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Efavirenz Capsule

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Description

Side Effects Dizziness, trouble sleeping, drowsiness, unusual dreams, and trouble concentrating may often occur. These side effects may begin 1-2 days after starting this medication and usually go away in 2-4 weeks. They are also reduced by taking efavirenz on an empty stomach at bedtime. Avoid alcohol and street drugs while taking efavirenz. They may worsen these side effects. Tiredness, headache, nausea, vomiting, and diarrhea may also occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly. 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. As your immune system gets stronger, it can begin to fight off infections you already had, possibly causing disease symptoms to come back. You could also have symptoms if your immune system becomes overactive. This reaction may happen at any time (soon after starting HIV treatment or many months later). Get medical help right away if you have any serious symptoms, including: unexplained weight loss, severe tiredness, muscle aches/weakness that doesn't go away, headaches that are severe or don't go away, joint pain, numbness/tingling of the hands/feet/arms/legs, vision changes, signs of infection (such as fever, chills, swollen lymph nodes, trouble breathing, cough, non-healing skin sores), signs of an overactive thyroid (such as irritability, nervousness, heat intolerance, fast/pounding/irregular heartbeat, bulging eyes, unusual growth in the neck/thyroid known as a goiter), signs of a certain nerve problem known as Guillain-Barre syndrome (such as unsteadiness, loss of coordination, trouble swallowing/speaking/chewing, trouble moving your eyes). Tell your doctor right away if you have any serious side effects, including: signs of liver problems (such as nausea/vomiting that doesn't stop, stomach/abdominal pain, severe tiredness, yellowing eyes/skin, dark urine), mental/mood changes (such as depression, rare thoughts of suicide, nervousness, angry behavior, hallucinations, confusion), loss of coordination. Changes in body fat may occur while you are taking this medication (such as increased fat in the upper back and stomach areas, decreased fat in the arms and legs). The cause and long-term effects of these changes are unknown. Discuss the risks and benefits of treatment with your doctor, as well as the possible use of exercise to reduce this side effect. Get medical help right away if you have any very serious side effects, including: fast/irregular heartbeat, severe dizziness, fainting. Efavirenz can commonly cause a rash that is usually not serious. In adults, a rash may occur in the first 2 weeks after starting treatment and if it is not serious, it will usually resolve in 4 weeks. In children, a rash may occur in the first 4 weeks after starting treatment. However, you may not be able to tell it apart from a rare rash that could be a sign of a severe reaction. Get medical help right away if you develop any rash. 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: rash, blisters, peeling skin, fever, 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.

Uses This drug is used with other HIV medications to help control HIV infection. It helps to decrease the amount of HIV in your body so your immune system can work better. This lowers your chance of getting HIV complications (such as new infections, cancer) and improves your quality of life. Efavirenz belongs to a class of drugs known as non-nucleoside reverse transcriptase inhibitors (NNRTIs). Efavirenz is not a cure for HIV infection. To decrease your risk of spreading HIV disease to others, continue to take all HIV medications exactly as prescribed by your doctor. Use an effective barrier method (latex or polyurethane condoms/dental dams) during sexual activity as directed by your doctor. Do not share personal items (such as needles/syringes, toothbrushes, and razors) that may have contacted blood or other body fluids. Consult your doctor or pharmacist for more details.

How to use Efavirenz Capsule Read the Patient Information Leaflet if available from your pharmacist before you start taking efavirenz and each time you get a refill. If you have any questions, ask your doctor or pharmacist. Take this medication by mouth on an empty stomach as directed by your doctor, usually once daily at bedtime. Taking efavirenz with food increases the blood level of this medication, which may increase your risk of certain side effects. See Side Effects section. Swallow this medication whole with water. If you have difficulty swallowing the capsule, it may be opened and the contents mixed gently in a small amount (1 to 2 teaspoons) of soft food such as applesauce, grape jelly, or yogurt. After taking the mixed medication, add 2 more teaspoons of food to the empty mixing container. Swallow the remaining mixture to make sure that you get the entire dose. Swallow within 30 minutes of mixing. Do not eat any food for 2 hours after taking this medication. For babies who cannot eat solid foods, the contents may be mixed in 2 teaspoons of infant formula and drawn up into an oral syringe to be given to the baby. (See Patient Information Leaflet.) The dosage is based on your medical condition, response to treatment, and other medications you may be taking. Be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). In children, the dosage is also based on weight. It is very important to continue taking this medication (and other HIV medications) exactly as prescribed by your doctor. Do not skip any doses. Do not increase your dose, take this drug more often than prescribed, or stop taking it (or other HIV medicines) even for a short time unless directed to do so by your doctor. Skipping or changing your dose without approval from your doctor may cause the amount of virus to increase, make the infection more difficult to treat (resistant), or worsen side effects. For the best effect, take this medication at evenly spaced times. To help you remember, take this medication at the same time every day.

