

What are efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?

This prescription medicine combines efavirenz, emtricitabine, and tenofovir disoproxil fumarate in one tablet. Efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets is used alone as a complete regimen, or in combination with other anti-HIV-1 medicines to treat people with HIV-1 infection who weigh at least 88 lbs. (40 kg).

It is not known if efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets are safe and effective for use in children with HIV-1 infection who weigh less than 88 lbs. (40 kg).

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?

Efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets can cause serious side effects, including:

- **Worsening of hepatitis B virus (HBV) infection.** Your healthcare provider will test you for HBV before starting treatment with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. If you have HBV infection and take efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets, your HBV may get worse (flare-up) if you stop taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. A “flare-up” is when your HBV infection suddenly returns in a worse way than before.
 - Do not stop taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets without first talking with your healthcare provider.
 - Do not run out of efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. Refill your prescription or talk to your healthcare provider before your efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets is all gone.
 - If you stop taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your HBV infection, or give you a medication to treat hepatitis B. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.

For more information about side effects see the section, **“What are the possible side effects of efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?”**

Who should not take efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?

Do not take efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets if you:

- are allergic to efavirenz
- take the medicine called voriconazole, elbasvir or grazoprevir

Ask your healthcare provider if you are not sure if you take any of these medicines.

Before taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets, **tell your healthcare provider about all of your medical conditions, including if you:**

- have liver problems, including hepatitis B or C virus infection
- have heart problems
- have or have had mental problems
- have a history of drug or alcohol abuse
- have nervous system problems
- have kidney problems or receive kidney dialysis treatment
- have bone problems
- have had seizures or take medicines used to treat seizures
- are pregnant or plan to become pregnant. Efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets can harm your unborn baby. If you are able to become pregnant, your healthcare provider should do a

pregnancy test before you start treatment with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. **You should not become pregnant during treatment with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets and for 12 weeks after stopping treatment.** Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.

- **Females who are able to become pregnant should use 2 effective forms of birth control (contraception) during treatment with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets and for 12 weeks after stopping treatment.**
 - **A barrier form of birth control should always be used along with another type of birth control.** Barrier forms of birth control may include condoms, contraceptive sponges, diaphragm with spermicide, and cervical cap.
 - **Birth control methods that contain the hormone progesterone such as birth control pills, injections, vaginal rings, or implants, may not work as well while taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.**
 - Talk to your healthcare provider about birth control methods that may be right for you during treatment with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.
 - **Pregnancy Registry:** There is a pregnancy registry for women who take efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. Efavirenz, emtricitabine and tenofovir disoproxil fumarate can pass into your breast milk. Do not breastfeed because of the risk of passing HIV-1 to your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

Efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets and some medicines may interact with each other causing serious side effects.

You can ask your healthcare provider or pharmacist for a list of medicines that interact with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. Do not start a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets with other medicines.

What should I avoid while taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?

- Efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets can cause dizziness, impaired concentration and drowsiness. If you have these symptoms, do not drive a car, use heavy machinery, or do anything that requires you to be alert.

What are the possible side effects of efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?

Efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets may cause serious side effects, including:

- **See “What is the most important information I should know about efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?”**
- **Rash.** Rash is a serious side effect but may also be common. Rashes will usually go away without any change in your treatment. Tell your healthcare provider right away if you develop a rash during treatment with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.
- **Severe liver problems.** In rare cases, severe liver problems can happen that can lead to death. **Tell your healthcare provider right away if you get these symptoms:** skin or the white part of your eyes turns

yellow, dark “tea-colored” urine, light-colored stools, loss of appetite for several days or longer, nausea, or stomach-area pain.

- **Mental problems.** Serious mental problems including severe depression, suicidal thoughts and actions, aggressive behavior, delusions, catatonia, and paranoid and manic reactions have happened in people who take efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. These mental health problems may happen more often in people who have a history of mental problems or drug use, or who take medicines to treat mental problems. Tell your healthcare provider right away if you develop serious mental problems during treatment with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.
- **Nervous system problems.** Nervous system problems usually begin during the first or second day of treatment with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets and usually go away after 2 to 4 weeks of treatment. Some symptoms may occur months to years after beginning efavirenz, emtricitabine and tenofovir disoproxil fumarate therapy. These symptoms may become more severe if you drink alcohol or take mood altering (street) drugs while taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. Tell your healthcare provider right away if you develop nervous system problems during treatment with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. Symptoms of nervous system problems may include:
 - dizziness
 - problems sleeping
 - problems concentrating
 - excessive sleepiness or difficulty awakening
 - abnormal dreams
 - seeing or hearing things that are not real (hallucinations)
 - unusually happy mood
 - confusion
 - agitation
 - memory problems
 - thought problems
 - lack of coordination or difficulty with balance
 - slow thoughts and physical movement

If you have dizziness, trouble concentrating or sleepiness, do not drive a car, use machinery, or do anything that needs you to be alert.

- **New or worse kidney problems, including kidney failure.** Your healthcare provider should do blood and urine tests to check your kidneys before you start and during treatment with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. Your healthcare provider may tell you to stop taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets if you develop new or worse kidney problems during treatment with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.
- **Bone problems** can happen in some people who take efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. Bone problems include bone pain or softening or thinning of bones, which may lead to fractures. Your healthcare provider may need to do tests to check your bones.
- **Seizures.** Your healthcare provider may do blood tests during treatment with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets if you take certain medicines used to prevent seizures.
- **Too much lactic acid in your blood (lactic acidosis).** Too much lactic acid is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you develop any of these symptoms:
 - weakness or being more tired than usual
 - unusual muscle pain
 - being short of breath or fast breathing
 - stomach pain with nausea and vomiting
 - cold or blue hands and feet
 - feel dizzy or lightheaded
 - fast or abnormal heartbeat

- **Changes in your immune system (Immune Reconstitution Syndrome) can happen when an HIV-1 infected person starts taking HIV-1 medicines.** Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you develop any new symptoms after starting treatment with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.
- **Changes in body fat.** Changes in body fat distribution or accumulation have happened in some people taking HIV-1 medicines, including an increased amount of fat in the upper back and neck ("buffalo hump"), in the breasts, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these body fat changes are not known.

The most common side effects of efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets include diarrhea, nausea, tiredness, headache, dizziness, depression, problems sleeping, abnormal dreams, and rash.

These are not all the possible side effects of efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.

Call your doctor for medical advice about side effects. **You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.**

Please read the Patient Information Leaflet in the accompanying full Prescribing Information including Boxed Warning.