IMPORTANT WARNING:

Taking too much acetaminophen can cause liver damage, sometimes serious enough to require liver transplantation or cause death. You might accidentally take too much acetaminophen if you do not follow the directions on the prescription or package label carefully, or if you take more than one product that contains acetaminophen.

To be sure that you take acetaminophen safely, you should

- not take more than one product that contains acetaminophen at a time. Read the labels of all the prescription and nonprescription medications you are taking to see if they contain acetaminophen. Be aware that abbreviations such as APAP, AC, Acetaminophen, Acetaminoph, Acetaminop, Acetamin, or Acetam. may be written on the label in place of the word acetaminophen. Ask your doctor or pharmacist if you don't know if a medication that you are taking contains acetaminophen.

- take acetaminophen exactly as directed on the prescription or package label. Do not take more acetaminophen or take it more often than directed, even if you still have fever or pain. Ask your doctor or pharmacist if you do not know how much medication to take or how often to take your medication. Call your doctor if you still have pain or fever after taking your medication as directed.

- be aware that you should not take more than 4000 mg of acetaminophen per day. If you need to take more than one product that contains acetaminophen, it may be difficult for you to calculate the total amount of acetaminophen you are taking. Ask your doctor or pharmacist to help you.

- tell your doctor if you have or have ever had liver disease.

- not take acetaminophen if you drink three or more alcoholic drinks every day. Talk to your doctor about the safe use of alcohol while you are taking acetaminophen.

- stop taking your medication and call your doctor right away if you think you have taken too much acetaminophen, even if you feel well.

Talk to your pharmacist or doctor if you have questions about the safe use of acetaminophen or acetaminophen-containing products.

Why is this medication prescribed?

Acetaminophen is used to relieve mild to moderate pain from headaches, muscle aches, menstrual periods, colds and sore throats, toothaches, backaches, and reactions to vaccinations (shots), and to reduce fever. Acetaminophen may also be used to relieve the pain of osteoarthritis (arthritis caused by the breakdown of the lining of the joints). Acetaminophen is in a class of medications called analgesics (pain relievers) and antipyretics (fever reducers). It works by changing the way the body senses pain and by cooling the body.
How should this medicine be used?

Acetaminophen comes as a tablet, chewable tablet, capsule, suspension or solution (liquid), extended-release (long-acting) tablet, and orally disintegrating tablet (tablet that dissolves quickly in the mouth), to take by mouth, with or without food. Acetaminophen also comes as a suppository to use rectally. Acetaminophen is available without a prescription, but your doctor may prescribe acetaminophen to treat certain conditions. Follow the directions on the package or prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand.

If you are giving acetaminophen to your child, read the package label carefully to make sure that it is the right product for the age of the child. Do not give children acetaminophen products that are made for adults. Some products for adults and older children may contain too much acetaminophen for a younger child. Check the package label to find out how much medication the child needs. If you know how much your child weighs, give the dose that matches that weight on the chart. If you don't know your child's weight, give the dose that matches your child's age. Ask your child's doctor if you don't know how much medication to give your child.

Acetaminophen comes in combination with other medications to treat cough and cold symptoms. Ask your doctor or pharmacist for advice on which product is best for your symptoms. Check nonprescription cough and cold product labels carefully before using two or more products at the same time. These products may contain the same active ingredient(s) and taking them together could cause you to receive an overdose. This is especially important if you will be giving cough and cold medications to a child.

Swallow the extended-release tablets whole; do not split, chew, crush, or dissolve them.

Place the orally disintegrating tablet ('Meltaways') in your mouth and allow to dissolve or chew it before swallowing.

Shake the suspension well before each use to mix the medication evenly. Always use the measuring cup or syringe provided by the manufacturer to measure each dose of the solution or suspension. Do not switch dosing devices between different products; always use the device that comes in the product packaging.

To insert an acetaminophen suppository into the rectum, follow these steps:

1. Remove the wrapper.

2. Dip the tip of the suppository in water.

3. Lie down on your left side and raise your right knee to your chest. (A left-handed person should lie on the right side and raise the left knee.)

4. Using your finger, insert the suppository into the rectum, about 1/2 to 1 inch (1.25 to 2.5 centimeters) in infants and children and 1 inch (2.5 centimeters) in adults. Hold it in place for a few moments.

