Memorial Sloan Kettering Cancer Center

PATIENT & CAREGIVER EDUCATION

Butalbital, Aspirin, 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

Ascomp-Codeine; Fiorinal/Codeine #3 [DSC]

Brand Names: Canada

Fiorinal-C 1/2; Fiorinal-C 1/4; TEVA-Tecnal C1/2; TEVA-Tecnal C1/4; Trianal C 1/2 [DSC]; Trianal C1/4 [DSC]

Warning
For all patients taking this drug:

- This drug is a strong pain drug that can put you at risk for addiction, abuse, and misuse. Misuse or abuse of this drug can lead to overdose and death. Talk with your doctor.
- You will be watched closely to make sure you do not misuse, abuse, or become addicted to this

drug.

- This drug may cause very bad and sometimes deadly breathing problems. Call your doctor right away if you have slow, shallow, or trouble breathing.
- The chance of very bad and sometimes deadly breathing problems may be greater when you first start this drug or anytime your dose is raised.
- 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.
- Using this drug for a long time during pregnancy may lead to withdrawal in the newborn baby. Withdrawal can be life-threatening if not treated.
- This drug has an opioid drug in it. Severe side effects have happened when opioid drugs were used with benzodiazepines, alcohol, marijuana or other forms of cannabis, or prescription or OTC drugs that may cause drowsiness or slowed actions. This includes slow or troubled breathing and death. Benzodiazepines include drugs like

alprazolam, diazepam, and lorazepam. Benzodiazepines may be used to treat many health problems like anxiety, trouble sleeping, or seizures. 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.
- Do not take with alcohol or products that have alcohol. Unsafe and sometimes deadly effects may happen.
- 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.

Children:

- 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.

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 gotten nasal polyps or had swelling of the mouth, face, lips, tongue, or throat; unusual hoarseness; or trouble breathing with aspirin or NSAID use.
- 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 hemophilia.
- If you have Reye’s syndrome.
- If you have kidney disease.
- 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 are taking probenecid.
- If you are taking any other NSAID.
- If you have been told by your doctor that you are a rapid metabolizer of some drugs.
- If you are pregnant, plan to become pregnant, or get pregnant while taking this drug. This drug may cause harm to an unborn baby if taken at 20 weeks or later in pregnancy. If you are between 20 to 30 weeks of pregnancy, only take this drug if your doctor has told you to. Do not take this drug if you are more than 30 weeks pregnant.
- 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.
- You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor.
- If you are taking aspirin to help prevent a heart

attack, talk with your doctor.

- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- Do not take this drug with other strong pain drugs or if you are using a pain patch without talking to your doctor first.
- Limit your use of caffeine (for example, tea, coffee, cola) and chocolate. Use with this drug may cause nervousness, shakiness, and a fast heartbeat.
- 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.
- 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.
- 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.
- A severe and sometimes deadly reaction has happened

with drugs like this one. Most of the time, this reaction has signs like fever, rash, or swollen glands with problems in body organs like the liver, kidney, blood, heart, muscles and joints, or lungs. If you have questions, talk with the doctor.

- 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.
- Do not give to children and teenagers who have or are getting better from flu signs, chickenpox, or other viral infections due to the chance of Reye's syndrome. Reye's syndrome causes very bad problems to the brain and liver.

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.
- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.
- Noisy breathing.
- Breathing problems during sleep (sleep apnea).
- Very bad dizziness or passing out.
- Feeling confused.
- Chest pain or pressure or a fast heartbeat.
- Any unexplained bruising or bleeding.
- Ringing in ears.
- Seizures.
- Severe constipation or stomach pain. These may be signs of a severe bowel problem.
- Mood changes.
- Swollen gland.
- Fever.

- 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.
- Very bad stomach ulcers or bleeding can happen with this drug. Taking it in high doses or for a long time, smoking, or drinking alcohol raises the chance of these side effects. Taking this drug with food will not lower the chance of these effects. Call your doctor or get medical help right away if you get very bad stomach or back pain; black, tarry, or bloody stools; throwing up blood or throw up that looks like coffee grounds; or weight gain or swelling that is not normal.

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:

- Constipation.

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

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.
- 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.

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 protected from light. Store 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. Your doctor may order naloxone for you to keep with you while you take this drug. If

you have questions about how to get or use naloxone, talk with your doctor or pharmacist. If you think there has been an overdose, get medical care right away even if naloxone has been used.

- 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 on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not

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If you have any questions, contact a member of your care team directly. If you're a patient at MSK and you need to reach a provider after 5 p.m., during the weekend, or on a holiday, call 212-639-2000.

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

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