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Efavirenz, Lamivudine, and Tenofovir

pronounced as (e fa veer' ens)(la miv' ue deen)(te noe' fo veer)

IMPORTANT WARNING:

Efavirenz, lamivudine and tenofovir should not be used to treat hepatitis B virus infection (HBV; an ongoing liver infection). Tell your doctor if you have or think you may have HBV. Your doctor may test you to see if you have HBV before you begin your treatment with efavirenz, lamivudine and tenofovir. If you have HBV and you take efavirenz, lamivudine and tenofovir, your condition may suddenly worsen when you stop taking efavirenz, lamivudine and tenofovir. Your doctor will examine you and order lab tests regularly for several months after you stop taking efavirenz, lamivudine and tenofovir to see if your HBV has worsened.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests before and during your treatment to check your body's response to efavirenz, lamivudine, and tenofovir.

Why is this medication prescribed?

The combination of efavirenz, lamivudine, and tenofovir is used to treat HIV in adults and children. Efavirenz is in a class of medications called non-nucleoside reverse transcriptase inhibitors (NNRTIs). Lamivudine and tenofovir are in a class of medications called nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs). They work by decreasing the amount of HIV in the body. Although efavirenz, lamivudine and tenofovir will not cure HIV, these medications may decrease your chance of developing acquired immunodeficiency syndrome (AIDS) and HIV-related illnesses such as serious infections or cancer. Taking these medications along with practicing safer sex and making other lifestyle changes may decrease the risk of getting or transmitting the HIV virus to other people.

How should this medicine be used?

The combination of efavirenz, lamivudine, and tenofovir comes as a tablet to take by mouth. It is usually taken once a day on an empty stomach (at least 1 hour before or 2 hours after a meal). Take efavirenz, lamivudine, and tenofovir at around the same time every day. Taking efavirenz, lamivudine, and tenofovir at bedtime may make certain side effects less bothersome. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take

efavirenz, lamivudine, and tenofovir exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Continue to take efavirenz, lamivudine, and tenofovir even if you feel well. Do not stop taking efavirenz, lamivudine, and tenofovir without talking to your doctor. If you stop taking efavirenz, lamivudine, and tenofovir even for a short time, or skip doses, the virus may become resistant to medications and may be harder to treat.

The combination of efavirenz, lamivudine, and tenofovir is available with brand names of Symfi and Symfi Lo. These two brands contain different amounts of the same medication, and cannot be substituted for each other. Be sure that you receive only the brand of efavirenz, lamivudine, and tenofovir that was prescribed for you by your doctor. Ask your pharmacist if you have any questions about the type of efavirenz, lamivudine, and tenofovir you were given.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking efavirenz, lamivudine, and tenofovir,

- tell your doctor and pharmacist if you are allergic to efavirenz, lamivudine, tenofovir, any other medications, or any of the ingredients in the efavirenz, lamivudine, and tenofovir tablet. Ask your pharmacist for a list of the ingredients.
- you should know that efavirenz, lamivudine and tenofovir are also available individually with the brand names of Sustiva, Epivir, Epivir-HBV (used to treat hepatitis B), Vemlidy (used to treat hepatitis B), and Viread, as well as in combination with other medications with brand names of Atripla, Biktarvy, Combivir, Complera, Descovy, Epzicom, Genvoya, Odefsey, Stribild, Symfi, Triumeq, Trizivir, and Truvada. Tell your doctor if you are taking any of these medications to be sure you do not receive the same medication twice.
- tell your doctor if you are taking elbasvir/grazoprevir (Zepatier). Your doctor will probably tell you not to take efavirenz, lamivudine, and tenofovir if you are taking this medication.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements you are taking or plan to take. Be sure to mention any of the following: acyclovir (Sitavig, Zovirax); adefovir (Hepsera); aminoglycosides such as gentamicin; artemether/lumefantrine (Coartem); aspirin and other nonsteroidal anti-inflammatory medications (NSAIDs) such as ibuprofen (Advil, Motrin) and naproxen (Aleve, Naprosyn); atorvastatin (Lipitor, in Caduet); atovaquone/proguanil (Malarone); bupropion (Forfivo, Wellbutrin, Zyban, others); calcium channel blockers such as diltiazem (Cardizem, Cartia, Diltzac, others), felodipine, nifedipine (Cardene), nifedipine (Adalat, Afeditab, Procardia), and verapamil (Calan, Verelan, in Tarka); carbamazepine (Carbatrol, Equetro, Tegretol, others); cidofovir; cyclosporine (Gengraf, Neoral, Sandimmune); ganciclovir (Cytovene); glecaprevir/pibrentasvir (Mavyret); itraconazole (Sporanox, Onmel); ketoconazole; ledipasvir/sofosbuvir (Harvoni); macrolide antibiotics such as clarithromycin (Biaxin, in Prevpac); methadone (Dolophine, Methadose); phenobarbital; phenytoin (Dilantin, in Phenytek); posaconazole (Noxafil); pravastatin (Pravachol); rifabutin (Mycobutin); rifampin (Rimactane, in Rifamate, Rifater); sertraline (Zoloft); simeprevir (Olyslo); simvastatin (Flolopid, Zocor,

in Vytorin); sirolimus (Rapamune); sofosbuvir/velpatasvir (Epcalsa); sofosbuvir/velpatasvir/voxilaprevir (Vosevi); sorbitol or medications that are sweetened with sorbitol; tacrolimus (Astagraf, Envarsus, Prograf); trimethoprim (Primisol, in Bactrim, Septra); valacyclovir (Valtrex); valganciclovir (Valcyte); and warfarin (Coumadin, Jantoven). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with efavirenz, lamivudine and tenofovir, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.

