PART III: CONSUMER INFORMATION

Pr Viramune®
(nevirapine) Immediate ReleaseTablets

Pr Viramune® XR
(nevirapine) Extended ReleaseTablets

This leaflet is part III of a three-part "Product Monograph" published when VIRAMUNE or VIRAMUNE XR was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VIRAMUNE or VIRAMUNE XR. Contact your doctor or pharmacist if you have any questions about the drug.

PLEASE READ THIS INFORMATION CAREFULLY AND COMPLETELY BEFORE YOU USE VIRAMUNE or VIRAMUNE XR EVEN IF YOU HAVE JUST REFILLED YOUR PRESCRIPTION, SINCE SOME INFORMATION MAY HAVE CHANGED. SINCE VIRAMUNE or VIRAMUNE XR IS ALWAYS TAKEN WITH OTHER DRUGS, IT IS IMPORTANT TO ALSO READ THE INFORMATION GIVEN WITH THE OTHER DRUGS BEFORE TAKING VIRAMUNE or VIRAMUNE XR. PLEASE CONSULT YOUR DOCTOR OR PHARMACIST IF YOU HAVE ANY QUESTIONS.

ABOUT THIS MEDICATION

What the medication is used for:

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

VIRAMUNE or VIRAMUNE XR does not cure HIV or AIDS, and it is not known if it will help you live longer with HIV. People taking VIRAMUNE or VIRAMUNE XR 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.

What it does:

VIRAMUNE or VIRAMUNE XR 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 or VIRAMUNE XR with other anti-HIV medicines. When taken with other anti-HIV medicines, VIRAMUNE or VIRAMUNE XR 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 or VIRAMUNE XR may not have these effects in every patient.

VIRAMUNE or VIRAMUNE XR is not a cure for HIV infection.

When it should not be used:

- If you are allergic (hypersensitive) to nevirapine or its components (see **What the non-medicinal ingredients are**).
- If you have a severe liver problem.
- If you have rare hereditary conditions of galactosemia, galactose intolerance, glucose/galactose malabsorption, Lapp lactase deficiency, as this product contains lactose.
- If you are allergic (hypersensitive) to nevirapine or its components (See **What the non-medicinal ingredients are**) or have used VIRAMUNE or VIRAMUNE XR and had a severe rash with associated symptoms such as malaise, fatigue, muscle/joint aches, blisters, facial edema (facial swelling), oral lesions, conjunctivitis, and/or hepatitis, eosinophilia(a lot of white blood cells called eosinophils in the blood), granulocytopenia (a decrease in white blood cells called granulocytes in the blood), lymphadenopathy (swelling of the lymph nodes), and renal dysfunction (kidneys not working properly), you must permanently discontinue VIRAMUNE or VIRAMUNE XR and seek medical evaluation immediately. (See **WARNINGS AND PRECAUTIONS**)
- Do not take VIRAMUNE or VIRAMUNE XR with St. John's wort (*Hypericum perforatum*) as it will reduce VIRAMUNE or VIRAMUNE XR blood levels.

What the medicinal ingredient is:

VIRAMUNE or VIRAMUNE XR tablets contain the active ingredient nevirapine.

What the non-medicinal ingredients are:

VIRAMUNE Immediate Release Tablets:
Non-medicinal Ingredients (in alphabetical order): colloidal silicon dioxide, lactose, magnesium stearate, microcrystalline cellulose, povidone, and sodium starch glycolate.

VIRAMUNE XR Extended Release Tablets:
Non-medicinal Ingredients (in alphabetical order): hypromellose, iron oxide (E172), lactose and magnesium stearate.

What dosage forms it comes in:

VIRAMUNE (nevirapine) comes as an immediate release white tablet containing 200 mg of nevirapine or as VIRAMUNE XR (nevirapine), an extended release yellow tablet containing 400 mg of nevirapine.

