

# Efavirenz (Sustiva)

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## What is Sustiva?

- Sustiva is an anti-HIV medication. It is in a category of HIV medicines called non-nucleoside reverse transcriptase inhibitors (NNRTIs). Sustiva prevents HIV from entering the nucleus of healthy T-cells. This prevents the cells from producing new virus and decreases the amount of virus in the body.
- Sustiva was approved by the U.S. Food and Drug Administration for the treatment of HIV in 1998. It was originally produced by DuPont Pharmaceuticals and is now manufactured by Bristol-Myers Squibb for sale in the United States. In Europe and many other parts of the world, Sustiva has a different brand name: Stocrin®. Stocrin is manufactured by Merck Sharp and Dohme. Stocrin and Sustiva are the same drug.
- Sustiva must be used in combination with other drugs to treat HIV. It is usually combined with two nucleoside analogues.

## What is known about Sustiva?

- The dose of Sustiva for adults is one 600mg tablet taken once a day.

- Because Sustiva can cause sleepiness, dizziness, and trouble concentrating, it's probably best to take it at bedtime.
- It is recommended that Sustiva be taken on an empty stomach.
- Children who are able to swallow capsules can take Sustiva. Capsules containing lower doses of Sustiva are available. Your child's doctor will determine the right dose based on your child's age and body weight. To learn more about Sustiva dosing for children, [click here](#). For children who aren't able to swallow capsules, a liquid formulation of Sustiva is being developed by the manufacturer. It is currently available through an "expanded access" program. If you are caring for a child requiring Sustiva who cannot swallow capsules, a healthcare provider can enroll the child in the expanded access program by calling this number: (877) 372-7097.
- For HIV-positive adults beginning anti-HIV drug therapy for the first time, Sustiva is listed as the "preferred" NNRTI option by the United States Department of Health and Human Services in its treatment guidelines.

The NNRTI Viramune® (nevirapine) is listed as an “alternative” option.

- If your viral load becomes detectable while taking a drug regimen that contains Sustiva, your doctor can order a drug-resistance test to see which drugs your virus are becoming less sensitive to.
- All of the currently available NNRTIs are affected by cross-resistance. This means that, if you’ve tried and failed a drug regimen in the past that contained either Viramune® (nevirapine) or Rescriptor® (delavirdine), your virus might be resistant to Sustiva. Similarly, if you take an anti-HIV drug regimen that contains Sustiva and your virus becomes resistant to the drug, your virus will most likely be resistant to the other NNRTIs. This is why it is very important to use drug-resistance testing to determine which drugs your virus is no longer responding to if you experience a rebound in your viral load while taking an anti-HIV drug regimen. Fortunately, new NNRTIs that are active against HIV strains resistant to current NNRTIs are being developed.

### What about drug interactions?

- Sustiva is broken down (metabolized) by the liver, like many medications used to treat HIV and AIDS. This means that Sustiva can interact with other medications. Sustiva can lower or raise the levels of other medications in the body. Similarly, other medications can lower or raise the levels of Sustiva in the body. While many interactions are not a problem, some can cause your medications to be less effective or increase the risk of side effects.
- Tell your doctors and pharmacists about all medicines you take. This includes those you buy over-the-counter and herbal or natural remedies, such as St. John’s Wort. Bring all your medicines when you see a doctor, or make a list of their names, how much you take, and how often you take them. Your doctor can then tell you if you need to change the dosages of any of your medications.

- The following medications should not be taken while you are being treated with Sustiva:
  - Antibiotics:** Priftin® (rifapentine)
  - Antifungals:** Vfend® (voriconazole)
  - Antihistamines:** Hismanal® (astemizole)
  - Acid reflux/heartburn medications:** Propulsid® (cisapride)
  - Sedatives:** Versed® (midazolam) and Halcion® (triazolam)
  - Antimigraine medications:** Wigraine® and Cafegot® (ergot medications).
- All of the available nucleoside reverse transcriptase inhibitors can be combined safely with Sustiva.
- Sustiva can reduce the amount of various protease inhibitors in the bloodstream, including Reyataz™ (atazanavir), Invirase® and Fortovase® (saquinavir), Crixivan® (indinavir), Kaletra® (lopinavir/ritonavir), and Agenerase® and Lexiva® (amprenavir/fosamprenavir). Sustiva can increase the amount of Viracept® (nelfinavir) and Norvir® (ritonavir) in the bloodstream. And when Sustiva and Norvir are combined, Sustiva levels also increase in the bloodstream. If Sustiva is taken with Reyataz, Invirase, Fortovase, Kaletra, Crixivan, Agenerase, or Lexiva, their doses may need to be increased or they may need to be combined with a low dose of Norvir (e.g., 100 mg) to help maintain necessary drug levels in the bloodstream.
- Sustiva can interact with some medications used to treat TB, MAC and other bacterial infections. Rifadin® (rifampin) can decrease Sustiva levels (Sustiva dose should be increased to 800 mg). Sustiva can decrease Mycobutin® (rifabutin) levels (Mycobutin dose should be increased). Sustiva can also decrease Biaxin® (clarithromycin) levels; an alternative to clarithromycin is recommended.
- Sustiva can interact with oral contraceptives/birth control pills (ethinyl estradiol). Sustiva increases the amount of ethinyl estradiol in the bloodstream. No alternative has been recommended.

