

MEDICATION GUIDE

VIRAMUNE® (VIH-rah-mune)
(nevirapine)
Tablets
VIRAMUNE® (VIH-rah-mune)
(nevirapine)
Oral Suspension

Read this Medication Guide before you start taking VIRAMUNE and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or treatment.

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

VIRAMUNE can cause serious side effects. These include severe liver and skin problems which can cause death. The risk of these problems is greatest during the first 18 weeks of treatment, but these problems can also happen at any time during treatment.

Severe liver problems: Anyone who takes VIRAMUNE may get severe liver problems. In some cases, these liver problems can lead to liver failure and the need for a liver transplant, or death. You may get a rash if you have liver problems. People with higher risk of these problems include women or anyone with higher CD4⁺ cell counts when they begin VIRAMUNE treatment. Women with CD4⁺ cell counts higher than 250 cells/mm³ at the start of treatment have the greatest risk for liver damage.

If you are a woman with CD4⁺ cell >250 cells/mm³ or a man with CD4⁺ cell >400 cells/mm³, you and your doctor will decide if VIRAMUNE is right for you.

People who have abnormal liver test results and people with hepatitis B or C have a greater chance of getting liver problems and further increases in liver test results during treatment.

If you get any of the following symptoms of liver problems, stop taking VIRAMUNE and call your doctor right away:

- fever
- “flu-like” symptoms or you do not feel well
- dark (tea colored) urine
- tiredness
- light-colored bowel movements (stools)
- nausea (feeling sick to your stomach)
- pain or tenderness on your right side below your ribs
- loss of appetite
- yellowing of your skin or whites of your eyes

Your doctor should see you and do blood tests often to check your liver function during the first 18 weeks of treatment with VIRAMUNE. You should continue to have your liver checked regularly during your treatment with VIRAMUNE. It is important for you to keep all of your doctor appointments.

Severe rash and skin reactions: Skin rash is the most common side effect of VIRAMUNE. Most rashes happen in the first 6 weeks of taking VIRAMUNE. **Rashes and skin reactions may be severe, life-threatening, and in some people, may lead to death. If you get a rash with any of the following symptoms, stop using VIRAMUNE and call your doctor right away:**

- “flu-like” symptoms or you do not feel well
- blisters
- fever

- mouth sores
- muscle or joint aches
- swelling of your face
- red or inflamed eyes, like “pink eye” (conjunctivitis)
- tiredness
- swollen glands (enlarged lymph nodes)
- liver problems (see symptoms of liver problems above)

If your doctor tells you to stop treatment with VIRAMUNE because you have had the serious liver or skin problems described above, you should 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.

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). VIRAMUNE works by lowering the amount of HIV in your blood (“viral load”). You must take VIRAMUNE with other anti-HIV medicines. When you take VIRAMUNE with other anti-HIV medicines, VIRAMUNE can lower your 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 person.

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). It is very important that you stay under the care of your doctor.

Who should not take VIRAMUNE?

Tell your doctor if you have or have had liver problems. Your doctor may tell you not to take VIRAMUNE if you have certain liver problems.

VIRAMUNE is only for people diagnosed with HIV. If you have not been diagnosed as HIV positive, then do not take VIRAMUNE.

What should I tell my doctor before taking VIRAMUNE?

Before you take VIRAMUNE, tell your doctor if you:

- have or have had hepatitis (inflammation of your liver) or problems with your liver. See **“What is the most important information I should know about VIRAMUNE?”** and **“Who should not take VIRAMUNE?”**
- receive dialysis
- have skin problems, such as a rash
- are pregnant or plan to become pregnant. It is not known if VIRAMUNE will harm your unborn baby.
Pregnancy Registry: There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of the 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.
- are breast-feeding or plan to breast-feed. VIRAMUNE can pass into your breast milk and may harm your baby. It is also recommended that HIV-positive women should not breast-feed their babies. Do not breast-feed during treatment with VIRAMUNE. Talk to your doctor about the best way to feed your baby.

Tell your doctor and pharmacist about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. VIRAMUNE may affect the way other medicines work, and other medicines may affect how VIRAMUNE works. Especially tell your doctor if you take:

- St. John’s Wort. You should not take products containing St. John’s Wort during treatment with VIRAMUNE because it can lower the amount of VIRAMUNE in your body.

