

ATTENTION PHARMACISTS: Detach “Medication Guide” and dispense with the product.

MEDICATION GUIDE

VIRAMUNE® (VIH-rah-mune) Tablets

VIRAMUNE® Oral Suspension

Generic name: nevirapine tablets and oral suspension

Read this Medication Guide before you start taking VIRAMUNE and each time you get a refill because there may be new information. This information does not take the place of talking with your doctor. You and your doctor should discuss VIRAMUNE when you start taking your medicine and at regular checkups. You should stay under a doctor's care while using VIRAMUNE. You should consult with your doctor before making any changes to your medications, except in any of the special circumstances described below regarding rash or liver problems.

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

Patients taking VIRAMUNE may develop severe liver disease or skin reactions that can cause death. The risk of these reactions is greatest during the first 18 weeks of treatment, but these reactions also can occur later.

Liver Reactions

Any patient can experience liver problems while taking VIRAMUNE. However, women and patients who have higher CD4 counts when they begin VIRAMUNE treatment have a greater chance of developing liver damage. Women with CD4 counts higher than 250 cells/mm³ are at the greatest risk of these events. If you are a woman with CD4>250 cells/mm³ or a man with CD4>400 cells/mm³ you should not begin taking VIRAMUNE unless you and your doctor have decided that the benefit of doing so outweighs the risk. Liver problems are often accompanied by a rash.

Patients starting VIRAMUNE with abnormal liver tests and patients with hepatitis B or C have a greater chance of developing further increases in liver tests after starting VIRAMUNE and throughout therapy.

In rare cases liver problems have led to liver failure and can lead to a liver transplant or death. Therefore, if you develop any of the following symptoms of liver problems stop taking VIRAMUNE and call your doctor right away:

- general ill feeling or “flu-like” symptoms
- dark urine (tea colored)
- tiredness
- pale stools (bowel movements)
- nausea (feeling sick to your stomach)
- pain, ache, or sensitivity to touch on your right side below your ribs
- lack of appetite
- yellowing of your skin or whites of your eyes

Your doctor should check you and do blood tests often to check your liver function during the first 18 weeks of therapy. Checks for liver problems should continue regularly during treatment with VIRAMUNE.

Skin Reactions

Skin rash is the most common side effect of VIRAMUNE. Most rashes occur in the first 6 weeks of treatment. In a small number of patients, **rash can be serious and result in death.** Therefore, **if you develop a rash with any of the following symptoms stop using VIRAMUNE and call your doctor right away:**

- general ill feeling or “flu-like” symptoms
- blisters
- fever
- mouth sores
- muscle or joint aches
- swelling of your face
- conjunctivitis (red or inflamed eyes, like “pink eye”)
- tiredness
- any of the symptoms of liver problems discussed above

If your doctor tells you to stop treatment with VIRAMUNE because you have experienced the serious liver or skin reactions described above, never take VIRAMUNE again.

These are not all the side effects of VIRAMUNE. See the section "**What are the possible side effects of VIRAMUNE?**" for more information. Tell your doctor if you have any side effects from VIRAMUNE.

What is VIRAMUNE?

VIRAMUNE is a medicine used to treat Human Immunodeficiency Virus (HIV), the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

VIRAMUNE is a type of anti-HIV medicine called a "non-nucleoside reverse transcriptase inhibitor" (NNRTI). It works by lowering the amount of HIV in the blood ("viral load"). You must take VIRAMUNE with other anti-HIV medicines. When taken with other anti-HIV medicines, VIRAMUNE can reduce viral load and increase the number of CD4 cells ("T cells"). CD4 cells are a type of immune helper cell in the blood. VIRAMUNE may not have these effects in every patient.

VIRAMUNE does not cure HIV or AIDS, and it is not known if it will help you live longer with HIV. People taking VIRAMUNE may still get infections common in people with HIV (opportunistic infections). Therefore, it is very important that you stay under the care of your doctor.

Who should not take VIRAMUNE?

- Do not take VIRAMUNE if you are allergic to VIRAMUNE or any of its ingredients. The active ingredient is nevirapine. Your doctor or pharmacist can tell you about the inactive ingredients.
- Do not restart VIRAMUNE after you recover from serious liver or skin reactions that happened when you took VIRAMUNE.
- **Do not take VIRAMUNE if you have severe liver problems.**
- Do not take VIRAMUNE if you take certain medicines. (See “**Can I take other medicines with VIRAMUNE?**” for a list of medicines.)
- Do not take VIRAMUNE if you are not infected with HIV.

What should I tell my doctor before taking VIRAMUNE?

