily amount for this product • With other drugs containing acetaminophen • While drinking 10 or more alcoholic drinks every day.
- Symptoms of liver damage may include yellow skin/eyes, dark urine, sweating, nausea, vomiting, stomach pain, unusual tiredness, and/or loss of appetite.
- Stop use and contact a doctor if you observe blood in the urine or you develop urgent, frequent, painful or difficult urination.
- Use with caution in the elderly or those taking diuretics.
- **Allergy alert:** This product may cause serious skin reactions and severe allergic reaction, especially in people allergic to ASA. Symptoms may include skin redness, skin blisters, rash, hives, severe itching, swelling of eyes and mouth, and difficulty breathing. If any of the above noted symptoms occur, stop use and seek medical help right away.

**What is Advil Plus Acetaminophen used for?**

For fast and effective temporary relief of muscle aches and joint and body pain, headache, muscle sprains and strain, pain of inflammation associated with conditions including arthritis and physical or athletic overexertion (eg, sprains or strains), headaches including tension headache, migraine pain, dental pain, pre-menstrual & menstrual pain, aches and pain due to the common cold and for reduction of fever.

**How does Advil Plus Acetaminophen work?**

Advil Plus Acetaminophen works via a dual action mechanism. Ibuprofen, a non-steroidal anti-inflammatory drug (NSAID), fights pain at its source and reduces fever. Acetaminophen blocks the transmission of pain signals to your brain. It also acts in the brain to reduce fever.

**What are the ingredients in Advil Plus Acetaminophen?**

**Medicinal ingredients:** Ibuprofen and acetaminophen.  
**Non-medicinal ingredients:** CanaRx wax, croscarmellose sodium, glyceryl behenate, hypromellose, iron oxides, mannitol 400 pharmaceutical ink, polyethylene glycol, silicon dioxide, titanium dioxide.

**Advil Plus Acetaminophen comes in the following dosage forms:**

Ibuprofen 125 mg/Acetaminophen 250 mg tablets.

**Do not use Advil Plus Acetaminophen if:**

- you have or use • active or recurrent stomach/duodenal (D) bleeding, or active inflammatory bowel disease (eg, Crohn's, colitis) • taking any other drug containing acetaminophen can cause severe or possibly fatal liver damage; if you are not sure if a drug contains acetaminophen ask a doctor or pharmacist, aspirin/ibuprofen/ASA or any other NSAID, including any other over-the-counter product • allergy/hypersensitivity to acetaminophen, ASA, ibuprofen, other salicylates, other NSAIDs or any of Advil Plus Acetaminophen ingredients (refer to the non-medicinal ingredients on the outer carton or composition section) • nasal polyps (swelling of the inside of the nose), or allergic manifestations such as asthma, angioedema (swelling of the face, lips, tongue, throat and/or airway) and/or anaphylaxis (allergic reaction) that may be due to allergic 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 • planning to have or have recently had heart surgery • serious liver or kidney disease • Systemic Lupus Erythematosus • high potassium in the blood • in your third trimester of pregnancy.

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

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Advil Plus Acetaminophen. Talk about any health conditions or problems you may have, including if you:**

- are on liver or kidney disease, or have a history of ulcers or feet ulcers or stomach bleeding history, high blood pressure, heart disease, diabetes, any other serious condition • have the blood thinning drug warfarin, take any other medication especially low-dose ASA (81 to 325 mg) or take any other drugs including over the counter drugs • trying to conceive, or in your first or second trimester of pregnancy, breastfeeding • plan to have a surgery • have asthma, diabetes, blood clotting disorder (such as hemophilia), infection, indigestion and heartburn, inflammation of the eye or any other dental problems, dizziness, vomiting blood, bleeding from back passage • continue to use alcohol.

