

Acetaminophen

Generic Name: acetaminophen/aspirin/caffeine (a-SEET-a-MIN-oh-fen/AS-pir-in/KAF-een)

Brand Name: Examples include Excedrin and Vanquish

Acetaminophen is used for:

Relieving headaches, migraine headaches, toothaches, muscle aches, premenstrual or menstrual aches, or other minor aches and pains (eg, due to sinusitis, arthritis, or colds). It may also be used for other conditions as determined by your doctor.

Acetaminophen is an analgesic and antipyretic combination. It works by blocking substances in the body that cause pain and inflammation.

Do NOT use acetaminophen if:

- · you are allergic to any ingredient in acetaminophen
- you are a child or teenager with influenza (flu) or chickenpox
- · you have bleeding problems, such as hemophilia, von Willebrand disease, or low blood platelets
- you have had a severe allergic reaction (eg, severe rash, hives, swelling of the face, breathing difficulties, dizziness) to aspirin, tartrazine, or a nonsteroidal anti-inflammatory drug (NSAID) (eg, celecoxib, ibuprofen, naproxen)
- you are taking an NSAID or another medicine that contains acetaminophen

Contact your doctor or <u>health care provider</u> **right away** if any of these apply to you.

Before using acetaminophen:

Some <u>medical conditions</u> <u>may interact with acetaminophen.</u> Tell your <u>health care</u> <u>may provider if you have any medical conditions, especially if any of the following apply to you:</u>

- if you are pregnant, planning to become pregnant, or are breast-feeding
- if you are taking any prescription or nonprescription medicine, herbal preparation, or dietary supplement
- if you have allergies to medicines, foods, or other substances
- if you have a history of alcohol abuse or if you consume 3 or more alcohol-containing drinks every day
- if you are 60 years old or older

- · if you are taking a diuretic
- if you have asthma, bleeding or clotting problems, growths in the nose (nasal polyps), kidney or liver problems (eg, cirrhosis), hepatitis, high blood pressure, heart problems, influenza (flu) or chickenpox, vitamin K deficiency, anxiety, or trouble sleeping
- if you have or have a history of stomach or peptic ulcers (bleeding ulcers) or other stomach problems (eg, heartburn, upset stomach, stomach pain)
- if the patient is a child with a stroke, a weakened blood vessel (cerebral aneurysm) or bleeding in the brain, or Kawasaki syndrome (a rare inflammation causing heart problems in children)
- if you are taking acetaminophen for a migraine and:
 - your doctor has never told you that you have migraines
 - you have your first headache after you are 50 years of age
 - this headache is different than your usual migraines
 - you have the worst headache of your life, your migraine causes vomiting, or you need bed rest because of your migraine
 - you have a fever and stiff neck or your headaches happen after injury, activity, coughing, or bending
 - you have headaches on a daily basis

Some MEDICINES MAY INTERACT with acetaminophen. Tell your health care provider if you are taking any other medicines, especially any of the following:

- Carbonic anhydrase inhibitors (eg, acetazolamide) because they may decrease acetaminophen's effectiveness
- Anticoagulants (eg, warfarin), clopidogrel, corticosteroids (eg, prednisone), heparin, ketorolac, NSAIDs (eg, celecoxib, ibuprofen, naproxen), or serotonin reuptake inhibitors (eg, fluoxetine) because the risk of bleeding may be increased
- Insulin, isoniazid, oral hypoglycemics (eg, glyburide, repaglinide), or quinolone antibiotics (eg, ciprofloxacin) because the risk of their side effects may be increased by acetaminophen
- Methotrexate, theophylline, or valproic acid because their actions and the risk of their side effects may be increased by acetaminophen
- Probenecid or sulfinpyrazone because their effectiveness may be decreased by acetaminophen

This may not be a complete list of all interactions that may occur. Ask your health care provider if acetaminophen may interact with other medicines that you take. Check with your health care provider before you start, stop, or change the dose of any medicine.

How to use acetaminophen:

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Use acetaminophen as directed by your doctor. Check the label on the medicine for exact dosing instructions.

- Take acetaminophen by mouth with or without food. If stomach upset occurs, take with food to reduce stomach irritation.
- Take acetaminophen with a full glass of water (8 oz [240 mL]). Do not lie down for 30 minutes after taking acetaminophen.
- Use acetaminophen exactly as directed on the package, unless instructed differently by your doctor.
 If you are taking acetaminophen without a prescription, follow any warnings and precautions on the label.
- If you miss a dose of acetaminophen and you are taking it regularly, take it as soon as possible. If it
 is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule.
 Do not take 2 doses at once.

Ask your health care provider any questions you may have about how to use acetaminophen.