Before starting VIRAMUNE, tell your doctor about all of your medical conditions, including if you:

- have problems with your liver or have had hepatitis
- are undergoing dialysis
- have skin conditions, such as a rash
- are pregnant, planning to become pregnant, or are breast feeding

How should I take VIRAMUNE?

- Take the exact amount of VIRAMUNE your doctor prescribes. The usual dose for adults is one tablet daily for the first 14 days followed by one tablet twice daily. Starting with one dose a day lowers the chance of rash, which could be serious. Therefore, it is important to strictly follow the once daily dose for the first 14 days. If you have a skin rash during the first 14 days immediately contact your doctor and do not increase your dose to VIRAMUNE twice a day. The total duration of the once daily lead-in dosing period should not exceed 28 days at which point an alternative regimen may need to be started. See the first section “**What is the most important information I should know about VIRAMUNE?**”
- The dose of VIRAMUNE for children is based on their size. Children’s dosing also starts with once a day for 14 days and then twice a day after that.
- You may take VIRAMUNE with water, milk, or soda, with or without food.
- If you or your child uses VIRAMUNE suspension (liquid), shake it gently before use. Use an oral dosing syringe or dosing cup to measure the right dose. After drinking the medicine, fill the dosing cup with water and drink it to make sure you get all the medicine. If the dose is less than 5 mL (one teaspoon), use the syringe.
- Do not miss a dose of VIRAMUNE, because this could make the virus harder to treat. If you forget to take VIRAMUNE, take the missed dose right away. If it is almost time for your next dose, do not take the missed dose. Instead, follow your regular dosing schedule by taking the next dose at its regular time.
- If you stop taking VIRAMUNE for more than 7 days, ask your doctor how much to take before you start taking it again. You may need to start with once-a-day dosing.
- If you suspect that you have taken too much VIRAMUNE, contact your local poison control center or emergency room right away.

Can I take other medicines with VIRAMUNE?

- VIRAMUNE may change the effect of other medicines, and other medicines can change the effect of VIRAMUNE. Tell your doctors and pharmacists about **all** medicines you take, including non-prescription medicines, vitamins and herbal supplements.
- Do **not** take Nizoral[®] (ketoconazole) or Rifadin[®]/Rifamate[®]/Rifater[®] (rifampin) with VIRAMUNE.
- Tell your doctor if you take Biaxin[®] (clarithromycin), Diflucan[®] (fluconazole), methadone, or Mycobutin[®] (rifabutin). VIRAMUNE may not be right for you, or you may need careful monitoring.
- It is recommended that you not take products containing St. John’s wort, which can reduce the amount of VIRAMUNE in your body.
- If you take birth control pills, you should not rely on them to prevent pregnancy. They may not work if you take VIRAMUNE. Talk with your doctor about other types of birth control that you can use.

What should I avoid while taking VIRAMUNE?

Avoid doing things that can spread HIV infection, as VIRAMUNE does not stop you from passing HIV infection to others. Do not share needles, other injection equipment or personal items that can have blood or body fluids on them, like toothbrushes and razor

blades. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

The Centers for Disease Control and Prevention advises mothers with HIV not to breast feed so they will not pass HIV to the infant through their milk. Ask your doctor about the best way to feed your infant.

What are the possible side effects of VIRAMUNE?

VIRAMUNE can cause serious liver damage and skin reactions that can cause death. Any patient can experience such side effects, but some patients are more at risk than others. See "**What is the most important information I should know about VIRAMUNE?**" at the beginning of this Medication Guide.

Other common side effects of VIRAMUNE include nausea, fatigue, fever, headache, vomiting, diarrhea, abdominal pain, and myalgia. This list of side effects is not complete. Ask your doctor or pharmacist for more information.

Changes in body fat have also been seen in some patients taking antiretroviral therapy. The changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the 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 at this time.

How do I store VIRAMUNE?

Store VIRAMUNE at room temperature, between 59° to 86°F (15° to 30°C).

Throw away VIRAMUNE that is no longer needed or out-of-date.

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

General information about VIRAMUNE

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VIRAMUNE for a condition for which it was not prescribed. Do not give VIRAMUNE to other people, even if they have the same condition you have. It may harm them.

This Medication Guide summarizes the most important information about VIRAMUNE. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about VIRAMUNE that is written for health professionals, or you can call 1-800-542-6257 for additional information.

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Ridgefield, CT 06877 USA

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Rev: June 2008

10003354/03

10003354/US/3

OT1801EF2408

This Medication Guide has been approved by the US Food and Drug Administration.