

# Nevirapine (Viramune)

reprinted from [www.aidsmeds.com](http://www.aidsmeds.com), united states

## What is Viramune?

- Viramune is an anti-HIV medication. It is in a category of HIV medicines called non-nucleoside reverse transcriptase inhibitors (NNRTIs). Viramune 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.
- Viramune, manufactured by Boehringer-Ingelheim, was approved by the U.S. Food and Drug Administration for the treatment of HIV in 1996.
- Viramune must be used in combination with other drugs to treat HIV. It is usually combined with two nucleoside analogues.

## What is known about Viramune?

- Taking Viramune is a two-step process. For the first two weeks (14 days) of treatment, the dose is one 200mg tablet once a day. Two weeks after starting treatment, the dose of Viramune is increased to one 200mg tablet twice a day. Following this schedule—which you should do under your doctor's guidance—can reduce the chance of developing a rash or other side effects.
- It might be possible to take Viramune only once a day. This would involve taking one 200mg tablet, once a day, for two weeks, followed by two 200mg tablets, also once a day, thereafter. Researchers are now testing the safety and effectiveness of this option—it has not yet

recommended by any experts and has not yet been evaluated by the U.S. Food and Drug Administration.

- You may take Viramune with water, milk, or soda. You may take Viramune either with or without foods.
- Researchers have found that Viramune passes easily into the brain. This is very important because HIV can infect brain cells. Anti-HIV drugs that pass through the brain's protective barrier—called the “blood-brain barrier”—may help prevent and/or treat conditions like AIDS-related dementia.
- Viramune can be given to children, using their size or their body weight to determine the dose. Most experts prefer to use body weight as the method for selecting a Viramune dose. To learn more about Viramune dosing for children, [click here](#). A liquid solution of Viramune is available for babies and children, which is easier to give to young children than the adult tablets.
- For HIV-positive adults beginning anti-HIV drug therapy for the first time, Viramune is listed as an “alternative” NNRTI option by the United States Department of Health and Human Services in its treatment guidelines. The NNRTI Sustiva® (efavirenz) is listed as the “preferred” option.
- If your viral load becomes detectable while taking a drug regimen that contains Viramune, 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 Sustiva® (efavirenz) or Rescriptor® (delavirdine), your virus might be resistant to Viramune. Similarly, if you take an anti-HIV drug regimen that contains Viramune 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?

- Viramune is broken down (metabolized) by the liver, like many medications used to treat HIV and AIDS. This means that Viramune can interact with other medications. Viramune can lower or raise the levels of other medications in the body. Similarly, other medications can lower or raise the levels of Viramune 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 Viramune:
  - Antibiotics:** Rifadin® (rifampin) and Priftin® (rifapentine).
- All of the available nucleoside reverse transcriptase inhibitors can be combined safely with Viramune.
- Viramune 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). Viramune can increase the amount of Viracept® (nelfinavir) and Norvir® (ritonavir) in the bloodstream. If Viramune 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.

- Viramune can interact with some medications used to treat TB, MAC and other bacterial infections. Rifadin® (rifampin) can decrease Viramune levels (Rifadin should not be used). Mycobutin® (rifabutin) can also decrease Viramune levels (no dose change necessary). Viramune can also decrease Biaxin® (clarithromycin) levels; similarly Biaxin can increase Viramune levels (an alternative to Biaxin is recommended).
- Viramune can interact with some medications used to treat thrush (candidiasis) and other fungal infections. Viramune can decrease Nizoral® (ketoconazole) levels in the bloodstream. Similarly, Nizoral can increase Viramune levels in the bloodstream. Taking these two drugs together is not recommended.
- Viramune can interact with oral contraceptives/birth control pills (ethinyl estradiol). Viramune decreases the amount of ethinyl estradiol in the bloodstream, which can increase the risk of pregnancy.
- If you take methadone, Viramune 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.
- It is not yet known what effect Viramune has on blood levels of Viagra® (sildenafil) or Levitra® (vardenafil), two drugs used for erectile dysfunction.

### What is known about side effects?

- Liver problems have been reported in HIV-positive people treated with Viramune. The greatest risk of liver problems is during the first six weeks of treatment. What's more, women (including pregnant

women) with T-cell counts greater than 250 at the time of starting Viramune treatment are more likely than men or people with lower T-cell counts to experience liver problems within the first six weeks of treatment. Because liver problems can be very serious, your doctor should make sure your liver is healthy—he or she can order simple blood tests to check for this—before you start taking this medication. Your doctor should also test your blood frequently during the first three to four months of Viramune therapy.

- In rare cases, these liver problems can be very serious and become life-threatening. Therefore, if you develop any of the following symptoms, call your doctor immediately: general ill feeling, tiredness, lack of appetite, yellowing of the skin or eyes, darkening of the urine, pale stools, liver tenderness.
- The most common side effect of Viramune is skin rash. In a small number of patients, rash has been serious and resulted in death. Therefore, if you develop a rash with any of the following symptoms, call your doctor immediately: general ill feeling, fever, muscle or joint aches, blisters, mouth sores, conjunctivitis (inflammation of the inner surface of the eyelids), swelling of the face, tiredness.
- If you must stop treatment with Viramune because you have these types of serious reactions, you must not take Viramune again.

### Can pregnant women take Viramune?

- Viramune 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.

- Viramune has been shown to easily pass from a pregnant woman's bloodstream, through the placenta, into the baby's bloodstream. This is important, as it helps protect a baby from HIV in his or her mother's bloodstream, both while it is developing and at the time of birth.
- Viramune has been studied in clinical trials of HIV-positive pregnant women. In one study funded by the U.S. federal government (PACTG 250), single doses of Viramune were given to HIV-positive pregnant women prior to delivery and to their babies within three days of being born. Viramune did not cause any significant short-term or long-term side effects in either the mother or her baby.
- Results from another study (HIVNET 012) suggested that giving a single dose of Viramune to an HIV-positive pregnant woman immediately before birth—followed by a dose given to her newborn baby—reduces transmission rates by nearly 50%. This study was conducted in African women, many of whom did not receive adequate prenatal care. Because they are effective and cheap, single doses of Viramune are now being used in many clinics in poor countries to help reduce the risk of mother-to-infant HIV transmission.
- More recently, a second study funded by the U.S. federal government (PACTG 316) concluded that anti-HIV regimens that contain a combination of drugs—which may include Viramune—reduced the risk of transmission to 1.5%. In other words, only 3 out of every 200 HIV-positive pregnant women who take a combination of anti-HIV drugs and have an undetectable viral load at the time of delivery will give birth to HIV-positive babies.
- Viramune can pass from a mother to her baby through breast milk. It is 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.



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

### Who should not take Viramune?

- Do not take Viramune if you are allergic to Viramune or any of its ingredients.
- Do not restart Viramune after you recover from serious liver or skin reactions which have occurred while taking this drug.

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

- Even though Viramune 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 Viramune, 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

This publication is reprinted here from another source ([www.aidsmeds.com](http://www.aidsmeds.com)). We do not always have the resources at Project Inform to produce our own treatment information on every treatment topic. In these cases, we try to provide reliable information from other sources but cannot confirm that every fact in these publications is accurate. References to other materials have been pulled. This information is designed to support, not replace, the relationship that exists between you and your doctor or medical provider.

TEXT LAST UPDATED: FEBRUARY 2004