

Efavirenz (EF-a-VIR-enz) tablets

Important: Ask your doctor or pharmacist about medicines that should not be taken with efavirenz tablets. For more information, see the section “What should I tell my doctor before taking efavirenz tablets?”

Read this Patient Information before you start taking efavirenz tablets and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment.

What are efavirenz tablets?

Efavirenz tablets are a prescription HIV-1 (Human Immunodeficiency Virus type 1) medicine used with other antiretroviral medicines to treat HIV-1 infection in adults and in children who are at least 3 months old and who weigh at least 7 pounds 12 ounces (3.5 kg). HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

It is not known if efavirenz tablets are safe and effective in children younger than 3 months of age or who weigh less than 7 pounds 12 ounces (3.5 kg).

When used with other antiretroviral medicines to treat HIV-1 infection, efavirenz tablets may help:

- reduce the amount of HIV-1 in your blood. This is called viral load.
- increase the number of CD4+ (T) cells in your blood that help fight off other infections.

Reducing the amount of HIV-1 and increasing the CD4+ (T) cells in your blood may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

Efavirenz tablets does not cure HIV-1 infection or AIDS. You should keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others:

- Do not share or reuse needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions, or blood.

Ask your doctor if you have any questions about how to prevent passing HIV to other people.

Who should not take efavirenz tablets?

Do not take efavirenz tablets if you are allergic to efavirenz or any of the ingredients in efavirenz tablets. See the end of this leaflet for a complete list of ingredients in efavirenz tablets.

Do not take efavirenz if you are currently taking elbasvir and grazoprevir (zepatier[®]).

What should I tell my doctor before taking efavirenz tablets?

Before taking efavirenz tablets, tell your doctor if you have any 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 or C virus infection
- have a history of seizures
- are pregnant or plan to become pregnant. Efavirenz tablets may harm your unborn baby. If you are able to become pregnant your healthcare provider should do a pregnancy test before you start efavirenz tablets. You should not become pregnant while taking efavirenz tablets and for 12 weeks after stopping treatment with efavirenz tablets.

Females who are able to become pregnant should use 2 effective forms of birth control during treatment and for 12 weeks after stopping treatment with efavirenz tablets. A barrier form of birth control should always be used along with another type of birth control.

- Barrier forms of birth control may include latex or polyurethane condom, contraceptive sponge, diaphragm with spermicide, and cervical cap.
- Hormonal forms of birth control, such as birth control pills, injections, vaginal rings, or implants may not work during treatment with efavirenz tablets.
- Talk to your doctor about forms of birth control that may be used during treatment with efavirenz tablets.
- Pregnancy Registry. There is a pregnancy registry for women who take antiretroviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your doctor about how you can take part in this registry.
- Do not breastfeed if you take efavirenz tablets.
- You should not breastfeed if you have HIV because of the risk of passing HIV to your baby.

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

Efavirenz tablets may affect the way other medicines work, and other medicines may affect how efavirenz tablets works, and may cause serious side effects. If you take certain medicines with efavirenz tablets, the amount of efavirenz tablets in your body may be too low and it may not work to help control your HIV infection. The HIV virus in your body may become resistant to efavirenz tablets or other HIV medicines that are like it.

You should not take efavirenz tablets if you take ATRIPLA (efavirenz, emtricitabine, tenofovir disoproxil fumarate) unless your doctor tells you to.

Tell your doctor and pharmacist about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with efavirenz tablets.

Keep a list of your medicines to show your doctor and pharmacist.

- You can ask your doctor or pharmacist for a list of medicines that interact with efavirenz tablets.
- Do not start taking a new medicine without telling your doctor. Your doctor can tell you if it is safe to take efavirenz tablets with other medicines.

How should I take efavirenz tablets?

- Take efavirenz tablets exactly as your doctor tells you to.
- Do not change your dose or stop taking efavirenz tablets unless your doctor tells you to.
- Stay under the care of your doctor during treatment with efavirenz tablets.
- Efavirenz tablets must be used with other antiretroviral medicines.
- Take efavirenz tablets 1 time each day.
- Efavirenz comes as tablets.
- Efavirenz tablets must not be broken.
- Swallow efavirenz tablets whole with liquid.

How and when to take efavirenz tablets.