5. Stand up after about 15 minutes. Wash your hands thoroughly and resume your normal activities.

Stop taking acetaminophen and call your doctor if your symptoms get worse, you develop new or unexpected symptoms, including redness or swelling, your pain lasts for more than 10 days, or your fever gets worse or lasts more than 3 days. Also stop giving acetaminophen to your child and call your child's doctor if your child develops new symptoms, including redness or swelling, or your child's pain lasts for longer than 5 days, or fever get worse or lasts longer than 3 days.

Do not give acetaminophen to a child who has a sore throat that is severe or does not go away, or that occurs along with fever, headache, rash, nausea, or vomiting. Call the child's doctor right away, because these symptoms may be signs of a more serious condition.

Other uses for this medicine

Acetaminophen may also be used in combination with aspirin and caffeine to relieve the pain associated with migraine headache.
What special precautions should I follow?

Before taking acetaminophen,

- tell your doctor and pharmacist if you are allergic to acetaminophen, any other medications, or any of the ingredients in the product. Ask your pharmacist or check the label on the package for a list of ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, or herbal products you are taking or plan to take. Be sure to mention anticoagulants ('blood thinners') such as warfarin (Coumadin); isoniazid (INH); certain medications for seizures including carbamazepine (Tegretol), phenobarbital, and phenytoin (Dilantin); medications for pain, fever, coughs, and colds; and phenothiazines (medications for mental illness and nausea). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have ever developed a rash after taking acetaminophen.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking acetaminophen, call your doctor.
- if you drink three or more alcoholic beverages every day, do not take acetaminophen. Ask your doctor or pharmacist about the safe use of alcoholic beverages while taking acetaminophen.
- you should know that combination acetaminophen products for cough and colds that contain nasal decongestants, antihistamines, cough suppressants, and expectorants should not be used in children younger than 2 years of age. Use of these medications in young children can cause serious and life-threatening effects or death. In children 2 through 11 years of age, combination cough and cold products should be used carefully and only according to the directions on the label.
- if you have phenylketonuria (PKU, an inherited condition in which a special diet must be followed to prevent mental retardation), you should know that some brands of acetaminophen chewable tablets may be sweetened with aspartame. a source of phenylalanine.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

This medication is usually taken as needed. If your doctor has told you to take acetaminophen regularly, take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Acetaminophen may cause side effects.

Some side effects can be serious. If you experience any of the following symptoms, stop taking acetaminophen and call your doctor immediately or get emergency medical attention:

- red, peeling or blistering skin
- rash
- hives
- itching
- swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
• hoarseness
• difficulty breathing or swallowing

Acetaminophen may cause other side effects. Call your doctor if you have any unusual problems while you are taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration’s (FDA) MedWatch Adverse Event Reporting program online [at http://www.fda.gov/Safety/MedWatch] or by phone [1-800-332-1088].

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

If someone takes more than the recommended dose of acetaminophen, get medical help immediately, even if the person does not have any symptoms. Symptoms of overdose may include the following:

• nausea
• vomiting
• loss of appetite
• sweating
• extreme tiredness
• unusual bleeding or bruising
• pain in the upper right part of the stomach
• yellowing of the skin or eyes
• flu-like symptoms

What other information should I know?

Before having any laboratory test, tell your doctor and the laboratory personnel that you are taking acetaminophen.

Ask your pharmacist any questions you have about acetaminophen.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