Precautions Before taking efavirenz, tell your doctor or pharmacist if you are allergic to it; 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: mental/mood conditions (such as depression, thoughts of suicide, psychosis), liver problems (such as hepatitis B or C, cirrhosis), drug/substance/alcohol abuse, seizures, high cholesterol/triglyceride levels. Efavirenz may cause a condition that affects the heart rhythm (QT prolongation). QT prolongation can rarely cause serious (rarely fatal) fast/irregular heartbeat and other symptoms (such as severe dizziness, fainting) that need medical attention right away. The risk of QT prolongation may be increased if you have certain medical conditions or are taking other drugs that may cause QT prolongation. Before using efavirenz, tell your doctor or pharmacist of all the drugs you take and if you have any of the following conditions: certain heart problems (heart failure, slow heartbeat, QT prolongation in the EKG), family history of certain heart problems (QT prolongation in the EKG, sudden cardiac death). Low levels of potassium or magnesium in the blood may also increase your risk of QT prolongation. This risk may increase if you use certain drugs (such as diuretics “water pills”) or if you have conditions such as severe sweating, diarrhea, or vomiting. Talk to your doctor about using efavirenz safely. This drug may make you dizzy or drowsy or cause trouble concentrating. Alcohol or marijuana (cannabis) can worsen these effects. 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). Before having

surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). A rash may be more common and serious in children taking efavirenz. Report any rash right away. The doctor may prescribe an antihistamine for your child to take before efavirenz is started. Consult the doctor for more information. Older adults may be more sensitive to the side effects of this drug, especially QT prolongation (see above). During pregnancy, this medication should be used only when clearly needed. Treatment can lower the risk of passing HIV infection to your baby, and efavirenz may be part of that treatment. Women of childbearing age should ask about reliable forms of birth control while using this medication and for 12 weeks after stopping treatment. If you become pregnant, talk to your doctor right away about the risks and benefits of this medication. This medication passes into breast milk. Because breast milk can transmit HIV, do not breast-feed. 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: a certain combination product used to treat chronic hepatitis C (ombitasvir/paritaprevir/ritonavir/dasabuvir), orlistat. Do not take this medication with other products that contain efavirenz unless specifically directed by your doctor. Other medications can affect the removal of efavirenz from your body, which may affect how efavirenz works. Examples include some drugs used to treat seizures (such as carbamazepine, phenobarbital, phenytoin), among others. Efavirenz can speed up the removal of many other medications from your body, which may affect how they work. Examples of affected drugs include atovaquone/proguanil, azole antifungals (such as itraconazole, ketoconazole), bedaquiline, cobicistat, elbasvir/grazoprevir, macrolide antibiotics (such as amoxil, zithromax, flagyl, levofloxacin, ciprofloxacin), methadone, rifabutin, sertraline, some cholesterol-lowering statins (such as atorvastatin, pravastatin, simvastatin), warfarin, among others. Some other drugs to treat HIV infection (such as elvitegravir, other NNRTIs including etravirine/nevirapine/rilpivirine) may also interact with efavirenz. If you are taking atazanavir with this medication, you may need to also take another medication (ritonavir). Consult 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. Talk to your doctor about additional or alternative reliable forms of birth control, and use an effective barrier method (latex or polyurethane condoms/dental dams) during sexual activity to decrease the risk of spreading HIV to others. Tell your doctor if you have any new spotting or breakthrough bleeding, because these may be signs that your hormonal birth control is not working well. () Tell your doctor or pharmacist if you are taking other products that cause drowsiness including alcohol, marijuana (cannabis), antihistamines (such as cetirizine, diphenhydramine), drugs for sleep or anxiety (such as diazepam, zolpidem), muscle relaxants, and opioid pain relievers (such as codeine). Check the labels on all your medicines (such as allergy or cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about using those products safely. This medication may interfere with certain lab tests (such as urine cannabinoid tests), possibly causing false test results. Make sure lab 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. Do not share this medication with others. Lab and/or medical tests (such as liver tests, viral load, T-cell counts, cholesterol and triglyceride levels) should be done before you start taking this medication and while you are taking it. Women of childbearing age should also have a pregnancy test before starting this medication. Keep all medical and lab appointments. Consult your doctor for more details. If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up. 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.

Side Effects

Uses

Interactions

Other Details