Important safety information:

- Acetaminophen has acetaminophen, aspirin, and caffeine in it. Before you start any new medicine, check the label to see if it has acetaminophen, aspirin, or caffeine in it too. If it does or if you are not sure, check with your doctor or pharmacist.
- Contact your doctor right away if you take more than 4,000 mg of acetaminophen per day, even if you feel well.
- Acetaminophen may harm your liver. Your risk may be greater if you drink alcohol while you are
 using acetaminophen. Talk to your doctor before you take acetaminophen or other fever reducers if
 you drink alcohol.
- A very bad skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It can
 cause very bad health problems that may not go away and sometimes death. Get medical help right
 away if you have signs like red, swollen, blistered, or peeling skin (with or without fever); red or
 irritated eyes; or sores in your mouth, throat, nose, or eyes.
- Do not take more than the dose recommended by your doctor or the package labeling. If you take
 more than recommended, your risk of severely harming your liver may be increased. If you are not
 sure how much medicine you may take, contact your doctor or pharmacist.
- Aspirin has been linked to a serious illness called Reye syndrome. Do not give acetaminophen to a
 child or teenager who has or is recovering from the flu, chickenpox, or a viral infection. Contact your
 doctor with any questions or concerns.
- Avoid large amounts of food or drink that have caffeine (eg, coffee, tea, cocoa, cola, chocolate). This
 includes any medicines that contain caffeine. Too much caffeine may cause nervousness, irritability,
 sleeplessness, or fast heartbeat.

- Serious stomach ulcers or bleeding can occur with the use of acetaminophen. Taking it in high doses
 or for a long time, smoking, or drinking alcohol increases the risk of these side effects. Taking
 acetaminophen with food will NOT reduce the risk of these effects. Contact your doctor or
 emergency room at once if you develop severe stomach or back pain; black, tarry stools; vomit that
 looks like blood or coffee grounds; or unusual weight gain or swelling.
- Acetaminophen may reduce the number of clot-forming cells (platelets) in your blood. Avoid activities
 that may cause bruising or injury. Tell your doctor if you have unusual bruising or bleeding. Tell your
 doctor if you have dark, tarry, or bloody stools.
- Tell your doctor or dentist that you take acetaminophen before you receive any medical or dental care, emergency care, or surgery.
- Do not take acetaminophen for at least 7 days after any surgery unless directed by your health care provider.
- If your pain does not get better or becomes worse, or if you have a fever that becomes worse or lasts for more than 3 days, contact your doctor.
- Acetaminophen may cause false results with some in-home test kits for blood cholesterol. Check with your doctor or pharmacist if you are taking acetaminophen and need to check your blood cholesterol at home.
- Use acetaminophen with caution in the ELDERLY; they may be more sensitive to its effects.
- Different brands of acetaminophen may have different dosing instructions for CHILDREN. Follow the
 dosing instructions on the package labeling. If your doctor has given you instructions, follow those. If
 you are unsure of the dose to give a child, check with your doctor or pharmacist.
- PREGNANCY and BREAST-FEEDING: If you become pregnant, contact your doctor. You will need
 to discuss the benefits and risks of using acetaminophen while you are pregnant. Acetaminophen is
 not recommended during the last 3 months (third trimester) of pregnancy. It may cause injury to the
 fetus. Acetaminophen is found in breast milk. If you are or will be breast-feeding while you use
 acetaminophen, check with your doctor. Discuss any possible risks to your baby.

Possible side effects of acetaminophen:

All medicines may cause side effects, but many people have no, or minor, side effects. Check with your doctor if any of these most COMMON side effects persist or become bothersome:

Heartburn; nausea; upset stomach.

Seek medical attention right away if any of these SEVERE side effects occur:

Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); confusion; fainting; hearing loss; ringing in the ears; symptoms of liver problems (eg, dark urine, pale stools, persistent loss of appetite, right-upper stomach pain, yellowing of the skin or eyes); unusual tiredness.

This is not a complete list of all side effects that may occur. If you have questions about side effects, contact your health care provider. Call your doctor for medical advice about side effects. To report side effects to the appropriate agency, please read the **Guide to Reporting Problems to FDA**.

If OVERDOSE is suspected:

Contact 1-800-222-1222 (the American Association of Poison Control Centers), your local **poison control center**, or emergency room immediately.

Proper storage of acetaminophen:

Store acetaminophen at room temperature, between 68 and 77 degrees F (20 and 25 degrees C), in a tightly closed container. Store away from heat, moisture, and light. Do not store in the bathroom. Keep acetaminophen out of the reach of children and away from pets.

General information:

- If you have any questions about acetaminophen, please talk with your doctor, pharmacist, or other health care provider.
- Acetaminophen is to be used only by the patient for whom it is prescribed. Do not share it with other people.
- · If your symptoms do not improve or if they become worse, check with your doctor.
- Check with your pharmacist about how to dispose of unused medicine.

This information should not be used to decide whether or not to take acetaminophen or any other medicine. Only your health care provider has the knowledge and training to decide which medicines are right for you. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about acetaminophen. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to acetaminophen. This information is not specific medical advice and does not replace information you receive from your health care provider. You must talk with your healthcare provider for complete information about the risks and benefits of using acetaminophen.

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