- You should take efavirenz tablets on an empty stomach at bedtime. Taking efavirenz tablets with food increases the amount of medicine in your body. Some side effects may bother you less if you take efavirenz tablets on an empty stomach and at bedtime.
- Your child's doctor will prescribe the right dose of efavirenz tablets based on your child's weight.
- If you have difficulty swallowing tablets, tell your doctor.
- Do not miss a dose of efavirenz tablets. If you forget to take efavirenz tablets, take the missed dose right away, unless it is almost time for your next dose. Do not take 2 doses at one time. Just take your next dose at your regularly scheduled time. If you need help in planning the best times to take your medicine, ask your doctor or pharmacist.
- If you take too much efavirenz tablets, call your doctor or go to the nearest hospital emergency room right away.
- When your efavirenz tablets supply starts to run low, get more from your doctor or pharmacy. It is important not to run out of efavirenz tablets. The amount of HIV-1 in your blood may increase if the medicine is stopped for even a short time. The virus may become resistant to efavirenz tablets and harder to treat.

What are the possible side effects of efavirenz tablets?

Efavirenz tablets may cause serious side effects, including:

• Serious mental health problems can happen in people who take efavirenz tablets. Tell your doctor right away if you have any of the following symptoms:

- feel sad or hopeless
- do not trust other people
- feel anxious or restless
- hear or see things that are not real
- have thoughts of hurting yourself (suicide) or have tried to hurt yourself or others
- are not able to move or speak normally.
- are not able to tell the difference between what is true or real and what is false or unreal

• Nervous system symptoms are common in people who take efavirenz tablets and can be severe. These symptoms usually begin during the first or second day of treatment with efavirenz tablets and usually go away after 2 to 4 weeks of treatment. 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 tablets. Symptoms may include:

- dizziness
- trouble sleeping
- trouble concentrating
- unusual dreams
- drowsiness

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

• Skin rash is common with efavirenz tablets 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 doctor right away:

- skin rash, with or without itching
- peeling skin
- fever
- mouth sores
- swelling of your face
- red or inflamed eyes, like “pink eye” (conjunctivitis)
- blisters or skin lesions

Liver problems, including liver failure and death can happen in people who take efavirenz liver problems can also happen in people without a history of liver problems. Your doctor will do blood tests to check your liver before you start efavirenz and during treatment. Tell your doctor right away if you get any of the following symptoms:

- your skin or the white part of your eyes turns yellow (jaundice)
- you don’t feel like eating food for several days or longer
- your urine turns dark
- you feel sick to your stomach (nausea)
- your bowel movements (stools) turn light in color (abdominal) pain
- you have lower stomach area

- Seizures can happen in people who take efavirenz tablets. Seizures are more likely to happen if you have had seizures in the past. Tell your doctor if you have had a seizure or if you take a medicine to help prevent seizures.
- Changes in your immune system (Immune Reconstitution Syndrome) can happen when you start 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 doctor if you start having new symptoms after starting your HIV-1 medicine.
- Changes in body fat can happen in people who take HIV-1 medicine. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these conditions are not known.

The most common side effects of efavirenz tablets include:

- rash
- abnormal dreams
- dizziness
- tiredness
- nausea
- trouble sleeping
- headache
- vomiting
- difficulty concentrating

Some patients taking efavirenz tablets have experienced increased levels of lipids (cholesterol and triglycerides) in the blood. Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of efavirenz tablets. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store efavirenz tablets?

- Store efavirenz tablets at room temperature between 68°F to 77°F (20°C to 25°C).

Keep efavirenz tablets and all medicines out of the reach of children.

General information about efavirenz tablets

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use efavirenz tablets for a condition for which it was not prescribed. Do not give efavirenz tablets to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about efavirenz tablets that is written for health professionals.

For more information call 1-886-495-1995.

What are the ingredients in efavirenz tablets?

Active Ingredient: efavirenz, USP

Inactive ingredients:

Efavirenz tablets: microcrystalline cellulose, sodium lauryl sulfate, croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate. The film coating contains Opadry® Yellow (hypromellose, titanium dioxide, iron oxide yellow and polyethylene glycol)

This Patient Information has been approved by the U.S. Food and Drug Administration.



Manufactured for:

Camber Pharmaceuticals, Inc.

Piscataway, NJ 08854

Manufactured by:

HETEROTM

HETERO LABS LIMITED

22-110, I.D.A., Jeedimetla,

Hyderabad – 500 055, India.

Revised: February 2018

All brand names listed are the registered trademarks of their respective owners and are not trademarks of Hetero Labs Limited.