WARNINGS AND PRECAUTIONS

Severe, life-threatening, and in some cases fatal liver toxicity, particularly in the first 18 weeks, has been reported in patients

treated with VIRAMUNE, including pregnant women receiving chronic VIRAMUNE therapy in conjunction with other antiretroviral medication. Female gender and higher CD4 counts at the start of therapy may increase the risk of liver problems (see SIDE EFFECTS AND WHAT TO DO ABOUT THEM).

Severe skin and allergic reactions, including fatal cases have occurred with accompanying symptoms such as severe rash with fever, fatigue, muscle/joint pain, swelling of the face, hepatitis (liver inflammation), blood and kidney problems. If this occurs discontinue VIRAMUNE or VIRAMUNE XR and contact your doctor immediately.

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 or VIRAMUNE XR and call your doctor right away:

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

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 or VIRAMUNE XR.

Skin Reactions
Skin rash is the most common side effect of VIRAMUNE or VIRAMUNE XR. 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 or VIRAMUNE XR 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 symptoms of liver problems discussed above

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

These are not all the side effects of VIRAMUNE or VIRAMUNE XR. See the section **SIDE EFFECTS AND WHAT TO DO ABOUT THEM** for more information. Tell your doctor if you have any side effects from VIRAMUNE or VIRAMUNE XR.

BEFORE you use VIRAMUNE or VIRAMUNE XR talk to your doctor or pharmacist:

- If you have or have had any diseases of the liver particularly hepatitis B or C infection;
- If you are pregnant or intend to become pregnant;
- If you are a breast-feeding mother. **It is recommended that HIV infected women not breast-feed, to avoid transmission of the virus to the infant;**
- If you are taking any medications, including prescription, non-prescription, herbal or homeopathic remedies;
- If you have any allergies to foods or drugs;
- If you are undergoing dialysis.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with VIRAMUNE or VIRAMUNE XR include:
VIRAMUNE or VIRAMUNE XR may change the effect of other medicines, and other medicines can change the effect of VIRAMUNE or VIRAMUNE XR. Tell your doctors and pharmacists about **all** medicines you take, including non-prescription medicines, vitamins and herbal supplements.

Do **not** take ketoconazole, rifampin, efavirenz, delavirdine, etravirine, rilpivirine, elvitegravir (in combination with cobicistat), or boceprevir; with VIRAMUNE or VIRAMUNE XR.

Tell your doctor if you take clarithromycin, fluconazole, methadone, rifabutin, indinavir, lopinavir/ritonavir combination, saquinavir or itraconazole.

VIRAMUNE or VIRAMUNE XR may not be right for you, or you may need careful monitoring.

You should be aware that VIRAMUNE or VIRAMUNE XR may change the effectiveness of oral contraceptives. Therefore oral contraceptives and other hormonal methods of birth control should not be used as a method of contraception in women taking VIRAMUNE or VIRAMUNE XR; other methods (barrier) must be used.

PROPER USE OF THIS MEDICATION

Usual dose:
Adult:
Follow the directions exactly as given to you by your doctor or pharmacist regarding the amount and frequency of dosing. The label will usually tell you this information as well. If you are not sure about dosing, ask your doctor or pharmacist.

VIRAMUNE Immediate Release Tablets:
As a general guide, swallow one tablet (200 mg) once a day for the first 14 days (this lead-in period should be used because it has been found to lessen the frequency of rash) followed by one 200 mg tablet twice daily as part of a multi-drug treatment program. VIRAMUNE immediate release tablets can be taken with or without food.

VIRAMUNE XR Extended Release Tablets:
Swallow one 200 mg tablet of VIRAMUNE immediate release once daily for the first 14 days to lessen the frequency of rash followed by one 400 mg tablet of VIRAMUNE XR extended release once daily. The VIRAMUNE XR extended release tablets should not be broken or chewed. VIRAMUNE XR extended release tablets can be taken with or without food.

It is important to strictly follow the once daily dose for the first 14 days. Do not start taking the 200 mg VIRAMUNE twice daily or the 400 mg VIRAMUNE XR once daily if you have any symptoms of liver problems or skin rash (see **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**). The manufacturer's recommended dosage and monitoring for the other administered anti-retroviral drugs should be followed.

