



# efavirenz (Sustiva)

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## **WHAT IS EFAVIRENZ?**

Efavirenz, also known as EFV (brand name Sustiva), is a drug used as part of [antiretroviral therapy \(ART\)](#). The FDA approved efavirenz in 1998 as an [antiretroviral drug \(ARV\)](#) for people with HIV infection. Generic versions have been approved under [PEPFAR](#). Efavirenz is manufactured by [Bristol Myers Squibb](#).

Efavirenz is a type of drug called a [non-nucleoside reverse transcriptase inhibitor \(NNRTI\)](#). NNRTIs bind to and block reverse transcriptase (an HIV enzyme). HIV uses reverse transcriptase to convert its RNA into DNA (reverse transcription). Blocking reverse transcriptase and reverse transcription prevents HIV from replicating.

When used with other ARVs to treat HIV infection, efavirenz may help:

- Reduce the amount of HIV in your blood. This is called [viral load](#).
- Increase the number of [CD4 cells](#) in your blood that help fight off other infections.

Reducing the amount of HIV and increasing the CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting [opportunistic infections \(OIs\)](#) that can happen when your immune system is weak. [Read more about viral suppression](#).

Efavirenz [does not cure](#) HIV infection or [AIDS](#). You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

## **WHO SHOULD TAKE EFAVIRENZ?**

Efavirenz is a prescription HIV medicine used in combination with other ARVs to treat HIV infection in adults and children who are at least 3 months old and who weigh at least 7 pounds 12 ounces (3.5 kg). The safety and effectiveness of efavirenz has not been established in children under 3 months of age weighing less than 7 pounds 12 ounces (3.5 kg). Efavirenz has not been carefully studied in the elderly (65 years of age and older).

All people living with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. [Read more about U.S. ART guidelines](#).

## **WHO SHOULD NOT TAKE EFAVIRENZ?**

Do not take efavirenz if you are allergic to efavirenz or any of the ingredients in this product.

Do not take efavirenz if you are currently taking the following medications:

- Anti-fungal medicines: itraconazole, ketoconazole, posaconazole
- Anti-seizure medicine: carbamazepine
- [Hepatitis C virus \(HCV\)](#) medicines: elbasvir, grazoprevir
- [Other NNRTIs](#)
- efavirenz/emtricitabine/tenofovir DF ([Atripla](#))
- Macrolide antibiotics (e.g., [azithromycin](#), [clarithromycin](#), erythromycin, and roxithromycin)

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of these medicines in the past 4 weeks, talk to your healthcare provider or pharmacist before starting treatment with efavirenz.

### ***WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING EFAVIRENZ?***

Before you take efavirenz, tell your healthcare provider about all of your medical conditions, and in particular if you:

- have a [heart condition](#)
- have ever had a mental health problem
- have ever used street drugs or large amounts of alcohol
- have liver problems, including [hepatitis B virus \(HBV\)](#) or HCV
- have a history of seizures

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with efavirenz. Efavirenz may harm your unborn baby. If you are able to become pregnant your healthcare provider should do a pregnancy test before you start efavirenz. You should not become pregnant while taking efavirenz and for 12 weeks after stopping treatment with efavirenz. People who are able to become pregnant should use **two** effective forms of birth control during treatment and for 12 weeks after stopping treatment with efavirenz. 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, diaphragms with spermicide, and cervical caps. Hormonal forms of birth control, such as birth control pills, injections, vaginal rings, or implants may not work during treatment with efavirenz. Talk to your healthcare provider about forms of birth control that may be used during treatment with efavirenz

There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. [Read more about pregnancy and HIV.](#)

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with efavirenz. It is not known if efavirenz can pass to your baby in your breastmilk. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

### ***WHAT ABOUT DRUG RESISTANCE?***

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. [Read more about HIV drug resistance.](#)

***Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.***

## **HOW IS EFAVIRENZ TAKEN?**

Efavirenz is taken by mouth as a tablet or capsule. The recommended dosage of efavirenz for adults and children weighing at least 88 pounds (40 kg) is 600 mg once daily, in combination with other ARVs. The recommended dosage in children who are at least 3 months old weighing between 7 pounds 12 ounces (3.5 kg) and 87 pounds (39 kg) varies based on the child's weight and age. Your healthcare provider will determine the correct dosage.

