

Brightside Specialty Pharmacy

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Patient Education for EFAVIR-EMTRI-TENOF 600-200-300

If available, dispense patient package insert and explain to pt Not recommended during pregnancy or breast feeding Report signs of liver trouble to doctor promptly (jaundice etc) Lactic acidosis may cause dyspnea or tachypnea; Seek medical care May cause drowsiness or dizziness Use caution driving. Use latex or polyurethane condoms during sexual activity. May reduce effectiveness of hormonal contraceptives. Food increases drug levels & side effects. Usually taken at bedtime.

If available, read the patient package insert Do not take while breast feeding or when pregnant Call MD if new abdominal pain/yellowing eyes/skin Seek medical care if breathing trouble occurs May make you drowsy or dizzy. Drive with caution Use latex or polyurethane condoms during sex. May reduce effectiveness of hormone contraceptives Take at bedtime on an empty stomach.

.....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.

EFAVIRENZ/EMTRICITABINE/TENOFOVIR - ORAL
(eh-FAV-er-enz/em-tri-SITE-ah-bean/te-NOE-fo-veer)

COMMON BRAND NAME(S):

Atripla

WARNING:

If you have hepatitis B infection, your hepatitis

symptoms may get worse or become very serious if you stop taking this medication. Talk with your doctor before stopping this medication. Your doctor will monitor liver tests for several months after you stop efavirenz/emtricitabine/tenofovir. Tell your doctor right away if you develop symptoms of worsening liver problems.

USES:

This product contains 3 different medications: efavirenz,

emtricitabine, and tenofovir. It is used alone or 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). Emtricitabine and tenofovir belong to a class of drugs known as nucleoside reverse transcriptase inhibitors (NRTIs).

Efavirenz/emtricitabine/tenofovir 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.

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 product may also be used to lessen the risk of HIV infection after contact with the virus (for example, due to a needle stick). Ask your doctor for more details.

HOW TO USE:

Read the Patient Information Leaflet if available

from your pharmacist before you start taking efavirenz/emtricitabine/tenofovir and each time you get a refill. If you have any questions regarding the information, consult your doctor or pharmacist.

Take this medication by mouth on an empty stomach, without food, usually once daily at bedtime or as directed by your doctor. Taking this medication at bedtime helps to decrease some of the side effects. See Side Effects section.

Because this combination product has fixed doses of efavirenz, emtricitabine, and tenofovir, you should only use it if your doctor has determined that the doses of all 3 medications in this product are right for you.

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.

SIDE EFFECTS:

Dizziness, trouble sleeping, drowsiness, unusual

dreams, and trouble concentrating may frequently 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 this medication on an empty stomach at bedtime.

Tiredness, headache, diarrhea, and skin discoloration (such as small spots/freckles, darkening of the palms of the hands/soles of the feet) 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: mental/mood changes (such as depression, rare thoughts of suicide, strange thoughts, anxiety, angry behavior, hallucinations, confusion), loss of coordination, signs of kidney problems (such as a change in the amount of urine), unusual thirst, signs of pancreatitis (such as nausea, vomiting, stomach/abdominal/back pain, fever).

Rarely, this medication can cause severe (sometimes fatal) liver and blood problems (lactic acidosis). Tell your doctor right away if you develop symptoms of liver problems (such as nausea/vomiting that doesn't stop, loss of appetite, stomach/abdominal pain, yellowing eyes/skin, dark urine) or lactic acidosis (such as deep/rapid breathing, drowsiness, nausea/vomiting, unusual weakness).

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.

Tenofovir may increase the risk of bone loss. Discuss the risks and benefits of treatment with your doctor, as well as the

possible use of calcium and vitamin D to reduce this side effect. If you are at risk for bone loss, your doctor may monitor your bone mineral density. Tell your doctor right away if any of the following serious side effects occur: bone pain, easily broken bones.

Get medical help right away if you have any very serious side effects, including: fast/irregular heartbeat, severe dizziness, fainting.

Efavirenz/emtricitabine/tenofovir can commonly cause a rash that is usually not serious. However, you may not be able to tell it apart from a rare rash that could be a sign of a severe reaction. Seek immediate medical attention 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.

PRECAUTIONS:

Before taking efavirenz/emtricitabine/tenofovir,

tell your doctor or pharmacist if you are allergic to any of the ingredients; 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: kidney problems, liver problems (such as hepatitis B or C, cirrhosis), mental/mood conditions (such as depression, thoughts of suicide, psychosis), drug/substance/alcohol abuse, seizures, high cholesterol/triglyceride levels, bone problems (such as bone disease, bone loss/osteoporosis, weak/broken bones), disease of the pancreas (pancreatitis).

Efavirenz/emtricitabine/tenofovir 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/emtricitabine/tenofovir, 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/emtricitabine/tenofovir 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 because they may also worsen the side effects of this medication (such as liver problems, pancreatitis, mental/mood symptoms). 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 this medication. Report any rash right away. The doctor may prescribe an antihistamine for your child to take before this medication 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/emtricitabine/tenofovir may be part of that treatment. Women of childbearing age should ask about reliable forms of birth control while taking 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.

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: orlistat, other drugs that may affect the kidneys (including adefovir, cidofovir, aminoglycosides such as amikacin/gentamicin), a certain combination product used to treat chronic hepatitis C (ombitasvir/paritaprevir/ritonavir/dasabuvir).

Do not take this medication with other products that contain emtricitabine or tenofovir. Do not take this medication with another efavirenz product unless specifically directed by your doctor. Also, lamivudine is similar to emtricitabine and should not be taken with this medication.

Other medications can affect the removal of efavirenz/emtricitabine/tenofovir from your body, which may affect how this product works. Examples include some drugs used to treat seizures (such as carbamazepine), among others.

Efavirenz/emtricitabine/tenofovir can speed up the removal of many other medications from your body, which may affect how they

work. Examples of affected drugs include atazanavir, atovaquone/proguanil, azole antifungals (such as voriconazole), bedaquiline, cobicistat, elbasvir/grazoprevir, elvitegravir, macrolide antibiotics (such as clarithromycin), sofosbuvir/velpatasvir, among others.

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. (See also Precautions section.)

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 laboratory tests (including urine cannabinoid 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.

NOTES:

Do not share this medication with others.

Lab and/or medical tests (such as kidney/liver function, test for hepatitis B virus, viral load, T-cell counts, cholesterol and triglyceride levels, blood mineral levels, bone density tests, urine glucose/protein) 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.

MISSED DOSE:

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.

STORAGE:

Store in the original container 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.

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