- If you take methadone, Sustiva can decrease the amount of it in your blood. This might cause you to experience withdrawal symptoms and may require that your doctor or your rehabilitation program increase your dose of methadone.
- Blood levels of Viagra® (sildenafil) and Levitra® (vardenafil), two drugs used for erectile dysfunction, can decrease if they are combined with Sustiva. In turn, it may be necessary to increase the dose of Viagra or Levitra to achieve the desired effect.

### What is known about side effects?

- Many patients have dizziness, trouble sleeping, drowsiness, trouble concentrating, and/or unusual dreams a few hours after starting treatment with Sustiva. These feeling may be less noticeable if you take Sustiva at bedtime. They also tend to go away after you've taken the medicine for a few weeks. If you have these side effects, such as dizziness, it does not mean that you will also have severe depression, strange thoughts or angry behavior. Tell your doctor promptly if any of these side effects continue or if they bother you. There is the possibility that these symptoms may be more severe if Sustiva is used with alcohol or mood-altering (recreational) drugs. You should also avoid driving or operating machinery if you are having these side effects.
- A small number of patients have had severe depression, strange thoughts, or angry behavior while taking Sustiva. Some patients have had thoughts of suicide and a few patients have actually committed suicide. These problems tend to occur more often in patients with a history of mental illness. You should contact your doctor immediately if you think you are having these symptoms, so your doctor can decide whether you should continue to take Sustiva.
- Rash is another common side effect of Sustiva. These rashes usually go away without any change in treatment. In a small number of patients, rash may be serious. If you develop rash, call your doctor as soon as possible.
- Other possible side effects include tiredness, upset stomach, vomiting, and diarrhea.
- Sustiva can cause someone to test positive for marijuana as a result of testing for illicit drug use. If you are asked to submit urine for a drug test, you may want to tell the person collecting the sample that you take Sustiva. This way, the laboratory conducting the test will know to use a more sensitive test to prevent false-positive results.
- Rash may be a serious problem in some children. Tell your child's doctor right away if you notice rash or any other side effects while your child is taking Sustiva.

### Can pregnant women take Sustiva?

- Sustiva is classified by the FDA as a pregnancy category C drug. All the FDA-approved anti-HIV drugs are classified as either category B or C. Pregnancy category B means that animal studies have failed to demonstrate a risk to the fetus, but there are no adequate and well-controlled studies in pregnant women. Pregnancy category C means that animal studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. HIV-positive women who become pregnant should discuss the benefits and possible side effects of anti-HIV treatment to help protect their babies from HIV.



For more treatment information, call Project Inform's toll-free National HIV/AIDS Treatment Information Hotline at 1-800-822-7422.

- Sustiva has caused serious side effects in infant monkeys born to adult female monkeys. Because of this, it is recommended that HIV-positive women refrain from using Sustiva while pregnant or practice birth control to prevent pregnancy while taking the drug. However, it is important to note that babies have been born to HIV-positive women who took Sustiva while pregnant and, thus far, no serious side effects have been reported.
- It is not known if Sustiva can pass from a mother to her baby through breast milk. It is also not known what effect this may have on a nursing baby. To prevent transmission of the virus to uninfected babies, it is recommended that HIV-positive mothers not breast-feed.

#### Who should not take Sustiva?

- Do not take Sustiva if you are allergic to Sustiva or any of its ingredients.

#### Where can I learn more about clinical trials of Sustiva?

- Even though Sustiva is approved for the treatment of HIV, it is still used in clinical trials, either to learn more about its safety and effectiveness or to determine how well it works in combination with experimental treatments.
- If you would like to find out if you are eligible for any clinical trials that include Sustiva, there is an interactive web site run by amfAR, the American Foundation for AIDS Research.
- Another useful service for finding clinical trials is *AIDSinfo.nih.gov*, a site run by the U.S. National Institutes of Health. They have “health information specialists” you can talk to at their toll-free number at 1-800-HIV-0440 (1-800-448-0440).

### a note about this publication

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