You should take efavirenz on an empty stomach at bedtime. Some side effects may bother you less if you take efavirenz on an empty stomach and at bedtime.

**You need to take efavirenz in combination with other ARVs.** Your healthcare provider will tell you what medicines to take and how to take them.

Efavirenz is also available in two combination medications. Combination HIV medicines contain two or more HIV medicines from one or more drug classes.

- efavirenz/emtricitabine/tenofovir DF ([Atripla](#))
- efavirenz/lamivudine/tenofovir DF ([Symfi](#))

## **WHAT ARE THE SIDE EFFECTS?**

When you start any ARV, you may have temporary [side effects](#) such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of efavirenz are rash, dizziness, nausea, headaches, difficulty concentrating, abnormal dreams, [fatigue](#), insomnia, and vomiting. Some people taking efavirenz have experienced increased levels of [lipids](#) (cholesterol and triglycerides) in the blood.

Efavirenz can cause serious side effects including:

**Serious mental health problems.** Tell your healthcare provider right away if you have any of the following symptoms:

- Feel sad or hopeless
- Feel anxious or restless
- Have thoughts of hurting yourself (suicide) or have tried to hurt yourself or others
- Are not able to tell the difference between what is true or real and what is false or unreal
- Do not trust other people
- Hear or see things that are not real

- Are not able to move or speak normally

**Nervous system symptoms.** [Nervous system symptoms](#) are common in people who take efavirenz and can be severe. These symptoms usually begin during the first or second day of treatment with efavirenz and usually go away after 2-4 weeks of treatment. Some symptoms may occur months to years after beginning efavirenz therapy. These symptoms may become worse if you drink alcohol, take a medicine for mental health problems, or use certain street drugs during treatment with efavirenz. Symptoms may include:

- Dizziness
- Trouble concentrating
- Trouble sleeping
- Drowsiness
- Unusual dreams
- Lack of coordination or difficulty with balance

If you have dizziness, trouble concentrating, or drowsiness, do not drive a car, use machinery, or do anything that needs you to be alert. Some nervous system symptoms (e.g. confusion, slow thoughts and physical movement, and delusions [false beliefs] or hallucinations [seeing or hearing things that others do not see or hear]) may occur months to years after beginning efavirenz therapy. Promptly contact your healthcare provider should any of these symptoms occur.

**Skin rash.** Skin rash is common with efavirenz but can sometimes be severe. Skin rash usually goes away without any change in treatment. If you develop a rash with any of the following symptoms, tell your healthcare provider right away:

- Skin rash, with or without itching
- Fever
- Swelling of your face
- Blisters or skin lesions
- Peeling skin
- Mouth sores
- Red or inflamed eyes, like “pink eye” (conjunctivitis)

**Liver problems, including liver failure and death.** Liver problems can happen in people without a history of liver problems. Your healthcare provider will do [blood tests](#) to check your liver before you start efavirenz and during treatment. Tell your healthcare provider right away if you get any of the following symptoms:

- Your skin or the white part of your eyes turns yellow (jaundice)
- Dark or “tea colored” urine
- Light-colored stools (bowel movements)
- No appetite for several days or longer
- Nausea or vomiting
- You have lower stomach area (abdominal) pain

**Seizures.** Seizures are more likely to happen if you have had seizures in the past. Tell your healthcare provider if you have had a seizure or if you take a medicine to help prevent seizures.

**Immune Reconstitution Inflammatory Syndrome (IRIS).** [IRIS](#) is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have

been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting efavirenz.

**Changes in body fat.** [Changes in body fat distribution or accumulation](#) have happened in some people taking HIV 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.

These are not all the possible side effects of efavirenz. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### ***HOW DOES EFAVIRENZ REACT WITH OTHER DRUGS?***

All ARVs can [interact](#) with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take efavirenz with other medicines.

See above for a list of medicines that should not be taken with efavirenz.

Efavirenz decreases blood levels of methadone. Efavirenz can lower concentrations of buprenorphine.

### ***MORE INFORMATION***

Download the full [Prescribing Information](#)

Download the [Patient Information](#) leaflet

Download the [Instructions for Use](#)

Apply for the [Bristol Myers Squibb Patient Support Program](#)

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