

Brightside Specialty Pharmacy

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Patient Education for BUTALBITAL-ASPIRIN-CAFFEINE CP



Call doctor if symptoms of GI bleeding Diagnosis recommended before use in children Not recommended during pregnancy or breast feeding Many drug-drug interactions possible with this drug May cause drowsiness or dizziness Use caution driving. May reduce effectiveness of hormonal contraceptives. Alcohol and nicotine can irritate the gastrointestinal system. Swallow whole with 8 oz. water. Remain erect for 10 minutes.

Call Dr if you have black stools or stomach pain Not recommended for use in children Do not take while breast feeding or when pregnant Review all drugs you are taking with your doctor May make you drowsy or dizzy. Drive with caution May reduce effectiveness of hormone contraceptives Avoid alcohol consumption and stop using tobacco. Swallow whole with water. Do not lie down for 10min

.....Education Section.....

IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

BUTALBITAL/ASPIRIN/CAFFEINE - ORAL

(bue-TAL-bi-tal/AS-pir-in/KAF-een)

COMMON BRAND NAME(S):

Fiorinal

USES:

This combination medication is used to treat tension

headaches. Aspirin helps to decrease the pain from the headache. Caffeine helps increase the effects of aspirin. Butalbital is a sedative that helps to decrease anxiety and cause sleepiness and relaxation.

OTHER USES:

This section contains uses of this drug that are not

listed in the approved professional labeling for the drug but that may be prescribed by your health care professional. Use this drug for a condition that is listed in this section only if it has been so prescribed by your health care professional.

This drug may also be used for migraine headaches.

HOW TO USE:

Take this medication by mouth, usually every 4 hours

as needed or as directed by your doctor. Do not take more than 6 capsules/tablets in a 24-hour period. Take with a full glass of water (8 ounces or 240 milliliters) unless your doctor directs you otherwise. Do not lie down for at least 10 minutes after taking this medication. To help prevent stomach upset, take it with food or milk.

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.

If you suddenly stop using this medication, you may have withdrawal symptoms (such as nausea/vomiting, mental/mood changes, seizures). To help prevent withdrawal, your doctor may lower your dose slowly. Withdrawal is more likely if you have used this medication for a long time or in high doses. Tell your doctor or pharmacist right away if you have withdrawal.

Though it helps many people, this medication may sometimes cause addiction. This risk may be higher if you have a substance use disorder (such as overuse of or addiction to drugs/alcohol). Do not increase your dose, take it more often, or use it for a longer time than prescribed. Use the smallest effective dose. Properly stop the medication when so directed.

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, stomach upset, gas, shaking

(tremor), lightheadedness, dizziness, or drowsiness may occur. If any of these effects last or get worse, tell 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 this medication has been prescribed because your doctor 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 right away if you have any serious side effects, including: mental/mood changes, fainting, fast/irregular heartbeat, increased thirst/urination, hearing changes (such as ringing in the ears), easy bruising/bleeding, heartburn, discomfort when swallowing, dark urine, yellowing eyes/skin, signs of kidney problems (such as change in the amount of urine), unusual tiredness.

Get medical help right away if you have any very serious side effects, including: black stools, severe stomach/abdominal pain, vomit that looks like coffee grounds, trouble speaking, weakness on one side of the body.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: fever, swollen lymph nodes, rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS:

Before taking this medication, tell your doctor or

pharmacist if you are allergic to aspirin, caffeine, or butalbital; or to other barbiturates (such as phenobarbital), salicylates (such as salsalate), nonsteroidal anti-inflammatory drugs (such as ibuprofen), or xanthine derivatives (such as theophylline); or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: breathing problems (such as bronchopneumonia), a certain enzyme disorder (porphyria), asthma (including a history of worsening breathing with runny/stuffy nose after taking aspirin or other NSAIDs), stomach/bowel problems (such as stomach/intestinal ulcers), bleeding/blood clotting disorders (such as hemophilia, von Willebrand's disease, thrombocytopenia), liver disease, kidney disease, heartburn, gout, growths in the nose (nasal polyps), personal or family history of a substance use disorder (such as overuse of or addiction to drugs/alcohol), certain enzyme deficiencies (pyruvate kinase or G6-PD deficiency), mental/mood disorders, heart disease (such as irregular heartbeat, recent heart attack).

