



PATIENT & CAREGIVER EDUCATION

Butalbital, Acetaminophen, Caffeine, and Codeine

This information from Lexicomp® explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Fioricet/Codeine

Warning

- This drug has acetaminophen in it. Liver problems have happened with the use of acetaminophen. Sometimes, this has led to a liver transplant or death. Most of the time, liver problems happened in people taking more than 4,000 mg (milligrams) of acetaminophen in a day. People were also often taking more than 1 drug that had acetaminophen.
- This drug has an opioid drug in it. Opioid drugs can put you at risk for drug use disorder. Misuse or abuse of this drug can lead to overdose and death. If you have questions, talk with your doctor.
- Severe breathing problems may happen with this drug. The risk is highest when you first start taking this drug or any time your dose is raised. These breathing problems can be deadly. Call your doctor right away if you have slow, shallow, or trouble breathing.
- Even one dose of this drug may be deadly if it is taken by someone else or by accident, especially in children. If this drug is taken by someone else or by accident, get medical help right away.

- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Severe side effects have happened when opioid drugs were used with benzodiazepines, alcohol, marijuana, other forms of cannabis, or street drugs. This includes severe drowsiness, breathing problems, and death. Benzodiazepines include drugs like alprazolam, diazepam, and lorazepam. If you have questions, talk with the doctor.
- Many drugs interact with this drug and can raise the chance of side effects like deadly breathing problems. Talk with your doctor and pharmacist to make sure it is safe to use this drug with all of your drugs.
- Get medical help right away if you feel very sleepy, very dizzy, or if you pass out. Caregivers or others need to get medical help right away if the patient does not respond, does not answer or react like normal, or will not wake up.
- If you are pregnant or plan to get pregnant, talk with your doctor right away about the benefits and risks of using this drug during pregnancy. Using this drug for a long time during pregnancy may lead to withdrawal in the newborn baby. Withdrawal in the newborn can be life-threatening if not treated.
- This drug is not approved for use in children. Severe and sometimes deadly breathing problems have happened with codeine in children. Most often, this happened after surgery to remove tonsils or adenoids and in children who were rapid metabolizers of codeine. Do not give to a child younger than 12 years of age. Do not give to a child younger than 18 years of age who is very overweight, has certain health problems like sleep apnea or other lung or breathing problems, or has had surgery to remove tonsils or adenoids. If your child has been given this drug, ask the doctor about the benefits and risks.

What is this drug used for?

- It is used to treat tension headaches when non-opioid drugs do not treat the headache well enough or you cannot take them.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have any of these health problems: Lung or breathing problems like asthma, trouble breathing, or sleep apnea; high levels of carbon dioxide in the blood; or stomach or bowel block or narrowing.
- If you have any of these health problems: Liver disease or porphyria.
- If you have taken certain drugs for depression or Parkinson's disease in the last 14 days. This includes isocarboxazid, phenelzine, tranylcypromine, selegiline, or rasagiline. Very high blood pressure may happen.
- If you are taking any of these drugs: Buprenorphine, butorphanol, linezolid, methylene blue, nalbuphine, or pentazocine.
- If you have been told by your doctor that you are a rapid metabolizer of some drugs.
- If you are breast-feeding. Do not breast-feed while you take this drug.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.
- To lower the chance of feeling dizzy or passing out, rise slowly if you have been sitting or lying down. Be careful going up and down stairs.
- Avoid taking other products that have acetaminophen in them. Check labels closely. Too much acetaminophen may cause liver problems.
- Follow the directions exactly. Do not take more acetaminophen in a day than directed. If you do not know how much acetaminophen you can take in a day, ask your doctor or pharmacist. Some people may take up to 4,000 mg (milligrams) in a day if told to do so by the doctor. Some people (like people with liver problems and children) should take less acetaminophen. Call your doctor right away if you have taken too much acetaminophen in a day, even if you feel well.
- Do not take with alcohol or products that have alcohol. Unsafe and sometimes deadly effects may happen.
- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- Be careful if you have low levels of an enzyme called G6PD. Anemia may happen. Low levels of G6PD may be more likely in patients of African, South Asian, Middle Eastern, and Mediterranean descent.
- Limit your use of caffeine (for example, tea, coffee, cola) and chocolate. Use with this drug may cause nervousness, shakiness, and a fast heartbeat.
- This drug may raise the chance of seizures in some people, including people who have had seizures in the past. Talk to your doctor to see if you have a greater chance of seizures while taking this drug.
- Long-term use of an opioid drug may lead to lower sex hormone levels.