- tell your doctor what herbal products you are taking, especially St. John's wort.
- tell your doctor if you have any of the conditions mentioned in the IMPORTANT WARNING section, or if you have or ever have had a prolonged QT interval (a rare heart problem that may cause irregular heartbeat, fainting, or sudden death), low level of potassium or magnesium in your blood, bone problems including osteoporosis (a condition in which the bones become thin and weak and break easily) or bone fractures, seizures, hepatitis C or other liver disease, or kidney disease. Also tell your doctor if you drink or have ever drunk large amounts of alcohol, use or have ever used street drugs, overuse or have ever overused prescription medications, or have or have ever had depression or other mental illness. For children taking this medication, tell your doctor if they have or have ever had pancreatitis or have received treatment with a nucleoside analog medication such as an NRTI in the past.
- tell your doctor if you are pregnant, or plan to become pregnant. You should not become pregnant during your treatment. If you can become pregnant, you will have to have a negative pregnancy test before you begin taking this medication and use effective birth control during your treatment. Efavirenz, lamivudine, and tenofovir may interfere with the action of hormonal contraceptives (birth control pills, patches, rings, implants, or injections), so you should not use these as your only method of birth control during your treatment. You must use a barrier method of birth control along with any other method of birth control you have chosen during your treatment and for 12 weeks after your final dose. Ask your doctor to help you choose a method of birth control that will work for you. If you become pregnant while taking efavirenz, lamivudine, and tenofovir, call your doctor immediately.
- you should not breastfeed if you are infected with HIV or are taking efavirenz, lamivudine, and tenofovir.
- you should be aware that your body fat may increase or move to different areas of your body, such as your upper back, neck ("buffalo hump"), breasts, and around your stomach. You may notice a loss of body fat from your face, legs, and arms.
- you should know that while you are taking medications to treat HIV infection, your immune system may get stronger and begin to fight other infections that were already in your body or cause other conditions to occur. This may cause you to develop symptoms of those infections or conditions. If you have new or worsening symptoms during your treatment with efavirenz, lamivudine, and tenofovir be sure to tell your doctor.
- you should know that efavirenz, lamivudine, and tenofovir may make you dizzy, drowsy, unable to concentrate, have trouble falling asleep or staying asleep, have unusual dreams or have hallucinations (seeing things or hearing voices that do not exist). These side effects usually go away 2 to 4 weeks after starting treatment. These side effects may be worse if you also drink alcohol, or take certain other medications such as antidepressants, medications for anxiety, medications for mental illness, medications for seizures, sedatives, sleeping pills, or tranquilizers. Do not drive a car or operate machinery until you know how this medication affects you.
- you should know that efavirenz, lamivudine, and tenofovir may cause changes in your thoughts, behavior, or mental health. Call your doctor immediately if you develop any of the following symptoms while you are taking efavirenz, lamivudine and tenofovir: depression, thinking about killing yourself or planning or trying to do so, angry or aggressive behavior, hallucinations (seeing things or hearing voices that do not exist), strange thoughts, loss of touch with reality, or not being able to move or talk

normally. Be sure your family knows which symptoms may be serious so that they can call your doctor if you are unable to seek treatment on your own.

- you should know that efavirenz may cause potentially serious nervous system problems, including encephalopathy (a serious and potentially fatal disorder of the brain) months or years after you first take efavirenz, lamivudine, and tenofovir. Although nervous system problems may begin after you have taken efavirenz, lamivudine, and tenofovir for some time, it is important for you and your doctor to realize that they may be caused by efavirenz. Call your doctor right away if you experience problems with balance or coordination, confusion, memory problems, and other difficulties caused by abnormal brain function, at any time during your treatment with efavirenz, lamivudine, and tenofovir. Your doctor may tell you to stop taking efavirenz, lamivudine, and tenofovir.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Efavirenz, lamivudine, and tenofovir may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- headache
- abdominal pain
- diarrhea
- heartburn
- nausea
- vomiting
- back, joint, or muscle pain
- lack of energy
- stinging, burning, or painful feeling in arms or legs

Some side effects can be serious. If you experience any of these symptoms or those in the SPECIAL PRECAUTIONS section, call your doctor immediately or get emergency medical treatment:

- hives, difficulty breathing or swallowing, swelling of the face, throat, tongue, lips, or eyes, hoarseness
- rash, peeling or blistering skin, itching, fever, swelling of face, sores in mouth, red or swollen eyes
- unusual muscle pain, trouble breathing, stomach pain, nausea, vomiting, feeling cold especially in your arms or legs, feeling dizzy or lightheaded, extreme tiredness or weakness, fast or irregular heartbeat

- yellowing of skin or eyes, dark urine, light colored stools, nausea, vomiting, loss of appetite, pain, aching, or tenderness in upper right part of stomach, swollen stomach, extreme tiredness, weakness, confusion
- decreased urination, swelling of legs
- bone pain, pain in arms or legs, bone fracture, muscle pain or weakness, joint pain
- seizures
- feeling faint, lightheaded, or dizzy; irregular or fast heartbeat
- ongoing pain that begins in the upper left or middle of the stomach but may spread to the back, nausea, vomiting

Efavirenz, lamivudine, and tenofovir may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- dizziness
- trouble concentrating

- sleepiness
- difficulty falling asleep or staying asleep
- unusual dreams
- seeing or hearing things that are not there
- muscle movements or shaking that you cannot control

What other information should I know?

Before having any laboratory test, tell your doctor and the laboratory personnel that you are taking efavirenz, lamivudine, and tenofovir.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

Keep a supply of efavirenz, lamivudine, and tenofovir on hand. Do not wait until you run out of medication to refill your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Symfi[®]
- Symfi Lo[®]

Other names

- EFV, 3TC and TDF

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