MEDICATION GUIDE

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

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

VIRAMUNE XR® (VIH-rah-mune)
(nevirapine)
Extended-Release Tablets

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 that can cause death. These problems can happen at any time during treatment, but your risk is higher during the first 18 weeks of treatment.

1. **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.

People who have a higher $CD4^+$ cell count when they begin VIRAMUNE treatment have a higher risk of liver problems, especially:

- Women with $CD4^+$ counts higher than 250 cells/mm^3. This group has the highest risk.
- Men with $CD4^+$ counts higher than 400 cells/mm^3.

If you are a woman with $CD4^+$ counts higher than 250 cells/mm^3 or a man with $CD4^+$ counts higher than 400 cells/mm^3, you and your doctor will decide whether starting VIRAMUNE is right for you.

In general, women have a higher risk of liver problems compared to men.

People who have abnormal liver test results before starting VIRAMUNE treatment and people with hepatitis B or C also have a greater chance of getting liver problems.

You may get a rash if you have liver problems.

Stop taking VIRAMUNE and call your doctor right away if you have any of the following symptoms of liver problems:

- dark (tea colored) urine
- yellowing of your skin or whites of your eyes
- light-colored bowel movements (stools)
- fever
- nausea (feeling sick to your stomach)
- feel unwell or like you have the flu
- pain or tenderness on your right side below your ribs
- tiredness
- loss of appetite

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.

2. **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. Stop using VIRAMUNE and call your doctor right away if you get a rash with any of the following symptoms:**

- blisters
- mouth sores
- red or inflamed eyes, like “pink eye” (conjunctivitis)
- liver problems (see symptoms of liver problems above)
- swelling of your face
- fever
- feel unwell or like you have the flu
- tiredness
- muscle or joint aches

If your doctor tells you to stop treatment with VIRAMUNE because you have had any of the serious liver or skin problems described above, you should never take VIRAMUNE again.

See the section "**What are the possible side effects of VIRAMUNE?**" for more information.

What is VIRAMUNE?

- VIRAMUNE tablets and VIRAMUNE oral solution are prescription HIV medicines used with other HIV medicines to treat HIV (Human Immunodeficiency Virus). HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).
- VIRAMUNE XR extended-release tablets are a prescription medicine used with other HIV medicines to treat HIV (Human Immunodeficiency Virus) in adults and in children who are 6 years of age to less than 18 years of age.
- VIRAMUNE and VIRAMUNE XR are a type of HIV medicine called a non-nucleoside reverse transcriptase inhibitor (NNRTI).

VIRAMUNE XR extended-release tablets are not for use in children less than 6 years of age.

When used with other HIV medicines, VIRAMUNE may:

1. Reduce the amount of HIV in your blood (called “viral load”)

2. Help increase the number of CD4 (T) cells in your blood which help fight off other infections.

Reducing the amount of HIV and increasing the CD4 (T) cell count may improve your immune system. This may reduce your risk of death or infections that can happen when your immune system is weak (opportunistic infections).

VIRAMUNE does not cure HIV infection or AIDS.
VIRAMUNE does not cure HIV or AIDS and you may continue to experience illnesses associated with HIV-1 infection, including opportunistic infections. You should remain under the care of a doctor when using VIRAMUNE.

You must stay on continuous HIV therapy to control HIV infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others:

- **Do not share needles or other injection equipment.**
- **Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.**
- **Do not have any kind of sex without protection.** Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Ask your doctor if you have any questions on how to prevent passing HIV to other people.

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
- or your child has trouble swallowing pills
- have any other medical conditions
- 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. You should not breastfeed if you have HIV

because of the risk of passing HIV to your baby. 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.

