

acetaminophen, butalbital, and caffeine

Pronunciation: a SEET a MIN oh fen, bue TAL bi tal, and KAF een

Brand: Esgic, Fioricet, Zebutal

What is the most important information I should know about acetaminophen, butalbital, and caffeine?

Do not use this medicine if you have used an MAO inhibitor in the past 14 days. A dangerous drug interaction could occur. MAO inhibitors include isocarboxazid, linezolid, methylene blue injection, phenelzine, and tranylcypromine.

Do not take more of this medication than is recommended. **An overdose of acetaminophen can damage your liver or cause death.** Call your doctor at once if you have nausea, pain in your upper stomach, itching, loss of appetite, dark urine, clay-colored stools, or jaundice (yellowing of your skin or eyes).

In rare cases, acetaminophen may cause a severe skin reaction. **Stop taking this medicine and call your doctor right away if you have skin redness or a rash that spreads and causes blistering and peeling.**

What is acetaminophen, butalbital, and caffeine?

Acetaminophen is a pain reliever and fever reducer.

Butalbital is in a group of drugs called barbiturates. It relaxes muscle contractions involved in a tension headache.

Caffeine is a central nervous system stimulant. It relaxes muscle contractions in blood vessels to improve blood flow.

Acetaminophen, butalbital, and caffeine is a combination medicine used to treat tension headaches that are caused by muscle contractions.

Acetaminophen, butalbital, and caffeine may also be used for purposes not listed in this medication guide.

What should I discuss with my healthcare provider before taking acetaminophen, butalbital, and caffeine?

Do not use this medicine if you have taken an MAO inhibitor in the past 14 days. A dangerous drug interaction could occur. MAO inhibitors include isocarboxazid, linezolid, phenelzine, rasagiline, selegiline, and tranylcypromine.

You should not use acetaminophen, butalbital, and caffeine if you are allergic to it, if you have porphyria, or if you have recently used alcohol, sedatives, tranquilizers, or other opioids.

Tell your doctor if you have ever had:

- liver disease, cirrhosis, a history of alcoholism or drug addiction, or if you drink more than 3 alcoholic beverages per day;
- kidney disease;
- stomach ulcer or bleeding;
- a history of skin rash caused by any medication; or

- a history of mental illness or suicidal thoughts.

It is not known whether this medicine will harm an unborn baby. **If you use butalbital while you are pregnant, your baby could become dependent on the drug.** This can cause life-threatening withdrawal symptoms in the baby after it is born. Babies born dependent on habit-forming medicine may need medical treatment for several weeks. Tell your doctor if you are pregnant or plan to become pregnant.

This medicine can pass into breast milk and may harm a nursing baby. Tell your doctor if you are breastfeeding a baby.

Not approved for use by anyone younger than 12 years old.

How should I take acetaminophen, butalbital, and caffeine?

Follow all directions on your prescription label. Do not take more of this medication than recommended. **An overdose can damage your liver or cause death.** Tell your doctor if the medicine seems to stop working as well in relieving your pain.

Butalbital may be habit-forming. **Never share this medicine with another person, especially someone with a history of drug abuse or addiction.** Keep the medication in a place where others cannot get to it. Selling or giving away this medicine is against the law.

Store at room temperature away from moisture and heat.

Keep track of the amount of medicine used from each new bottle. Butalbital is a drug of abuse and you should be aware if anyone is using your medicine improperly or without a prescription.

What happens if I miss a dose?

Since this medicine is used when needed, you may not be on a dosing schedule. If you are on a schedule, use the missed dose as soon as you remember. Skip the missed dose if it is almost time for your next scheduled dose. **Do not** use extra medicine to make up the missed dose.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222. **An overdose of acetaminophen, butalbital, and caffeine can be fatal.**

The first signs of an acetaminophen overdose include loss of appetite, nausea, vomiting, stomach pain, sweating, and confusion or weakness. Later symptoms may include pain in your upper stomach, dark urine, and yellowing of your skin or the whites of your eyes.

Overdose symptoms may also include insomnia, restlessness, tremor, diarrhea, increased shallow breathing, uneven heartbeats, seizure (convulsions), or fainting.

What should I avoid while taking acetaminophen, butalbital, and caffeine?

This medication can cause side effects that may impair your thinking or reactions. Be careful if you drive or do anything that requires you to be awake and alert.

Avoid drinking alcohol. It may increase your risk of liver damage while taking acetaminophen.

Ask a doctor or pharmacist before using any other cold, allergy, pain, or sleep medication. Acetaminophen

(sometimes abbreviated as APAP) is contained in many combination medicines. **Taking certain products together can cause you to get too much acetaminophen which can lead to a fatal overdose.** Check the label to see if a medicine contains acetaminophen or APAP.

While you are taking this medication, avoid taking diet pills, caffeine pills, or other stimulants (such as ADHD medications) without your doctor's advice.

What are the possible side effects of acetaminophen, butalbital, and caffeine?

Get emergency medical help if you have **signs of an allergic reaction**: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

In rare cases, acetaminophen may cause a severe skin reaction that can be fatal. This could occur even if you have taken acetaminophen in the past and had no reaction. **Stop taking this medicine and call your doctor right away if you have skin redness or a rash that spreads and causes blistering and peeling.** If you have this type of reaction, you should never again take any medicine that contains acetaminophen.

Stop using this medicine and call your doctor at once if you have:

- confusion, a seizure;
- shortness of breath;
- a light-headed feeling, like you might pass out; or
- nausea, upper stomach pain, itching, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes).

Common side effects may include:

- drowsiness, dizziness;
- feeling light-headed;
- nausea, vomiting, stomach pain;
- drunk feeling; or
- shortness of breath.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What other drugs will affect acetaminophen, butalbital, and caffeine?

Taking this medicine with other drugs that make you sleepy or slow your breathing can cause dangerous or life-threatening side effects. Ask your doctor before taking acetaminophen, butalbital, and caffeine with a sleeping pill, opioid pain medicine, muscle relaxer, or medicine for anxiety, depression, or seizures.

Other drugs may affect acetaminophen, butalbital, and caffeine, including prescription and over-the-counter medicines, vitamins, and herbal products. Tell your doctor about all other medicines you use.

Where can I get more information?

Your doctor or pharmacist can provide more information about acetaminophen, butalbital, and caffeine.

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.

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