**Other warnings you should know about:**

- When using this product: • Take with food or milk if upset stomach occurs • the risk of heart attack or stroke may increase if you use more than directed or for longer than directed. Stop use and call a doctor if: • you have signs of stomach bleeding (see Serious Warnings and Precautions – Stomach bleeding warning) • pain gets worse or lasts more than 5 days • fever gets worse or lasts more than 3 days • any new symptoms appear.
- Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. The following may interact with Advil Plus Acetaminophen (NOT a complete list): • medicines that affect or have to avoid taking alcohol (eg, antibiotics, disulfiram) • medicines that are anti-coagulant (eg, thin blood prevent) (diclofenac, aspirin, acetylsalicylic acid, warfarin) may increase the risk of ulceration and bleeding • acetylsalicylic acid (ASA) or other NSAIDs. Ibuprofen may interfere with the preventive benefits of ASA • medicines that reduce high blood pressure (ACE-inhibitors, beta-blockers, angiotensin II receptor antagonists) • agents to treat abnormal heart rhythm • diuretics also called water pills used to increase urine output • serotonin reuptake inhibitors (SSRIs) used to treat depression • corticosteroids, such as prednisone, cortisone • antidepressants, a medicine to treat some types of cancer • lithium, a medicine used to treat some types of depression • benzodiazepines a medicine used to treat some types of depression • protein-bound drugs including probenecid • oral antidiabetic agents and insulin.

**How to take Advil Plus Acetaminophen:**

Take the lowest dose of this medicine for the shortest time period, taking two Advil Plus Acetaminophen may increase your chances of unwanted and sometimes dangerous side effects, especially if you are elderly, have other diseases or take other medications.

**Usual dose:**

Adults 18 years and over: Take 2 tablets every 6 hours while symptoms persist. Do not exceed 6 tablets in 24 hours, unless directed by a doctor. Do not take more than directed (see liver warning). Do not use longer than 3 days for a fever or 5 days for pain relief. Advil Plus Acetaminophen provides up to 8 hours of pain relief.

**Overdose:** Call a Poison Control Centre or a healthcare professional immediately, even if you do not notice any signs or symptoms. Early symptoms of liver damage may seem like the flu, or you may have nausea, vomiting, stomach pain, loss of appetite, yellowing of the skin/eyes, or dark urine.

**Missed Dose:** If you miss a dose, take it as soon as you remember. But if it is almost time for the next dose, do not take the missed dose. Instead, take the next scheduled dose. Do not try to make up for the missed dose by taking a double dose next time.

**What are possible side effects from using Advil Plus Acetaminophen?** There are not all the possible side effects you may feel when taking Advil Plus Acetaminophen. If you experience any side effects not listed here, contact your healthcare professional. Possible serious side effects are summarized below from data available for the individual drugs, ibuprofen and acetaminophen.

Symptom / effect	Serious side effects and what to do about them		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b>			
• Dizziness	✓		
<b>UNCOMMON</b>			
• Abdominal pain	✓		
• Bloody or black stools		✓	✓
• Skin rashes, skin redness		✓	✓
• Itching or hives on the skin		✓	✓
<b>RARE</b>			
• Vomiting blood or dark coloured vomit		✓	✓
• Shortness of breath, wheezing		✓	✓
• Fluid retention (eg, swelling in the hands or feet)		✓	✓
<b>VERY RARE</b>			
• Severe allergic reactions (swelling, breathing or chest tightness, hives, swelling or itching)		✓	✓
• Serious skin reactions (skin redness, peeling)		✓	✓
• Swelling (inflammation) of the eyes or skin due to eye problems		✓	✓
• Low blood platelet count		✓	✓

Other self-limiting side effects that may occur include heartburn, nausea or vomiting, dizziness, drowsiness or constipation, nervousness, sleeplessness or itching. If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

**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.zco.gc.ca/chrp-rpcc/medinfo/epi-sondage/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.

**Storage:**

- Store at room temperature (15°-30°C).
- Keep out of reach of children. This package contains enough medicine to seriously harm a child.
- If you want more information about Advil Plus Acetaminophen: • Talk to your healthcare professional • Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hsc.gc.ca/india-eng.php>), the manufacturer's website [www.zco.ca](http://www.zco.ca), or by calling 1-888-275-9938.

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Last Revised Mar-04-2021

PM163034

