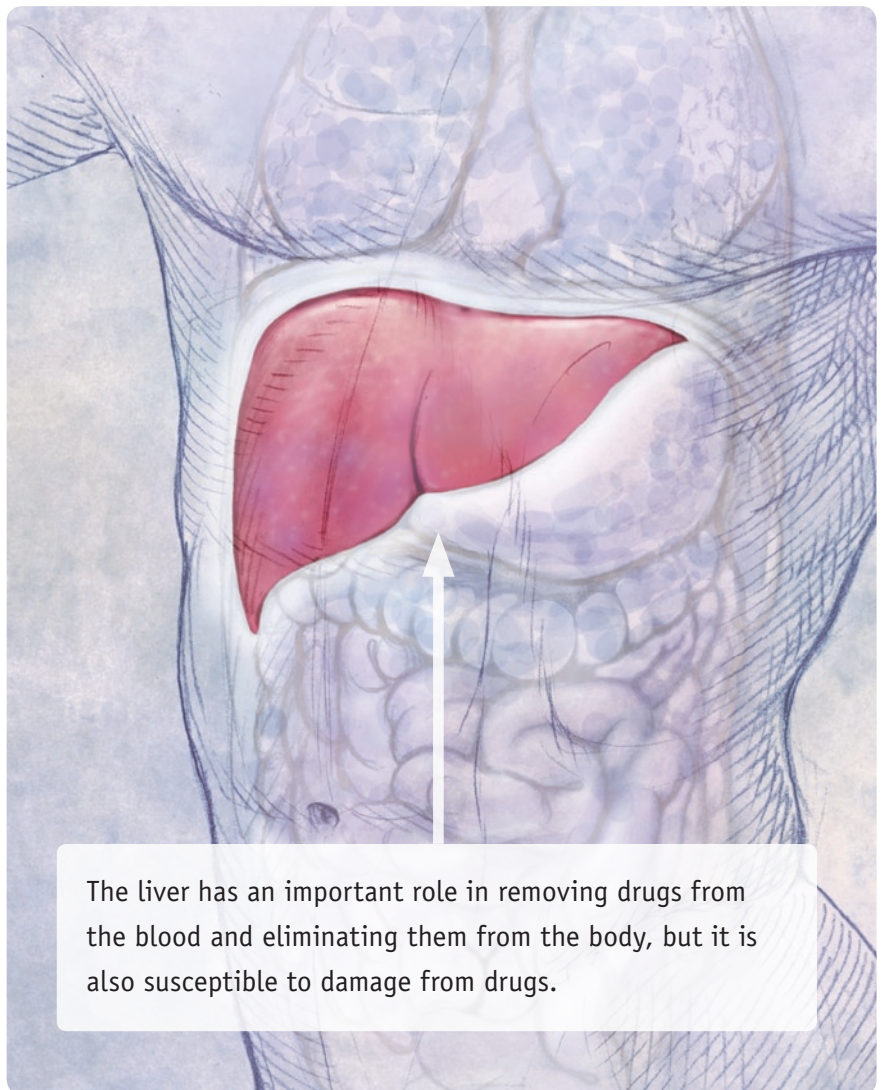


Acetaminophen and Liver Injury:

Q & A for Consumers

On June 29 and 30, 2009, FDA will hold an advisory committee meeting in Adelphi, Md., about how to address the problem of liver injury related to the use of acetaminophen in both over-the-counter (OTC) and prescription products. For more information about the meeting, visit www.fda.gov/AdvisoryCommittees/Calendar/ucm143083.htm

Acetaminophen is the generic name of a drug found in many common brand name OTC products such as Tylenol, as well as prescription products such as Vicodin and Percocet. Acetaminophen is an important drug, and its effectiveness in relieving pain and fever is widely known. This drug is generally considered safe when used according to the directions on its labeling. But taking more than the recommended amount can cause liver damage, ranging from abnormalities in liver function blood tests, to acute liver failure, and even death.



The liver has an important role in removing drugs from the blood and eliminating them from the body, but it is also susceptible to damage from drugs.

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Don't take more than one medicine that contains acetaminophen at a time.

Q: What is acetaminophen?

A: Acetaminophen (pronounced: a·seet·a·min·o·fen), is an active ingredient found in many OTC and prescription medicines to help relieve pain and reduce fever.

It is also found in combination with other active ingredients, called combination medicines, which treat conditions such as:

- symptoms of colds and flu
- allergy
- sleeplessness

Medicines containing acetaminophen are available in many forms, including drops, syrups, capsules, and pills.

Many people call OTC acetaminophen by a brand name, Tylenol. Others may know Percocet or Vicodin, which are prescription brand names that contain acetaminophen and other active ingredients to help relieve pain.

You might see acetaminophen abbreviated as "APAP" on prescription medicines.

In other countries, acetaminophen may have a different name. For example, acetaminophen is known as paracetamol in the United Kingdom.

Q. Are there risks from taking too much acetaminophen?

A: Yes, acetaminophen can cause serious liver damage if you take too much. It is very important to follow your doctor's directions and the directions on the medicine label.