• Acephen Rectal
• Genapap®
• Pediapap®
Brand names of combination products

- Aceta-Gesic® (containing Acetaminophen, Phenyltoloxamine)¶
- Actifed Plus® (containing Acetaminophen, Pseudoephedrine, Triprolidine)
- Acuflex® (containing Acetaminophen, Phenyltoloxamine)§
- Ali Flex® (containing Acetaminophen, Phenyltoloxamine)§
- Alka-Seltzer Plus Cold & Sinus® (containing Acetaminophen, Phenylephrine)
- Allay® (containing Acetaminophen, Hydrocodone)¶
- Alpain® (containing Acetaminophen, Phenyltoloxamine)§
- Anabar® (containing Acetaminophen, Phenyltoloxamine, Salicylamide)§
- Anacin® (containing Acetaminophen, Aspirin, Caffeine)
- Anexsia® (containing Acetaminophen, Hydrocodone)
- Anolor DH5® (containing Acetaminophen, Hydrocodone)
- Apagesic® (containing Acetaminophen, Phenyltoloxamine)§
- Axocet® (containing Acetaminophen, Butalbital)
- Backprin® (containing Acetaminophen, Caffeine, Magnesium Salicylate)
- Novagesic® (containing Acetaminophen, Phenyltoloxamine)§
- NyCair® (containing Acetaminophen, Dextromethorphan, Doxylamine, Pseudoephedrine)
- NyQuil Cold/Flu Relief® (containing Acetaminophen, Dextromethorphan, Doxylamine)
- Oncet® (containing Acetaminophen, Hydrocodone)
- Ornex® (containing Acetaminophen, Pseudoephedrine)
- Pamprin® (containing Acetaminophen, Pamabrom, Pyrilamine)
- Panacet® (containing Acetaminophen, Hydrocodone)
- Panlor® (containing Acetaminophen, Hydrocodone)
- Panitis Forte® (containing Acetaminophen, Salicylamide)
- Percocet® (containing Acetaminophen, Oxycodone)
- Percogesic® (containing Acetaminophen, Phenyltoloxamine)¶
- Perisine® (containing Acetaminophen, Phenyltoloxamine)§
- Perloxx® (containing Acetaminophen, Oxycodone)
- Bancap HC® (containing Acetaminophen, Hydrocodone)
- Bucet® (containing Acetaminophen, Butalbital)
- Butapap® (containing Acetaminophen, Butalbital)
- Butex Forte® (containing Acetaminophen, Butalbital)
- Cafgesic® (containing Acetaminophen, Caffeine, Phenyltoloxamine, Salicylamide)
- Cephadyn® (containing Acetaminophen, Butalbital)
- Ceta Plus® (containing Acetaminophen, Hydrocodone)
- Cetazone T® (containing Acetaminophen, Phenyltoloxamine, Salicylamide)
- Co-Apap® (containing Acetaminophen, Chlorpheniramine, Dextromethorphan, Pseudoephedrine)
- Codimal® (containing Acetaminophen, Chlorpheniramine, Pseudoephedrine)
- Co-Gesic® (containing Acetaminophen, Hydrocodone)
- Combiflex® (containing Acetaminophen, Caffeine, Phenyltoloxamine, Salicylamide)
- Comtrex Cold and Cough® (containing Acetaminophen, Dextromethorphan, Phenylephrine)
- Contac Sinus® (containing Acetaminophen, Pseudoephedrine)
- Coricidin® (containing Acetaminophen, Chlorpheniramine)
- Dayquil® (containing Acetaminophen, Dextromethorphan, Phenylephrine)
- Dimetapp Cold And Fever® (containing Acetaminophen, Brompheniramine, Pseudoephedrine)
- Dolacet® (containing Acetaminophen, Hydrocodone)
- Dolagesic® (containing Acetaminophen, Hydrocodone)
- Doligic® (containing Acetaminophen, Butalbital)
- Dologesic® (containing Acetaminophen, Phenyltoloxamine)
- Dolorex Forte® (containing Acetaminophen, Hydrocodone)
- Dristan Cold Non-Drowsy® (containing Acetaminophen, Pseudoephedrine)
- Drixoral Sinus® (containing Acetaminophen, Dextrompheniramine, Pseudoephedrine Extended Release Tablet)
- Phenagesic® (containing Acetaminophen, Phenyltoloxamine)
- Phenapap® (containing Acetaminophen, Pseudoephedrine)
- Phenflu DM® (containing Acetaminophen, Dextromethorphan, Guaifenesin, Phenylephrine)
- Phenylgesic® (containing Acetaminophen, Phenyltoloxamine)
- Phlemgesic® (containing Acetaminophen, Dextromethorphan, Guaifenesin, Pseudoephedrine)
- Phrenilin® (containing Acetaminophen, Butalbital)
- Polygesic® (containing Acetaminophen, Hydrocodone)
- Premesyn PMS® (containing Acetaminophen, Pamabrom, Pyrilamine)
