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## **Efavirenz, Emtricitabine, and Tenofovir**

pronounced as (ef" a vir' enz) (em" trye sye' ta been) (ten of' oh vir)

### **IMPORTANT WARNING:**

Efavirenz, emtricitabine, 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, emtricitabine, and tenofovir. If you have HBV and you take efavirenz, emtricitabine, and tenofovir, your condition may suddenly worsen when you stop taking this medication. Your doctor will examine you and order lab tests regularly for several months after you stop taking this medication 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, emtricitabine, and tenofovir.

Talk to your doctor about the risks of taking efavirenz, emtricitabine, and tenofovir.

### **Why is this medication prescribed?**

The combination of efavirenz, emtricitabine, and tenofovir is used alone or along with other medications to treat human immunodeficiency virus (HIV) infection in adults and children weighing more than 40 kg (88 lb). Efavirenz is in a class of medications non-nucleoside reverse transcriptase inhibitors (NNRTIs). Emtricitabine and tenofovir are in a class of medications called nucleoside reverse transcriptase inhibitors (NRTIs). They work by decreasing the amount of HIV in the body. Although efavirenz, emtricitabine, 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, emtricitabine, and tenofovir comes as a tablet to take by mouth. It is usually taken once a day with water on an empty stomach (at least 1 hour before or 2 hours after a meal). Take efavirenz, emtricitabine, and tenofovir at around the same time every day. Taking efavirenz

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

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, emtricitabine, and tenofovir,

- tell your doctor and pharmacist if you are allergic to efavirenz, emtricitabine, or tenofovir, any other medications, or any of the ingredients in efavirenz, emtricitabine, and tenofovir tablets. Ask your pharmacist for a list of the ingredients.
- tell your doctor if you are taking voriconazole (Vfend) or elbasvir and grazoprevir (Zepatier). Your doctor will probably tell you not to take efavirenz, emtricitabine, and tenofovir if you are taking one or more of these medications.
- 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); antidepressants; artemether and lumefantrine (Coartem); atazanavir (Reyataz); atorvastatin (Lipitor, in Caduet); atovaquone and proguanil (Malarone); boceprevir (Victrelis); bupropion (Wellbutrin, Zyban, others); carbamazepine (Carbatrol, Epitol, Equetro, Tegretol, Teril); clarithromycin (Biaxin, in Prevpac); cidofovir; cyclosporine (Gengraf, Neoral, Sandimmune); darunavir (Prezista) with ritonavir (Norvir); delavirdine (Rescriptor); didanosine (Videx); diltiazem (Cardizem, Cartia, Diltzac, Taztia, Tiazac); ethinyl estradiol and norgestimate (Estarylla, Ortho-Tri-Cyclen, Sprintec, others); etonogestrel (Nexplanon, in Nuvaring); etravirine (Intelence); felodipine; fosamprenavir (Lexiva); ganciclovir (Cytovene); gentamicin; glecaprevir and pibrentasvir (Mavyret); indinavir (Crixivan); itraconazole (Onmel, Sporanox); ketoconazole; lamivudine (Epivir, Epivir HBV, in Combivir, Epzicom, Triumeq, Trizivir); ledipasvir and sofosbuvir (Harvoni); lopinavir and ritonavir (Kaletra); maraviroc (Selzentry); medications for anxiety, mental illness, and seizures; methadone (Dolophine, Methadose); nevirapine (Viramune); nicardipine (Cardene); nifedipine (Adalat, Afeditab, Procardia); phenobarbital; phenytoin (Dilantin, Phenytek); nonsteroidal anti-inflammatory medications (NSAIDs) such as celecoxib (Celebrex), ibuprofen (Advil, Motrin), meloxicam (Mobic), and naproxen (Aleve, Naprelan, Naprosyn); other HIV medications containing efavirenz, emtricitabine, and tenofovir (Complera, Descovy, Genvoya, Odefsey, Stribild, Truvada, Sustiva, Emtriva, Viread); posaconazole (Noxafil); pravastatin (Pravachol); raltegravir (Isentress); rifabutin (Mycobutin); rifampin (Rifadin, Rimactane, in Rifamate, Rifater); ritonavir (Norvir, in Kaletra, Technivie, Viekira Pak); saquinavir (Invirase); sedatives; sertraline (Zoloft); sleeping pills; simeprevir (Olysio); simvastatin (Zocor, in Vytorin); sirolimus (Rapamune); sofosbuvir and velpatasvir (Epclusa); sofosbuvir, velpatasvir, and voxilaprevir (Vosevi); tacrolimus (Astagraf, Envarsus, Prograf); tranquilizers; valacyclovir (Valtrex); valganciclovir (Valcyte); verapamil (Calan, Covera, Tarka, Verelan); 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, emtricitabine, and tenofovir, or may increase the risk that you will develop liver damage during your treatment with efavirenz, emtricitabine, 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 currently or have a prolonged QT interval (rare heart problem that may cause irregular heartbeat, fainting, or sudden death), or low levels of potassium or magnesium in your blood, ever drunk large amounts of alcohol, used street drugs, or over-used prescription medications. Also tell your doctor if you have or have ever had any of the conditions mentioned in the IMPORTANT WARNING section, depression or other mental illness, bone problems including osteoporosis (a condition in which the bones become thin and weak and break easily) or bone fractures, seizures, or liver or kidney disease.
- tell your doctor if you are pregnant, or plan to become pregnant. You should not become pregnant during your treatment and for 12 weeks after your final dose. 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, emtricitabine, 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 (device that blocks sperm from entering the uterus such as a condom or a diaphragm) along with any other method of birth control you have chosen. Ask your doctor to help you choose a method of birth control that will work for you. If you become pregnant while taking efavirenz, emtricitabine, and tenofovir, call your doctor immediately.
- you should not breastfeed if you are infected with HIV or are taking efavirenz, emtricitabine, 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, emtricitabine, and tenofovir be sure to tell your doctor.
- you should know that efavirenz, emtricitabine, and tenofovir may make you drowsy, dizzy, or unable to concentrate. Do not drive a car or operate machinery until you know how this medication affects you.
- you should know that efavirenz, emtricitabine, 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: 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, or loss of touch with reality. 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.
- ask your doctor about the safe use of alcoholic beverages while you are taking efavirenz, emtricitabine, and tenofovir. Alcohol can make the side effects from efavirenz, emtricitabine, and tenofovir worse.
- 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, emtricitabine, and tenofovir. Although nervous system problems may begin after you have taken efavirenz, emtricitabine, 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 and coordination, confusion, memory problems, and other difficulties caused by abnormal brain function, at any time during your treatment with efavirenz, emtricitabine, and tenofovir. Your doctor may tell you to stop taking efavirenz, emtricitabine, and tenofovir.