Patients Switching to VIRAMUNE XR Extended Release Tablets:
Patients already on a regimen of VIRAMUNE immediate release 200 mg twice daily in combination with other antiretroviral agents can be switched to VIRAMUNE XR extended release 400 mg once daily in combination with other antiretroviral agents without a lead-in period of VIRAMUNE immediate release.

Overdose:

In case of drug overdosage, contact a healthcare practitioner (e.g. doctor), hospital emergency department or regional Poison Control Centre, even if there are no symptoms.

Missed Dose:
If you miss a dose: If you forget to take your medicine, take it as soon as you remember. Then continue as before; do not double your next dosage.

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 or VIRAMUNE XR 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 200 mg VIRAMUNE tablet dosing.

Avoid doing things that can spread HIV infection, as VIRAMUNE or VIRAMUNE XR 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 safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

This medicine is for you. Never give it to someone else, as it may harm them even if their symptoms are the same as yours.

Take your medications exactly as prescribed by your doctor. Do not change the dose without consulting your doctor.

Do not take any other medication including prescription, non prescription, herbal or homeopathic remedies without your doctor's advice. Also, inform any other doctor, dentist or pharmacist you consult that you are taking this medication.

Keep out of reach of children.

If you have any other questions about VIRAMUNE or VIRAMUNE XR, contact your doctor or pharmacist.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

VIRAMUNE or VIRAMUNE XR can cause serious liver damage and skin reactions that can cause death. Any patients can experience such side effects, but some patients are more at risk than others. See WARNINGS AND PRECAUTIONS.

Other common side effects of VIRAMUNE or VIRAMUNE XR include nausea, fatigue, fever, headache, vomiting, diarrhea, abdominal pain, skin rash and itching, myalgia (muscle pain) and arthralgia (joint pain). This list of side effects is not complete. Ask your doctor or pharmacist for more information.

Abnormal liver function test results, decrease in red blood cells or white blood cells called granulocytes, decrease in blood phosphorus, increase in blood pressure amd hypersensitivity including severe allergic reaction with facial swelling may also occur.

If you feel unwell in any other way or have any symptoms that you do not understand, you should contact your doctor immediately.

Sleepiness can occur. Do not drive or operate machinery if you become drowsy.

Always tell your doctor or pharmacist about any undesirable effects you experience after taking VIRAMUNE or VIRAMUNE XR, even those not mentioned above.

Changes in body fat have been seen in some patients taking anti-retroviral therapy. These 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.

Occasionally, the inactive ingredients of VIRAMUNE XR extended release tablets may be eliminated in the stool as a soft hydrated mass that looks like a whole tablet. There is no cause for alarm.

Consult your doctor immediately if you experience any symptoms as listed above, or any symptoms that you do not understand.

This is not a complete list of side effects. For any unexpected effects while taking* VIRAMUNE or VIRAMUNE XR*, contact your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Severe liver disease with symptoms such as nausea, abdominal pain, aches, tiredness, lack of appetite, dark urine, pale stools (bowel movement) , yellowing of skin and eyes, and a general ill feeling or "flu-like" symptoms.			T
	Severe skin reactions such as rash, blistering accompanied by symptoms such as fever, muscle/joint pain, tiredness, mouth sores, swelling of the face, conjunctivitis, and a general ill feeling or "flu-like" symptoms.			T

HOW TO STORE IT

Store VIRAMUNE or VIRAMUNE XR tablets at normal room temperature (between 15°C and 30°C). As with all medicines, keep VIRAMUNE or VIRAMUNE XR tightly closed and out of the reach of children. Do not take your medicine after the expiry date shown on the bottle.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  Fax toll-free to 1-866-678-6789, or
  Mail to: Canada Vigilance Program
  Health Canada
  Postal Locator 0701D
  Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect

NOTE: Should you require information related to the management of side effects contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: http://www.boehringer-ingelheim.ca or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, ext. 84633 (Medical Information). Please visit our website to see if more up-to-date information has been posted.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd.

Last revised: November 18, 2013