

Patient Information

SUSTIVA[®] (sus-TEE-vah)
(efavirenz)
capsules

SUSTIVA[®] (sus-TEE-vah)
(efavirenz)
tablets

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

Read this Patient Information before you start taking SUSTIVA 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 is SUSTIVA?

SUSTIVA is 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 SUSTIVA is 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, SUSTIVA 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).

SUSTIVA 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 SUSTIVA?

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

What should I tell my doctor before taking SUSTIVA?

Before taking SUSTIVA, 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. SUSTIVA may harm your unborn baby. If you are able to become pregnant your healthcare provider should do a pregnancy test before you start SUSTIVA. You should not become pregnant while taking SUSTIVA and for 12 weeks after stopping treatment with SUSTIVA.

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 SUSTIVA. 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 SUSTIVA.**
- Talk to your doctor about forms of birth control that may be used during treatment with SUSTIVA.
- **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 SUSTIVA.**
- 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.

SUSTIVA may affect the way other medicines work, and other medicines may affect how SUSTIVA works, and may cause serious side effects. If you take certain medicines with SUSTIVA, the amount of SUSTIVA 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 SUSTIVA or other HIV medicines that are like it.

You should not take SUSTIVA 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 SUSTIVA.

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 SUSTIVA.
- **Do not start taking a new medicine without telling your doctor.** Your doctor can tell you if it is safe to take SUSTIVA with other medicines.

How should I take SUSTIVA?

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

How and when to take SUSTIVA.

- You should take SUSTIVA on an empty stomach at bedtime. Taking SUSTIVA with food increases the amount of medicine in your body. Some side effects may bother you less if you take SUSTIVA on an empty stomach and at bedtime.
- Your child's doctor will prescribe the right dose of SUSTIVA based on your child's weight.
- If you have difficulty swallowing tablets or capsules, tell your doctor. Your doctor may recommend opening the SUSTIVA capsule and mixing the contents with food or infant formula. **See the detailed "Instructions for Use" at the end**

of this Patient Information to learn the right way to take SUSTIVA using the capsule sprinkle method.

- Adults and children who take SUSTIVA using the capsule sprinkle method should not eat for 2 hours after taking a dose of SUSTIVA.
- Babies should not be given infant formula for 2 hours after taking a dose of SUSTIVA using the capsule sprinkle method.
- Do not miss a dose of SUSTIVA. If you forget to take SUSTIVA, 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 SUSTIVA, call your doctor or go to the nearest hospital emergency room right away.
- When your SUSTIVA supply starts to run low, get more from your doctor or pharmacy. It is important not to run out of SUSTIVA. 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 SUSTIVA and harder to treat.

What are the possible side effects of SUSTIVA?

SUSTIVA may cause serious side effects, including:

- **Serious mental health problems** can happen in people who take SUSTIVA. Tell your doctor 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** are common in people who take SUSTIVA and can be severe. These symptoms usually begin during the first or second day of treatment with SUSTIVA 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 SUSTIVA. Symptoms may include:
 - dizziness
 - trouble sleeping
 - trouble concentrating
 - drowsiness

- unusual dreams

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 SUSTIVA 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
 - 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.** If you have liver problems, including hepatitis B or C infection or take another medicine that can cause liver problems, your doctor may do blood tests to check your liver before you start SUSTIVA and during treatment. Liver problems can also happen in people without a history of liver problems. 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)
 - your urine turns dark
 - your bowel movements (stools) turn light in color
 - you don’t feel like eating food for several days or longer
 - you feel sick to your stomach (nausea)
 - you have lower stomach area (abdominal) pain
- **Seizures** can happen in people who take SUSTIVA. 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 SUSTIVA include:

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

Some patients taking SUSTIVA 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 SUSTIVA. 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 SUSTIVA?

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

Keep SUSTIVA and all medicines out of the reach of children.

General information about SUSTIVA

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use SUSTIVA for a condition for which it was not prescribed. Do not give SUSTIVA 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 SUSTIVA that is written for health professionals. For more information, go to www.sustiva.com or call 1-800-321-1335.

What are the ingredients in SUSTIVA?

Active ingredient: efavirenz

Inactive ingredients:

SUSTIVA capsules: lactose monohydrate, magnesium stearate, sodium lauryl sulfate, and sodium starch glycolate. The capsule shell contains gelatin, sodium lauryl sulfate, titanium dioxide, and/or yellow iron oxide. The capsule shell may also contain silicon dioxide. The capsules are printed with ink containing carmine 40 blue, FD&C Blue No. 2, and titanium dioxide.

SUSTIVA tablets: croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and sodium lauryl sulfate. The tablet film coating contains Opadry Yellow and Opadry Clear. The tablets are polished with carnauba wax and printed with purple ink, Opacode WB.

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

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