## What special dietary instructions should I follow?

Talk to your doctor about eating grapefruit and drinking grapefruit juice while taking this medication.

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

- headache
- diarrhea
- gas
- indigestion
- darkening of skin color, especially on the palms of the hands or the soles of the feet
- pale skin
- difficulty falling asleep or staying asleep
- confusion
- forgetfulness
- feeling agitated, worried, or nervous
- abnormally happy mood
- unusual dreams
- joint or back pain
- itching

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

- decreased urination
- urinating large amounts
- increased thirst

- ongoing or worsening bone pain
- bone fractures
- pain in the arms, hands, feet, or legs
- muscle pain or weakness
- rash
- peeling, blistering, or shedding skin
- numbness, burning, or tingling in the hands, arms, feet, or legs
- swelling of the face, throat, tongue, lips, eyes, legs, ankles, or feet
- difficulty swallowing or breathing
- hoarseness
- seizures
- flu-like symptoms
- nausea
- vomiting
- extreme tiredness
- yellowing of skin or eyes; light-colored bowel movements; dark yellow or brown urine; loss of appetite; pain in upper right part of stomach; or unusual bleeding or bruising
- weakness; muscle pain; shortness of breath or fast breathing; stomach pain with nausea and vomiting; cold or blue hands and feet; feeling dizzy or lightheaded; or fast or irregular heartbeat

Efavirenz, emtricitabine, 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>) 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>

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:

- movements of your body that you cannot control
- dizziness
- difficulty concentrating
- nervousness
- confusion
- forgetfulness
- difficulty falling asleep or staying asleep
- unusual dreams
- drowsiness
- hallucinations (seeing things or hearing voices that do not exist)
- abnormally happy mood
- strange thoughts

## What other information should I know?

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

- Atripla® (as a combination product containing Efavirenz, Emtricitabine, Tenofovir)

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