

MEDICATION GUIDE

VIRAMUNE® (VIH-rah-mune)
(nevirapine)
oral suspension

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

VIRAMUNE XR® (VIH-rah-mune)
(nevirapine)
extended-release tablets

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

VIRAMUNE can cause severe liver and skin problems that may lead to death. These problems can happen at any time during treatment, but your risk is higher during the first 18 weeks of treatment.

VIRAMUNE can cause serious side effects, including:

- **Severe liver problems.** Some people taking VIRAMUNE may develop severe liver problems that can lead to liver failure and the need for a liver transplant, or death. If you have liver problems you may get a rash.
 - Women have a higher risk of developing liver problems during treatment with VIRAMUNE than men.
 - People who have abnormal liver test results before starting VIRAMUNE and people with hepatitis B or C also have a greater risk of getting liver problems.

People who have higher CD4⁺ cell counts when they begin VIRAMUNE have a higher risk of liver problems, especially:

- Women with CD4⁺ counts higher than 250 cells/mm³. This group has the highest risk.
- Men with CD4⁺ counts higher than 400 cells/mm³.

Stop taking VIRAMUNE and call your doctor right away if you have any of the following symptoms of liver problems with or without a skin rash:

- dark (tea colored) urine
 - light-colored bowel movements (stools)
 - feeling sick to your stomach (nausea)
 - pain or tenderness on your right side below your ribs
 - loss of appetite
 - yellowing of your skin or whites of your eyes
 - fever
 - feel unwell or like you have the flu
 - tiredness
- **Severe skin reactions and rash.** Some skin reactions and rashes may be severe, life-threatening, and in some people, may lead to death. Most severe skin reactions and rashes happen in the first 6 weeks of treatment with VIRAMUNE.
 - Women have a higher risk of developing a rash during treatment with VIRAMUNE than men.

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

- blisters
 - red or inflamed eyes, like "pink eye" (conjunctivitis)
 - swelling of your face
 - feel unwell or like you have the flu
 - muscle or joint aches
 - mouth sores
 - fever
 - tiredness
- Your doctor should do blood tests often to check your liver function and check for severe skin reactions during the first 18 weeks of treatment with VIRAMUNE. You should continue to see your doctor and have your liver checked regularly during your treatment with VIRAMUNE. It is important for you to keep all of your doctor appointments.
 - **If your doctor tells you to stop treatment with VIRAMUNE because you have had any of the severe liver or skin symptoms listed above, you should never take VIRAMUNE again.**

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

What is VIRAMUNE?

VIRAMUNE tablets and VIRAMUNE oral solution are prescription HIV-1 medicines used with other HIV-1 medicines to treat HIV-1 (Human Immunodeficiency Virus 1) in adults and in children 15 days of age and older. HIV-1 is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

VIRAMUNE XR extended-release tablets is a prescription medicine used with other HIV-1 medicines to treat HIV-1 (Human Immunodeficiency Virus 1) in adults and in children 6 years of age to less than 18 years of age.

- If you are a woman with CD4⁺ counts higher than 250 cells/mm³ or a man with CD4⁺ counts higher than 400 cells/mm³, you and your doctor will decide if starting VIRAMUNE is right for you.
- VIRAMUNE XR extended-release tablets are not recommended for use in children less than 6 years of age.

Do not take VIRAMUNE:

- if you have liver problems.
- as part of occupational and non-occupational post-exposure prophylaxis (PEP) regimens. VIRAMUNE is only for people diagnosed with HIV-1. If you have not been diagnosed as HIV positive, then do not take VIRAMUNE.

Before taking VIRAMUNE, tell your doctor about all your or your child's medical conditions, including if you or your child:

- 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?”**
- receive dialysis
- have trouble swallowing pills
- 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 VIRAMUNE 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 breastfeeding or plan to breastfeed. VIRAMUNE can pass into your breast milk and may harm your baby. You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby. Do not breastfeed during treatment with VIRAMUNE. Talk to your doctor about the best way to feed your baby.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Especially tell your doctor if you take St. John's wort.

- Some medicines interact with VIRAMUNE. Keep a list of your medicines to show your doctor or pharmacist.
- You can ask your doctor or pharmacist for a list of medicines that interact with VIRAMUNE.
- **Do not start taking a new medicine without telling your doctor.** Your doctor can tell you if it is safe to take VIRAMUNE with other medicines.

How should I take VIRAMUNE?

- **Take VIRAMUNE exactly as your doctor tells you to take it. Do not change your dose unless your doctor tells you to.**
- VIRAMUNE is always taken in combination with other antiretroviral medicines.
- VIRAMUNE comes in three different forms. Your doctor will prescribe the form of VIRAMUNE that is right for you.
 - o VIRAMUNE tablets
 - o VIRAMUNE oral suspension
 - o VIRAMUNE XR extended-release tablets
- You should not 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.
- VIRAMUNE can be taken with or without food.
- Swallow VIRAMUNE XR extended-release tablets whole. Do not chew, crush, or divide VIRAMUNE XR extended-release tablets.
- 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. You should take the next dose at your regular time. Do not take 2 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-1 medicine for you instead of VIRAMUNE.
2. Day 15, you will take 1 VIRAMUNE tablet 2 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 risk 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-1 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 extended-release tablets 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 extended-release tablets 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 oral 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 oral 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?**"

- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 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 right away if you start having new symptoms after starting your HIV-1 medicine.
- **Changes in body fat** can happen in people who take HIV-1 medicines. 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 may also happen. The exact cause and long-term health effects of these conditions are not known.

The most common side effect of VIRAMUNE is rash.

VIRAMUNE may cause decreased fertility in females. Talk to your doctor if you have concerns about fertility.

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 68°F to 77°F (20°C to 25°C).
- Throw away VIRAMUNE that is no longer needed.

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

General information about the safe and effective use of 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. You can ask your pharmacist or doctor for information about VIRAMUNE that is written for health professionals.

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

Distributed by:

Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877, USA

For current prescribing information for VIRAMUNE or VIRAMUNE XR, scan the codes below or for additional information you may also call Boehringer Ingelheim Pharmaceuticals, Inc., at 1-800-542-6257, (TTY) 1-800-459-9906.

VIRAMUNE tablets and oral suspension



VIRAMUNE XR extended-release tablets



Copyright © 2017 Boehringer Ingelheim International GmbH.

ALL RIGHTS RESERVED

OT1801ZD32017

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

Revised: March 2017