

Palmetto State Pharmaceuticals

Patient Drug Education

FIORICET TABLET

USES:

This combination medication is used to treat tension headaches. Acetaminophen helps to decrease the pain from the headache. Caffeine helps increase the effects of acetaminophen. Butalbital is a sedative that helps to decrease anxiety and cause sleepiness and relaxation.

HOW TO TAKE THIS MEDICATION:

HOW TO USE: Take this medication by mouth with or without food, usually every 4 hours as needed or as directed by your doctor. The dosage is based on your medical condition and response to therapy. This medication works best if it is used as the first signs of a headache occur. If you wait until the headache has worsened, the medication may not work as well. This medication may cause dependence, especially if it has been used regularly for an extended time or if it has been used in high doses. In such cases, withdrawal reactions (e.g., nausea/vomiting, mental/mood changes, seizures) may occur if you suddenly stop this drug. To prevent withdrawal reactions when stopping extended, regular treatment with this drug, gradually reduce the dosage as directed. Consult your doctor or pharmacist for more details, and report any withdrawal reactions immediately. Though very unlikely, abnormal drug-seeking behavior (addiction) is possible with this medication. To lessen the risk of becoming addicted, do not increase your dose, take it more frequently, or take it for a longer time than prescribed. Properly stop the medication when so directed. This medication contains acetaminophen. Do not take more acetaminophen than recommended. (See also Side Effects, Drug Interactions sections.) Inform your doctor if you notice increased use of this medication, a worsening of headaches, an increase in the number of headaches, the medication not working as well, or use of this medication for more than 2 headache episodes a week. Your doctor may need to change your medication and/or add a separate medication to prevent the headaches.

SIDE EFFECTS:

Nausea, vomiting, abdominal pain, shaking (tremor), shortness of breath, lightheadedness, dizziness, or drowsiness may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. To lower your risk of dizziness and lightheadedness, get up slowly when rising from a sitting or lying position. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: mental/mood changes, fainting, seizure, fast/irregular heartbeat, increased thirst/urination. Tell your doctor immediately if any of these rare but very serious side effects occur: signs of infection (e.g., fever, persistent sore throat), easy bruising/bleeding, change in the amount of urine. If you do not have liver problems, the adult maximum dose of acetaminophen is 4 grams per day (4000 milligrams). If you take more than the maximum daily amount, it may cause serious (possibly fatal) liver disease. Tell your doctor immediately if you have any of the following symptoms of liver damage: persistent nausea/vomiting, yellowing eyes/skin, dark urine, severe stomach/abdominal pain, extreme tiredness. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS:

Before taking this medication, tell your doctor or pharmacist if you are allergic to acetaminophen, caffeine, or butalbital; or to other barbiturates (e.g., phenobarbital) or xanthine derivatives (e.g., theophylline); or if you have any other allergies. This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: severe breathing problems (e.g., bronchopneumonia), a certain enzyme disorder (porphyria). Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver disease, kidney disease, personal or family history of regular use/abuse of drugs/alcohol, mental/mood disorders, abdominal/stomach problems (e.g., stomach ulcer), heart disease (e.g., irregular heartbeat, recent heart attack). This drug may make you dizzy or drowsy. Use caution while driving, using machinery, or taking part in any other activity that requires alertness. Avoid alcoholic beverages because they may increase the risk of this drug's side effects. Before having surgery, tell your doctor or dentist that you are using this medication. This product contains acetaminophen, which may cause liver damage. Daily use of alcohol, especially when combined with acetaminophen, may increase your risk for liver damage. Check with your doctor or pharmacist for more information. Kidney function declines as you grow older. This medication is removed by the kidneys. Therefore, elderly people may be at greater risk for side effects while using this drug. During pregnancy, this medication should be used only when clearly needed. Using it for long periods or in high doses near the expected delivery date is not recommended because of possible harm to the unborn baby. Discuss the risks and benefits with your doctor. Infants born to mothers who have used this medication for an extended time may have withdrawal symptoms such as irritability, abnormal/persistent crying, vomiting, seizures, or diarrhea. Tell your doctor immediately if you notice any of these symptoms in your newborn. This drug passes into breast milk and could have undesirable effects on a nursing infant. Therefore, breast-feeding is not recommended while using this drug. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Your doctor or pharmacist may already be aware of any possible drug interactions and may be monitoring you for them. Do not start, stop, or change the dosage of any medicine before checking with them first. This drug should not be used with the following medications because very serious interactions may occur: sodium oxybate. If you are currently using the medication listed above, tell your doctor or pharmacist before starting this medication. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: adenosine, anti-seizure drugs (e.g., carbamazepine, phenytoin), beta agonists (e.g., albuterol), drugs affecting liver enzymes that remove this medication from your body (such as macrolide antibiotics including erythromycin, cimetidine, disulfiram, valproic acid, fluvoxamine, MAO inhibitors including furazolidone,

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isocarboxazid, linezolid, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, tranylcypromine), isoniazid, lithium, methoxyflurane, phenothiazines (e.g., chlorpromazine). This drug can speed up the removal of other drugs from your body by affecting certain liver enzymes. These affected drugs include "blood thinners" (e.g., warfarin), cyclosporine, corticosteroids such as prednisone, estrogen, felodipine, metronidazole, quinidine, certain beta blockers such as metoprolol, theophylline, doxycycline. Tell your doctor or pharmacist if you also take drugs that cause drowsiness such as certain antihistamines (e.g., diphenhydramine), medicine for sleep or anxiety (e.g., alprazolam, diazepam, zolpidem), muscle relaxants, narcotic pain relievers (e.g., codeine), psychiatric medicines (e.g., risperidone, amitriptyline, trazodone). Check the labels on all your medicines (e.g., cough-and-cold products) because they may contain caffeine or drowsiness-causing ingredients. Also keep in mind that certain beverages (e.g., coffee, colas, tea) contain caffeine. Ask your pharmacist about using those products safely. Acetaminophen is an ingredient in many nonprescription products and in some combination prescription medications. Read the labels carefully before taking other pain relievers, fever reducers, or cold products to see if they also contain acetaminophen. Consult your pharmacist if you are uncertain whether your other prescription or nonprescription products contain acetaminophen. (See also adult maximum daily dose information in Side Effects section.) This medication may decrease the effectiveness of combination-type birth control pills. This can result in pregnancy. Ask your doctor or pharmacist for details, and discuss whether you should use additional reliable birth control methods while taking any of these drugs. This medication may interfere with certain medical/laboratory tests (including urine 5-HIAA levels, urine VMA levels, urine catecholamine levels, dipyridamole-thallium imaging tests), possibly causing false test results. Make sure laboratory personnel and all your doctors know you use this drug.

NOTES:

Do not share this medication with others. Massage, hot baths, and other relaxation methods can help with tension headaches. Consult your doctor or pharmacist for more details. Laboratory and/or medical tests (e.g., liver and kidney function tests) may be performed periodically to monitor your progress or check for side effects. Consult your doctor for more details.

MISSED DOSE:

Not applicable.

STORAGE:

Store at room temperature below 86 degrees F (30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.