Before having surgery or certain medical procedures (such as a heart stress test or a procedure to restore a normal heart rhythm if you have an unusually fast heartbeat), tell your doctor or dentist that you use this medication and about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

This drug may make you dizzy or drowsy. Alcohol or marijuana (cannabis) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Avoid alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis).

This medicine may cause stomach bleeding. Daily use of alcohol and tobacco, especially when combined with this medicine, may increase your risk for stomach bleeding. Limit alcohol and stop

smoking. Consult your doctor or pharmacist for more information.

This medication contains aspirin. Children and teenagers less than 18 years old should not take aspirin if they have chickenpox, flu, or any undiagnosed illness, or if they have just been given a live virus vaccine, without first consulting a doctor about Reye's syndrome, a rare but serious illness.

Older adults may be more sensitive to the side effects of this drug, especially drowsiness, stomach/intestinal bleeding and ulcers, and trouble falling asleep. Drowsiness and trouble falling asleep can increase the risk of falling.

Before using this medication, women of childbearing age should talk with their doctor(s) about the benefits and risks. Tell your doctor if you are pregnant or if you plan to become pregnant. This medication may harm an unborn baby and cause problems with normal labor/delivery. It is not recommended for use in pregnancy from 20 weeks until delivery. If your doctor decides that you need to use this medication between 20 and 30 weeks of pregnancy, you should use the lowest effective dose for the shortest possible time. You should not use this medication after 30 weeks of pregnancy.

This drug passes into breast milk and could have undesirable effects on a nursing infant. Breast-feeding is not recommended while using this drug. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Drug interactions may change how your

medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug include: acetazolamide, darunavir, dichlorphenamide, ketorolac, lithium, 6-mercaptopurine, methotrexate, methoxyflurane, mifepristone, phenytoin, sodium oxybate, certain antibiotics (including penicillin, sulfonamides such as sulfamethoxazole), certain drugs used to treat gout (including uricosuric drugs such as probenecid, sulfinpyrazone).

This medication may increase the risk of bleeding when taken with other drugs that also may cause bleeding. Examples include anti-platelet drugs such as clopidogrel, "blood thinners" such as dabigatran/enoxaparin/warfarin, among others.

This drug can speed up the removal of other drugs from your body by affecting certain liver enzymes. These affected drugs include doxycycline, estrogen, felodipine, lonafarnib, quinidine, rilpivirine, tamoxifen, theophylline, voriconazole, certain beta blockers (such as metoprolol), corticosteroids (such as prednisone), among others.

Tell your doctor or pharmacist if you are taking other products that cause drowsiness such as opioid pain or cough relievers (such as codeine, hydrocodone), alcohol, marijuana (cannabis), other drugs for sleep or anxiety (such as alprazolam, lorazepam, zolpidem), muscle relaxants (such as carisoprodol, cyclobenzaprine), or antihistamines (such as cetirizine, diphenhydramine).

Check the labels on all your medicines (allergy or

cough-and-cold products, other headache medications) because they may contain aspirin, caffeine, or ingredients that cause drowsiness. Also keep in mind that certain beverages (such as coffee, colas, tea) contain caffeine. Ask your pharmacist about using those products safely.

Also, check all prescription and nonprescription medicine labels carefully since many medications contain pain relievers/fever reducers (NSAIDs such as ibuprofen, naproxen, aspirin) that may increase your risk for side effects if taken together with this medication. However, if your doctor has directed you to take low-dose aspirin to prevent heart attack or stroke (usually 81-162 milligrams a day), you should continue taking the aspirin unless your doctor instructs you otherwise. Ask your doctor or pharmacist for more details.

This medication may decrease the effectiveness of hormonal birth control such as pills, patch, or ring. This could cause pregnancy. Discuss with your doctor or pharmacist if you should use additional reliable birth control methods while using this medication. Also tell your doctor if you have any new spotting or breakthrough bleeding, because these may be signs that your birth control is not working well.

This medication may interfere with certain medical/laboratory tests (including fasting blood glucose, cholesterol levels, prothrombin time, urine 5-HIAA levels, urine VMA levels, certain urine glucose tests, dipyridamole-thallium imaging tests), possibly causing false test results. Make sure laboratory personnel and all your doctors know you use this drug.

OVERDOSE:

If someone has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: nausea/vomiting that doesn't stop, severe drowsiness, slow breathing, severe dizziness, ringing in the ears.

NOTES:

Do not share this medication with others. Sharing it is against the law.

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 (such as 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 away from light and moisture.

Do not store in the bathroom. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a

drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

Information last revised March 2022.

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