- Primlev® (containing Acetaminophen, Oxycodone)
- Procet® (containing Acetaminophen, Hydrocodone)
- Prodrin® (containing Acetaminophen, Caffeine, Isometheptene)
- Promacet® (containing Acetaminophen, Butalbital)
- Prominal® (containing Acetaminophen, Butalbital)
- Protil® (containing Acetaminophen, Chlorpheniramine, Phenylephrine)
- Q-Gesic® (containing Acetaminophen, Phenyltoloxamine)
- Relagesic® (containing Acetaminophen, Phenyltoloxamine)
- Repan CF® (containing Acetaminophen, Butalbital)
- Rhinoflex® (containing Acetaminophen, Phenyltoloxamine)
- Rhinogesic® (containing Acetaminophen, Chlorpheniramine, Phenylephrine, Salicylamide)
- Robitussin Cold Cough and Flu® (containing Acetaminophen, Dextromethorphan, Guaifenesin, Pseudoephedrine)
- Roxicet® (containing Acetaminophen, Oxycodone)
- Saleto® (containing Acetaminophen, Aspirin, Caffeine, Salicylamide)
- Sedapap® (containing Acetaminophen, Butalbital)
Dryphen® (containing Acetaminophen, Chlorpheniramine, Phenylephrine)
DuoCet® (containing Acetaminophen, Hydrocodone)
Duogesic® (containing Acetaminophen, Phenyltoloxamine)§
Durabac® (containing Acetaminophen, Caffeine, Phenyltoloxamine, Salicylamide)§
Durabac Forte® (containing Acetaminophen, Caffeine, Magnesium Salicylate, Phenyltoloxamine)§
Duraflu® (containing Acetaminophen, Dextromethorphan, Guaifenesin, Pseudoephedrine)
Duratuss A® (containing Acetaminophen, Guaifenesin, Phenylephrine)
Emagrin Forte® (containing Acetaminophen, Caffeine, Guaifenesin, Phenylephrine)
Endocet® (containing Acetaminophen, Oxycodone)
Excedrin® (containing Acetaminophen, Aspirin, Caffeine)
Excedrin Back & Body® (containing Acetaminophen, Aspirin)
Excedrin PM® (containing Acetaminophen, Diphenhydramine)
Flextra® (containing Acetaminophen, Phenyltoloxamine)§
Frenadol® (containing Acetaminophen, Salicylamide)
Genace® (containing Acetaminophen, Aspirin, Caffeine)
Genasec® (containing Acetaminophen, Phenyltoloxamine)§
Gendecon® (containing Acetaminophen, Chlorpheniramine, Phenylephrine)
Goody's Extra Strength® (containing Acetaminophen, Aspirin, Caffeine)
Goody's PM® (containing Acetaminophen, Diphenhydramine)
Hycet® (containing Acetaminophen, Hydrocodone)
Hycomed® (containing Acetaminophen, Hydrocodone)
Hycomine Compound® (containing Acetaminophen, Caffeine, Chlorpheniramine, Hydrocodone, Phenylephrine)
Hydrocet® (containing Acetaminophen, Hydrocodone)
Hydrogesic® (containing Acetaminophen, Chlorpheniramine, Pseudoephedrine)
Sinarest® (containing Acetaminophen, Chlorpheniramine, Pseudoephedrine)
Sine-Aid® (containing Acetaminophen, Pseudoephedrine)
Sine-Off Sinus and Cold® (containing Acetaminophen, Chlorpheniramine, Phenylephrine)
Singlet® (containing Acetaminophen, Chlorpheniramine, Pseudoephedrine)
Sinumed® (containing Acetaminophen, Chlorpheniramine, Pseudoephedrine)
Sinus Aid® (containing Acetaminophen, Pseudoephedrine)
Sinutab® (containing Acetaminophen, Pseudoephedrine)
Sominex Pain Relief® (containing Acetaminophen, Diphenhydramine)
Staflex® (containing Acetaminophen, Phenyltoloxamine)§
Stagesic® (containing Acetaminophen, Hydrocodone)
Sudafed PE Cold & Cough® (containing Acetaminophen, Dextromethorphan, Guaifenesin, Phenylephrine)
Sudafed PE Sinus Headache® (containing Acetaminophen, Phenylephrine)
Sudogest® (containing Acetaminophen, Pseudoephedrine)
Supac® (containing Acetaminophen, Aspirin, Caffeine)
Suphedrin Sinus® (containing Acetaminophen, Pseudoephedrine)
Talacen® (containing Acetaminophen, Pentazocine)
Tavist Allergy/Sinus/Headache® (containing Acetaminophen, Clemastine, Pseudoephedrine)
Tavist Sinus® (containing Acetaminophen, Pseudoephedrine)
Taxadone® (containing Acetaminophen, Oxycodone)
Tencon® (containing Acetaminophen, Butalbital)
T-Gesic® (containing Acetaminophen, Hydrocodone)
