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## Acetaminophen and Codeine

(a set a mee' noe fen) (koe' deen)

URL of this page: <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a601005.html>

### Notice:

[Posted 01/14/2014] **ISSUE:** FDA is recommending health care professionals discontinue prescribing and dispensing prescription combination drug products that contain more than 325 milligrams (mg) of acetaminophen per tablet, capsule or other dosage unit. There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death.

Cases of severe liver injury with acetaminophen have occurred in patients who:

1. took more than the prescribed dose of an acetaminophen-containing product in a 24-hour period
2. took more than one acetaminophen-containing product at the same time; or
3. drank alcohol while taking acetaminophen products.

**BACKGROUND:** In January 2011 FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage which can result from taking too much acetaminophen. This category of prescription drugs combines acetaminophen with another ingredient intended to treat pain (most often an opioid), and these products are commonly prescribed to consumers for pain, such as pain from acute injuries, post-operative pain, or pain following dental procedures.

Acetaminophen is also widely used as an over-the-counter (OTC) pain and fever medication, and is often combined with other ingredients, such as cough and cold ingredients. FDA will address OTC acetaminophen products in another regulatory action. Many consumers are often unaware that many products (both prescription and OTC) contain acetaminophen, making it easy to accidentally take too much.

More than half of manufacturers have voluntarily complied with the FDA request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

**RECOMMENDATION:** FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that they contact the prescriber to discuss a product with a lower dose of acetaminophen. A two tablet or two capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

Health care providers and pharmacists who have further questions are encouraged to contact the Division of Drug Information at 888.INFO.FDA (888-463-6332) or [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov).

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Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

For more information visit the FDA website at: <http://www.fda.gov/Safety/MedWatch/SafetyInformation> and <http://www.fda.gov/Drugs/DrugSafety>.

### Why is this medication prescribed?

This combination of drugs is used to relieve mild to moderate pain.

This medication is sometimes prescribed for other uses; ask your doctor or pharmacist for more information.

### How should this medicine be used?

The combination of acetaminophen and codeine comes as a tablet, capsule, and liquid to take by mouth. It usually is taken every 6 hours as needed. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take acetaminophen and codeine exactly as directed.

Codeine can be habit-forming. Do not take a larger dose, take it more often, or for a longer period than your doctor tells you to.

### What special precautions should I follow?

Before taking acetaminophen and codeine,

- tell your doctor and pharmacist if you are allergic to acetaminophen, codeine, sulfite or any other drugs.
- tell your doctor and pharmacist what prescription and nonprescription medications you are taking, especially acetaminophen (Tylenol); antidepressants; medications for cough, cold, or allergies; other pain relievers; sedatives, sleeping pills, tranquilizers; and vitamins.
- tell your doctor if you have or have ever had liver or kidney disease, a history of alcoholism, lung or thyroid disease, prostatic hypertrophy, or urinary retention.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking acetaminophen and codeine, call your doctor.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking acetaminophen and codeine.
- you should know that this drug may make you drowsy. Do not drive a car or operate machinery until you know how this drug affects you.
- remember that alcohol can add to the drowsiness caused by this drug.

### What should I do if I forget a dose?

This medication usually is taken as needed. If your doctor has told you to take acetaminophen and codeine 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 and codeine may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- dizziness
- lightheadedness

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- drowsiness
- upset stomach
- vomiting
- constipation
- stomach pain
- rash
- difficulty urinating

If you experience either of the following symptoms, call your doctor immediately:

- difficulty breathing
- mood changes

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.

## What other information should I know?

Keep all appointments with your doctor.

Too much acetaminophen may cause liver damage; do not take more than 4000 mg of acetaminophen per day.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

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 of combination products

- Capital<sup>®</sup> & Codeine (containing Acetaminophen, Codeine)
- Codrix<sup>®</sup> (containing Acetaminophen, Codeine)<sup>¶</sup>
- Empracet<sup>®</sup> (#3, #4) (containing Acetaminophen, Codeine)<sup>¶</sup>
- Fioricet<sup>®</sup> with Codeine (containing
- Phenaphen<sup>®</sup> with Codeine (#2, #3, #4) (containing Acetaminophen, Codeine)<sup>¶</sup>
- Phrenilin<sup>®</sup> with Caffeine, Codeine (containing Acetaminophen, Butalbital, Caffeine, Codeine)
- Proval<sup>®</sup> #3 (containing Acetaminophen, Codeine)<sup>¶</sup>

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- Acetaminophen, Butalbital, Caffeine, Codeine)
- Papa-deine® (#3, #4) (containing Acetaminophen, Codeine)<sup>¶</sup>
- Tylenol® with Codeine (#3, #4) (containing Acetaminophen, Codeine)

## Other names

- APAP and Codeine (containing Acetaminophen and Codeine)

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

Last Reviewed - 09/01/2010



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