



Patient Information about VIRAMUNE for HIV (Human Immunodeficiency Virus) Infection

Generic name: nevirapine

Please read this information before you start taking VIRAMUNE. Read it again each time you refill your prescription, in case there is any new information. Remember, this leaflet does not take the place of careful discussions with your doctor. You and your doctor should discuss VIRAMUNE when you start taking your medication and at regular checkups. You should remain under a doctor's care when using VIRAMUNE. You should not change or stop treatment without first talking to your doctor.

What is VIRAMUNE?

VIRAMUNE is a medicine used for the treatment of adults and children with HIV, the virus that causes AIDS (acquired immune deficiency syndrome). VIRAMUNE is a type of HIV drug called a "non-nucleoside reverse transcriptase inhibitor" (NNRTI).

How does VIRAMUNE work?

VIRAMUNE works by lowering the amount of HIV in the blood (called "viral load"). VIRAMUNE must be taken with other anti-HIV medicines. When taken with other anti-HIV medicines, VIRAMUNE has been shown to reduce viral load and increase the number of CD4 cells (a type of immune cell in the blood). VIRAMUNE may not have these effects in every patient.

What is the most important information I should know about VIRAMUNE?

Severe, life-threatening, and in some cases fatal liver disease (hepatitis, liver failure) and skin reactions have been reported in patients treated with VIRAMUNE. These reactions occur most frequently during the first 12 weeks of therapy, but also occur after this period. Therefore, evaluations by your doctor, including liver function tests, should be done before starting treatment and frequently in the first 12 weeks of therapy, and should be continued regularly throughout therapy.

In rare cases liver disease has resulted in liver transplantation or death. 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, never take VIRAMUNE again.

What are other possible side effects of VIRAMUNE?

VIRAMUNE can cause other side effects. In clinical trials when VIRAMUNE was taken with other anti-HIV drugs, other side effects included: nausea, fatigue, diarrhea, fever and vomiting. This is only a list of more common side effects; do not rely on this leaflet alone for information about side effects. Your doctor can discuss with you a more complete list of side effects. Tell your doctor or other healthcare provider if you notice any side effects while taking VIRAMUNE.

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 VIRAMUNE.

Does VIRAMUNE cure HIV or AIDS?

VIRAMUNE is not a cure for HIV or AIDS. People taking VIRAMUNE may still develop other infections associated with HIV. Because of this, it is very important that you remain under the care of your doctor.

It is not yet known whether taking VIRAMUNE will extend your life or reduce your chances of getting other illnesses associated with HIV.

Does VIRAMUNE reduce the risk of passing HIV to others?

VIRAMUNE has not been shown to reduce the risk of passing HIV to others through sexual contact or blood contamination.

How should I take VIRAMUNE?

- The dose of VIRAMUNE for adults is one 200 mg tablet daily for the first 14 days, followed by one 200 mg tablet twice daily. This is done to lessen frequency of rash and it is important to strictly follow the initial once daily dose. Do not start taking VIRAMUNE twice a day if you have any symptoms of liver disease or skin rash until discussion with your doctor and these symptoms have resolved. (see "**What is the most important information I should know about VIRAMUNE?**")
- The dose of VIRAMUNE for children is adjusted according to their age and weight by your doctor. (see "**Can children take VIRAMUNE?**")
- You may take VIRAMUNE with water, milk, or soda. You may take VIRAMUNE with or without meals.

- Do not miss a dose of VIRAMUNE. If you forget to take VIRAMUNE, take the missed dose right away. If you do miss a dose, do not double the next dose. Carry on with your regular dosing schedule. If you need help in planning the best times to take your medicine, ask your doctor or pharmacist.
- If you or your child are using VIRAMUNE suspension, it should be gently shaken before using. Use an oral dosing syringe or dosing cup to measure the right dose. Rinse the dosing cup with water and swallow the rinse to make sure you get all the medication. If you or your child are taking less than 5 ml (one teaspoon), use the syringe.
- Take the exact amount of VIRAMUNE your doctor prescribes. Never change the dose on your own. Do not stop this medicine unless your doctor tells you to stop. If you have signs of liver disease or develop a rash with symptoms **call your doctor immediately** (see **“What is the most important information I should know about VIRAMUNE?”**)
- When your VIRAMUNE supply starts to run low, get more from your doctor or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to VIRAMUNE and become harder to treat.

Can children take VIRAMUNE?

Yes. Your child's doctor will determine the right dose based on your child's age and weight. For children 2 months up to 8 years of age the oral suspension dose is 4 mg per kilogram once daily for the first 14 days followed by 7 mg per kilogram twice daily thereafter. For patients 8 years and older the dose is 4 mg per kilogram once daily for two weeks followed by 4 mg per kilogram twice daily thereafter. This is done to lessen frequency of rash and it is important to strictly follow the initial once daily dose.

What medical problems or conditions should I discuss with my doctor?

Talk to your doctor if you:

- Have problems with your liver, or have had hepatitis
- Have skin conditions, such as rash
- Have side effects while taking VIRAMUNE
- Start or change any medicine
- Are pregnant or want to become pregnant
- Are breast-feeding

What about birth control or pregnancy?

Women should not become pregnant while taking VIRAMUNE. Barrier contraception (condoms) should be used to prevent pregnancy. VIRAMUNE may reduce the effectiveness of birth control pills which may result in pregnancy. Therefore, birth control pills should not be used to prevent pregnancy if you are taking VIRAMUNE. They may be used for other purposes, such as controlling symptoms of endometriosis. Inform your doctor immediately if you are pregnant. If you want to become pregnant, talk to your doctor.

Can I take other medicines with VIRAMUNE?

VIRAMUNE may change the effect of other medicines (including ones for HIV). Your doctor may change your medicines or change their doses. For this reason, it is very important to:

- Let all your doctors and pharmacists know that you take VIRAMUNE.
- 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. This will give your doctor a complete picture of the medicines you use. Then he or she can decide the best approach for your situation.

You should **not** take NIZORAL (ketoconazole) or St. John's wort with VIRAMUNE.

Nucleoside analogues such as RETROVIR (zidovudine, ZDV, AZT), VIDEX (didanosine, ddI) and HIVID (zalcitabine, ddC) may be taken with VIRAMUNE.

Protease inhibitors, such as NORVIR (ritonavir), CRIVAN (indinavir) or FORTOVASE (saquinavir) may be taken with VIRAMUNE. VIRAMUNE may have an effect on the amount of these drugs in your blood, so this should be discussed with your doctor.

If you are taking methadone, you may experience withdrawal symptoms and may have to increase the dose of methadone while taking VIRAMUNE.

How should I store VIRAMUNE?

VIRAMUNE is available as 200 mg tablets or as oral suspension.

Keep VIRAMUNE at room temperature (59° to 86° F) in the bottle given to you by your pharmacist.

Keep VIRAMUNE out of the reach of children.

How can I learn more about VIRAMUNE?

Talk to your doctor or other healthcare provider if you have questions about either VIRAMUNE or HIV.

This medicine was prescribed for your particular condition. Do not use it for any other condition or give it to anybody else. Keep VIRAMUNE out of the reach of children. If you suspect that more than the prescribed dose of this medicine has been taken, contact your local poison control center or emergency room immediately.