You may not notice the signs and symptoms of liver damage right away because they take time to appear. Or, you may mistake early symptoms of

liver damage (for example, loss of appetite, nausea, and vomiting) for something else, like the flu. Liver damage can develop into liver failure or death over several days.

Acetaminophen is generally safe when taken as directed. To lower your risk of liver damage make sure you do the following:

- Follow dosing directions and never take more than directed; even a small amount more than directed can cause liver damage.
- Don't take acetaminophen for more days than directed.
- Don't take more than one medicine that contains acetaminophen at a time. For example, your risk of liver damage goes up if you take a medicine that contains acetaminophen to treat a headache, and while that medicine is still working in your body, you take another medicine that contains acetaminophen to treat a cold.

Q: How can I tell which medicines contain acetaminophen?

A: Medicines have ingredients listed on their labels. On OTC medicines, check the "Drug Facts" label under the section called Active Ingredients. If your medicine contains acetaminophen, it will be listed in this section. On prescription medicine containers, the label will say "acetaminophen" or "APAP."

Q: When should I talk to a doctor before taking acetaminophen?

A: Talk to your doctor before taking acetaminophen if you

- drink alcohol (three or more drinks every day)
- have liver disease

Under these conditions, taking acetaminophen puts you at greater risk of getting liver damage, even when taking acetaminophen at the recommended dose.

If you take the blood thinner warfarin, you should also talk to your doctor before taking acetaminophen because taking warfarin and acetaminophen together may raise your risk of bleeding.

Q: How can I safely take acetaminophen?

A: Follow this advice to take acetaminophen safely:

- Read all the information given to you by your doctor and follow directions.
- Read the information on the OTC "Drug Facts" label or on the prescription label and follow directions.
- Be sure you understand the following:
 - the dose, which is how much acetaminophen you can take at one time
 - how many hours you must wait before taking another dose of acetaminophen
 - how many doses of acetaminophen you can take safely each day
 - when to stop taking acetaminophen and ask a doctor for help
- Never take more than directed, even if your pain or fever isn't any better. Taking more acetaminophen than directed can put you at risk for liver damage.
- Never take more than one medicine that contains acetaminophen. Check the active ingredients of all your medicines to make sure you are taking no more than one medi-

Keep medicine where it can't be seen or reached by children and pets.

cine containing acetaminophen at a time.

Q: How can I safely give acetaminophen to my child?

A: You can safely give acetaminophen to infants, children, and teenagers if you

- Check the active ingredients in the other medicines that your child is taking (or that your child may take) to make sure they don't contain the active ingredient acetaminophen. Your child should never be taking more than one medicine containing acetaminophen at a time.
- Read all the information given by your child's doctor and follow directions.
- Read the information on the OTC "Drug Facts" label or on the prescription label and follow directions.
- Choose the right medicine based on your child's weight and age. On OTC medicines, the *Directions* section of the "Drug Facts" label tells you:
 - if the medicine is right for your child
 - how much medicine to give
 - how many hours you must wait before giving another dose
 - when to stop giving acetaminophen and ask a doctor for help
 If a dose for your child's weight or age is not listed on the label, or you can't tell how much to give, ask your pharmacist or doctor what to do.
- Use the measuring tool that comes with the medicine. It will give the exact dose. If you don't have the right measuring tool, ask a pharmacist. Don't use a spoon that's meant

to be used for cooking or eating. A spoon should not be used to measure medicine because it may give the wrong amount.

- Never give more than one medicine that contains acetaminophen. If you give more, it could harm your child.

Prevent medicine accidents:

- Keep a record of the medicines you give your child. Write down the dose and time when you give the medicine. This will help everyone who cares for your child know how much medicine your child has had. This will help everyone avoid giving an extra dose by mistake.
- Keep medicine where it can't be seen or reached by children and pets; a locked box, cabinet, or closet is best.

Q: What should I do if the pain or fever doesn't get better after taking acetaminophen as directed?

A: Take the medicine only as directed. Don't take more. If the medicine doesn't help you feel better, talk to your doctor, nurse, or pharmacist.

Q: What should I do if I took too much acetaminophen? What should I do if I gave too much acetaminophen to my child?

A: Don't wait! Call 9-1-1 or Poison Control at 1-800-222-1222 right away to find out what to do. The signs or symptoms of liver damage may not be noticeable for hours or even days after taking acetaminophen. By the time you notice changes, the liver damage may be severe and could lead to death.

Q: Where can I get more information on acetaminophen?

A:

- Talk to a doctor, nurse, or pharmacist.
- Visit FDA's consumer Web pages at:

www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/SafeUseofOver-the-CounterPainRelieversandFeverReducers/default.htm

A Guide to Safe Use of Pain Medicine

www.fda.gov/ForConsumers/ConsumerUpdates/ucm095673.htm

- Contact the FDA at 1-888-INFO-FDA.
- Or, email questions to FDA at druginfo@fda.hhs.gov

This article appears on FDA's Consumer Updates page (www.fda.gov/ForConsumers/ConsumerUpdates/default.htm), which features the latest on all FDA-regulated products.