- efavirenz (Sustiva[®], Atripla[®]). You should not take efavirenz during treatment with VIRAMUNE. You may have an increased chance of side effects if this is taken together with VIRAMUNE.
- atazanavir (Reyataz[®]). You should not take atazanavir during treatment with VIRAMUNE.
- itraconazole (Sporanox[®]). You should not take itraconazole during treatment with VIRAMUNE.
- ketoconazole (Nizoral[®]). You should not take ketoconazole during treatment with VIRAMUNE.
- rifampin (Rifadin[®], Rifamate[®], Rifater[®]). You should not take rifampin during treatment with VIRAMUNE.
- Birth control pills. Birth control pills taken by mouth (oral contraceptives) and other hormone types of birth control may not work to prevent pregnancy if you use them during VIRAMUNE treatment. Talk with your doctor about other types of birth control that you can use to prevent pregnancy during treatment with VIRAMUNE.

Also tell your doctor if you are taking the following drugs:

- clarithromycin (Biaxin)
- fluconazole (Diflucan)
- methadone
- rifabutin (Mycobutin)

Know the medicines you take. Keep a list of them to show your doctor or pharmacist when you get a new medicine.

How should I take VIRAMUNE?

- Take VIRAMUNE exactly as your doctor tells you to take it.
- The dose of VIRAMUNE for children is based on their size and thus may not be the same as in adults.
- You may take VIRAMUNE with or without food.
- If you or your child takes VIRAMUNE suspension (liquid), shake it gently before use. Use an oral dosing syringe or dosing cup to measure the right dose. The oral dosing syringe and dosing cup are not provided with VIRAMUNE Suspension.
- 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 1 teaspoon (5 mL), use the syringe instead of the dosing cup.
- Do not change your dose unless your doctor tells you to.
- Your doctor should start you with one dose each day to lower your chance of getting a serious rash. It is important that you only take one dose of VIRAMUNE each day for the first 14 days.
- Call your doctor right away if you get a skin rash during the first 14 days of VIRAMUNE treatment and do not increase your dose to 2 times a day.
- You should never take your starting dose (200 mg one time each day) for longer than 28 days. If after 28 days you are still receiving this starting dose because you have a rash, you and your doctor should discuss replacing VIRAMUNE with another HIV medicine. Never increase your dose to 2 times a day if you have a rash.
- Do not miss a dose of VIRAMUNE, because this could make HIV harder to treat. If you miss a dose of VIRAMUNE, take the missed dose as soon as you remember. If it is almost time for your next dose, do not take the missed dose, just take the next dose at your 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 one time each day dosing again.
- If you take too much VIRAMUNE, call your local poison control center or emergency room right away.

What are the possible side effects of VIRAMUNE?

VIRAMUNE may cause serious side effects.

- See **“What is the most important information I should know about VIRAMUNE?”**
- Other common side effects of VIRAMUNE include nausea, fatigue, fever, headache, vomiting, diarrhea, abdominal pain, and muscle pain.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV 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 medicine.
- **Changes in body fat** can happen in some people who take antiretroviral therapy. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the middle of your body (trunk). Loss of fat from your legs, arms, and face can also happen. The cause and long-term health effects of these problems are not known at this time.

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 VIRAMUNE. 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 VIRAMUNE?

- Store VIRAMUNE at 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.

For more information, call Boehringer Ingelheim Pharmaceuticals, Inc., at 1-800-542-6257, or (TTY) 1-800-459-9906.

What are the ingredients in VIRAMUNE?

Active Ingredient: nevirapine

Inactive ingredients:

Viramune Tablets: microcrystalline cellulose, lactose monohydrate, povidone, sodium starch glycolate, colloidal silicon dioxide, and magnesium stearate

Viramune Oral Suspension: carbomer 934P, methylparaben, propylparaben, sorbitol, sucrose, polysorbate 80, sodium hydroxide, and purified water

Distributed by:

Boehringer Ingelheim Pharmaceuticals, Inc.
Ridgefield, CT 06877 USA

Rev: June 2010

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

Atripla, Reyataz, and Sustiva are trademarks of Bristol-Myers Squibb. Biaxin is a trademark of Abbott Laboratories. Diflucan is a trademark of Pfizer, Inc. Mycobutin is a trademark of Pharmacia & Upjohn Company. Nizoral and Sporanox are trademarks of Janssen Pharmaceutica. Rifadin, Rifamate, and Rifater are trademarks of Aventis Pharmaceuticals, Inc.

©Copyright 2010 Boehringer Ingelheim Pharmaceuticals, Inc.
ALL RIGHTS RESERVED

OT1801LE1910
10003354/06

OT1803D
090340228/5