Call your doctor if you have a lowered interest in sex, fertility problems, no menstrual period, or ejaculation problems.

- Taking an opioid drug like this drug may lead to a rare but severe adrenal gland problem. Call your doctor right away if you feel very tired or weak, you pass out, or you have severe dizziness, very upset stomach, throwing up, or decreased appetite.
- A severe skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It can cause severe 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.
- If you are 65 or older, use this drug with care. You could have more side effects.
- The chance of very bad side effects may be higher in children. This may be more likely to happen in children who have breathing problems. Deadly breathing problems have happened with the use of codeine in some children. Talk with the doctor.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat. Rarely, some allergic reactions have been life-threatening.
- Signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.

- Signs of kidney problems like unable to pass urine, change in how much urine is passed, blood in the urine, or a big weight gain.
- Signs of low blood sugar like dizziness, headache, feeling sleepy, feeling weak, shaking, a fast heartbeat, confusion, hunger, or sweating.
- Trouble breathing, slow breathing, or shallow breathing.
- Noisy breathing.
- Breathing problems during sleep (sleep apnea).
- Severe dizziness or passing out.
- Feeling confused.
- Severe constipation or stomach pain. These may be signs of a severe bowel problem.
- Fever, chills, or sore throat; any unexplained bruising or bleeding; or feeling very tired or weak.
- Mood changes.
- Seizures.
- Chest pain or pressure or a fast heartbeat.
- Shakiness.
- Feeling sluggish, drunk, or out of sorts.
- A severe and sometimes deadly problem called serotonin syndrome may happen if you take this drug with certain other drugs. Call your doctor right away if you have agitation; change in balance; confusion; hallucinations; fever; fast or abnormal heartbeat; flushing; muscle twitching or stiffness; seizures; shivering or shaking; sweating a lot; severe diarrhea, upset stomach, or throwing up; or severe headache.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Stomach pain.
- Upset stomach or throwing up.
- Constipation.
- Feeling dizzy, sleepy, tired, or weak.
- Headache.
- Feeling nervous and excitable.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at <https://www.fda.gov/medwatch>.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take by mouth only.
- Take with or without food. Take with food if it causes an upset stomach.
- Drink lots of noncaffeine liquids unless told to drink less liquid by your doctor.
- Keep a diary of your headaches.
- Do not inject or snort this drug. Doing any of these things can cause very bad side effects like trouble breathing and death from overdose.
- If you drink grapefruit juice or eat grapefruit often, talk with your doctor.
- If you have been taking this drug for a long time or at high doses, it may not work as well and you may need higher doses to get the same effect. This is known as tolerance. Call your doctor if this drug stops working well. Do not take more than ordered.

- Long-term or regular use of opioid drugs like this drug may lead to dependence. Lowering the dose or stopping this drug all of a sudden may cause a greater risk of withdrawal or other severe problems. Talk to your doctor before you lower the dose or stop this drug. You will need to follow your doctor's instructions. Tell your doctor if you have more pain, mood changes, thoughts of suicide, or any other bad effects.
- If you are allergic to tartrazine (FD&C Yellow No. 5), talk with your doctor. Some products have tartrazine.
- Do not take more than what your doctor told you to take. Do not take more often or for longer than you were told. Doing any of these things may raise the chance of severe side effects.
- Do not take this drug with other strong pain drugs or if you are using a pain patch without talking to your doctor first.
- If your pain gets worse, if you feel more sensitive to pain, or if you have new pain after you take this drug, call your doctor right away. Do not take more than ordered.

What do I do if I miss a dose?

- If you take this drug on a regular basis, take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.
- Many times this drug is taken on an as needed basis. Do not take more often than told by the doctor.

How do I store and/or throw out this drug?

- Store at room temperature in a dry place. Do not store in a bathroom.
- Store this drug in a safe place where children cannot see or reach it, and where other people cannot get to it. A locked box or area may help keep this drug safe. Keep all drugs away from pets.

- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, pharmacist, or other health care provider.
- A drug called naloxone can be used to help treat an overdose of this drug. Talk with your doctor or pharmacist about how to get or use naloxone. If you think there has been an overdose, get medical care right away even if naloxone has been used. Be ready to tell or show what was taken, how much, and when it happened.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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