You should not take VIRAMUNE if you also take:

- St. John's Wort. St. John's Wort can lower the amount of VIRAMUNE in your body.
- efavirenz (Sustiva®, Atripla®) , etravirine (Intelence®), rilpivirine (Edurant® Complera®), or delavirdine (Rescriptor®).
- atazanavir (Reyataz®)
- lopinavir and ritonavir (Kaletra®) once daily
- fosamprenavir calcium (Lexiva®) without ritonavir (Norvir®)
- itraconazole (Sporanox®)
- ketoconazole (Nizoral®)
- rifampin (Rifadin®, Rifamate®, Rifater®)
- Birth control pills. Birth control pills taken by mouth (oral contraceptives) and other hormone types of birth control may not work to prevent pregnancy. 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 take:

- clarithromycin (Biaxin®)
- fluconazole (Diflucan®)
- indinavir sulfate (Crixivan®)
- methadone
- nelfinavir mesylate (Viracept®)
- rifabutin (Mycobutin®)
- warfarin (Coumadin®, Jantoven®)
- saquinavir mesylate (Invirase®)
- amiodarone, disopyramide (Norpace®), lidocaine
- carbamazepine, clonazepam (Klonopin®), ethosuximide (Zarontin®)
- diltiazem, nifedipine, verapamil
- cyclophosphamide
- ergotamine
- cyclosporine, tacrolimus, sirolimus (Rapamune®)
- cisapride (Propulsid®)
- fentanyl

If you are not sure if you take a medicine above, ask your doctor or pharmacist.

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?

- VIRAMUNE is always taken in combination with other anti-HIV medications.
- VIRAMUNE comes in 3 different forms. Your doctor will prescribe the form of VIRAMUNE that is right for you.

- VIRAMUNE tablets
- VIRAMUNE oral suspension
- VIRAMUNE XR extended-release tablets

- Take VIRAMUNE exactly as your doctor tells you to take it. Do not change your dose unless your doctor tells you to.
- You should never take more than one form of VIRAMUNE at the same time. Talk to your doctor if you have any questions.
- If your child is prescribed VIRAMUNE, your child's doctor will tell you exactly how VIRAMUNE should be taken.
- Swallow VIRAMUNE XR extended-release tablets whole. Do not chew, crush, or divide VIRAMUNE XR extended-release tablets.
- Do not crush or chew VIRAMUNE XR extended-release tablets.
- You may take VIRAMUNE with or without food.
- Do not miss a dose of VIRAMUNE. 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. Do not take two doses at the same 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 begin taking the VIRAMUNE starting dose again, which is taken 1 time each day for 14 days.

Starting VIRAMUNE tablets:

1. Your doctor should start you with 1 dose each day to lower your chance of getting a serious rash. **It is important that you only take 1 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**.
   - **Do not increase your dose to 2 times a day if you have a rash.**
   - You should never take your starting dose 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 talk about prescribing another HIV medicine for you instead of VIRAMUNE.
2. Day 15, you will take 1 VIRAMUNE tablet two times a day.

Starting VIRAMUNE XR extended-release tablets when this is the first time you are taking any form of VIRAMUNE:

1. Your doctor should start you with 1 dose of VIRAMUNE tablets or oral suspension each day to lower your chance of getting a serious rash. **It is important that you only take 1 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.**
   - You should never take your starting dose 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 talk about prescribing another HIV medicine for you instead of VIRAMUNE.
   - **Do not start VIRAMUNE XR extended-release tablets if you have a rash.**
2. Day 15, take VIRAMUNE XR 1 time a day as prescribed by your doctor.

Switching from VIRAMUNE tablets or oral suspension to VIRAMUNE XR extended-release tablets:

Take VIRAMUNE XR 1 time a day as prescribed by your doctor.

You may sometimes pass a soft mass in your stools (bowel movement) that looks like your VIRAMUNE XR extended-release tablets. This will not affect the way your medicine works.

If you take VIRAMUNE Oral Suspension:

- If you or your child takes VIRAMUNE suspension (liquid), shake it gently before each 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. Ask your pharmacist for a syringe or cup if you do not have one.
- 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.

What are the possible side effects of VIRAMUNE?

VIRAMUNE may cause serious side effects, including:

- See "**What is the most important information I should know about VIRAMUNE?**"

VIRAMUNE may cause other serious side effects, including:

- **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.

The most common side effect of VIRAMUNE is rash.

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 room temperature between 59°F to 86°F (15°C 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, go to www.viramune.com or www.viramunexr.com or 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
VIRAMUNE XR Tablets: lactose monohydrate, hypromellose, iron oxide, and magnesium stearate

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