Theraflu Sore Throat® (containing Acetaminophen, Chlorpheniramine, Pseudoephedrine)
Triaminic Cold And Fever® (containing Acetaminophen, Chlorpheniramine, Dextromethorphan, Pseudoephedrine)
Hydrocodone
- Hyflex® (containing Acetaminophen, Phenyltoloxamine)§
- Hy-Phen® (containing Acetaminophen, Hydrocodone)
- Kolephrin® (containing Acetaminophen, Chlorpheniramine, Pseudoephedrine)
- Levacet® (containing Acetaminophen, Aspirin, Caffeine, Salicylamide)
- Liquicet® (containing Acetaminophen, Hydrocodone)
- Lobac® (containing Acetaminophen, Phenyltoloxamine, Salicylamide)§
- Lorcet® (containing Acetaminophen, Hydrocodone)
- Lorsin® (containing Acetaminophen, Chlorpheniramine, Pseudoephedrine)
- Lortab® (containing Acetaminophen, Hydrocodone)
- Lurline PMS® (containing Acetaminophen, Pamabrom, Vitamin B6)
- Lynox® (containing Acetaminophen, Oxycodone)
- Magnacet® (containing Acetaminophen, Oxycodone)
- Major-gesic® (containing Acetaminophen, Phenyltoloxamine)§
- Margesic-H® (containing Acetaminophen, Hydrocodone)
- Marten-Tab® (containing Acetaminophen, Butalbital)
- Masophen PM® (containing Acetaminophen, Pamabrom, Vitamine B6)
- Maxidone® (containing Acetaminophen, Hydrocodone)
- Maxiflu DM® (containing Acetaminophen, Dextromethorphan, Guaifenesin, Pseudoephedrine)
- Midol PMS® (containing Acetaminophen, Pamabrom, Pyrilamine)
- Migralam® (containing Acetaminophen, Caffeine, Isometheptene)
- MigraTen® (containing Acetaminophen, Caffeine, Isometheptene)
- Migrend® (containing Acetaminophen, Caffeine, Isometheptene)
- Narvox® (containing Acetaminophen, Oxycodone)
- Norco® (containing Acetaminophen, Hydrocodone)
- Triaprin® (containing Acetaminophen, Butalbital)¶
- Tricom® (containing Acetaminophen, Chlorpheniramine, Pseudoephedrine)
- Tylefon® (containing Acetaminophen, Chlorzoxazone)
- Tylenol Cold® (containing Acetaminophen, Dextromethorphan, Pseudoephedrine)
- Tylox® (containing Acetaminophen, Oxycodone)
- Ugesic® (containing Acetaminophen, Hydrocodone)
- Ultracet® (containing Acetaminophen, Tramadol)
- Uni-Case® (containing Acetaminophen, Aspirin, Caffeine)
- Uni-Perr® (containing Acetaminophen, Phenyltoloxamine)§
- Unisom With Pain Relief® (containing Acetaminophen, Diphenhydramine)
- Valorin Extra® (containing Acetaminophen, Caffeine)
- Vanaceit® (containing Acetaminophen, Hydrocodone)
- Vanquish® (containing Acetaminophen, Aspirin, Caffeine)
- Vendone® (containing Acetaminophen, Hydrocodone)
- Vicks 44 Cold, Flu and Cough® (containing Acetaminophen, Chlorpheniramine, Dextromethorphan, Pseudoephedrine)
- Vicodin® (containing Acetaminophen, Hydrocodone)
- Vidone® (containing Acetaminophen, Hydrocodone)
- Vistra® (containing Acetaminophen, Phenyltoloxamine)§
- Vitoxapap® (containing Acetaminophen, Phenyltoloxamine)§
- Xodol® (containing Acetaminophen, Hydrocodone)
- Xolox® (containing Acetaminophen, Oxycodone)
- Zamicet® (containing Acetaminophen, Oxycodone)
- Zflex® (containing Acetaminophen, Phenyltoloxamine)§
- Zgesic® (containing Acetaminophen, Phenyltoloxamine)§
- Zydone® (containing Acetaminophen, Hydrocodone)

Other names

- APAP
- N-acetyl-para-aminophenol
- Paracetamol

§ These products are not currently approved by the FDA for safety, effectiveness, and quality. Federal law generally requires that prescription drugs in the U.S. be shown to be both safe and effective prior to marketing. Please see the FDA website for more information on unapproved drugs (http://www.fda.gov/AboutFDA/Transparency/Basics/ucm213030.htm) and the approval process (http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm054420.htm).

¶ This branded product is no longer on the market. Generic alternatives may be available.

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