

PART III: CONSUMER INFORMATION

**PrMYLAN-EFAVIRENZ/EMTRICITABINE/TENOFOVIR
DISOPROXIL FUMARATE
(Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate
Tablets)**

This leaflet is Part III of a three part “Product Monograph” published when Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about Mylan-Efavirenz/Emtricitabine/ Tenofovir Disoproxil Fumarate. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate contains 3 medicines, efavirenz, emtricitabine and tenofovir disoproxil fumarate, combined in one pill. Emtricitabine and tenofovir disoproxil fumarate are HIV (human immunodeficiency virus) nucleoside/nucleotide analog reverse transcriptase inhibitors (NRTIs) and efavirenz is an HIV non-nucleoside analog reverse transcriptase inhibitor (NNRTI). Tenofovir and emtricitabine are components of TRUVADA®. Mylan-Efavirenz/Emtricitabine/ Tenofovir Disoproxil Fumarate can be used alone as a complete regimen or in combination with other medications to treat people with HIV infection. Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate is for adults age 18 and older. Mylan-Efavirenz/Emtricitabine/ Tenofovir Disoproxil Fumarate has not been studied in children under age 18 or adults over age 65.

What it does:

Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate helps block HIV reverse transcriptase, a chemical in your body (enzyme) that is needed for HIV to multiply. Mylan-Efavirenz/Emtricitabine/ Tenofovir Disoproxil Fumarate lowers the amount of HIV in the blood (viral load). Lowering the amount of HIV in the blood lowers the chance of infections that happen when your immune system is weak (opportunistic infections).

HIV infection destroys CD4+ (T) cells, which are important to the immune system. The immune system helps fight infection. After a large number of T cells are destroyed, acquired immune deficiency syndrome (AIDS) develops. Efavirenz/emtricitabine/ tenofovir disoproxil fumarate may also help to increase the number of T cells (CD4+ cells).

Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate does not cure HIV infection or AIDS. The long-term effects of Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate are not known at this time. People taking Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate may still get opportunistic infections or other conditions that happen with

HIV infection. Opportunistic infections are infections that develop because the immune system is weak. Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium* complex (MAC) infections. **It is very important that you see your doctor regularly while taking Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate.**

Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate has not been shown to reduce the risk of passing HIV to others through sexual contact or blood contamination. Continue to practice safe sex and do not use or share dirty needles.

When it should not be used:

Together with your doctor, you need to decide whether Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate is right for you.

Do not take Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate if:

- you are taking any medication that is listed in this pamphlet under “**Drugs that must not be taken with Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate**” (see **INTERACTIONS WITH THIS MEDICATION**).
- you have or are at known risk for any type of bone disease or bone-related problems and have not discussed this with your doctor.
- you are allergic to Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate or any of its ingredients. The medicinal ingredients are efavirenz, emtricitabine and tenofovir DF (see: **What the important nonmedicinal ingredients are**).

What the medicinal ingredients are:

efavirenz
emtricitabine
tenofovir disoproxil fumarate (tenofovir DF)

What the important nonmedicinal ingredients are:

Colloidal silicon dioxide, croscarmellose sodium, ferric oxide red, hydroxyl propyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate, iron oxide black, iron oxide red, macrogol/PEG, polyvinyl alcohol, talc and titanium dioxide.

What dosage forms it comes in:

Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate is available as tablets. Each tablet contains 600 mg of efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate (which is equivalent to 245 mg of tenofovir disoproxil), as active ingredients. The tablets are pink, film-coated, capsule shaped, biconvex, beveled edge tablet debossed with “M” on one side of the tablet and “EETF” on the other side. Each bottle contains 30 tablets and a Molecular Sieve desiccant and is closed with a child-resistant closure.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

The class of medicines to which emtricitabine and tenofovir DF, two of the components of Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate, belongs (NRTIs) can cause a condition called lactic acidosis, together with an enlarged liver. This rare but serious side effect has occasionally been fatal.

- The symptoms of lactic acidosis include: feeling very weak, tired or uncomfortable; unusual or unexpected stomach discomfort; feeling cold; feeling dizzy or lightheaded; suddenly developing an irregular heartbeat. Lactic acidosis occurs more often in women, particularly if they are very overweight. You should consult your doctor immediately if such symptoms occur while you are receiving Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate.
- Non-specific symptoms of liver problems may include nausea, vomiting, stomach pain and yellowing of the skin and eyes.

If you notice these symptoms of lactic acidosis or liver problems, stop taking Mylan-Efavirenz / Emtricitabine / Tenofovir Disoproxil Fumarate and consult a doctor immediately.

- **“Flare-ups” of hepatitis B virus infection**, in which the disease suddenly returns in a worse way than before, can occur if you stop taking Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate. Do not stop taking Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate without your doctor’s advice. If you stop taking Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate, tell your doctor immediately about any new, unusual or worsening symptoms that you notice after stopping treatment. After you stop taking Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate, your doctor will still need to check your health and take blood tests to check your liver. Mylan-Efavirenz / Emtricitabine/Tenofovir Disoproxil Fumarate is not approved for the treatment of hepatitis B virus infection.
- The most serious possible side effect is harm to the kidneys, including damage to kidney cells, kidney tissue inflammation and kidney failure. Your doctor may monitor your kidney function before beginning and while receiving Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate. Some patients treated with tenofovir DF (a component of Mylan-Efavirenz/Emtricitabine/ Tenofovir Disoproxil Fumarate) have had kidney problems. Your doctor may need to perform additional blood tests if you have had kidney problems in the past or need to take another drug that can cause kidney problems.

- Tenofovir DF, a component of Mylan-Efavirenz/ Emtricitabine/Tenofovir Disoproxil Fumarate, caused harm to the bones of animals. If you notice bone pain, suffer a bone fracture, or other bone problem, consult your doctor. **If you have bone problems, you may wish to discuss calcium and/or vitamin D supplementation with your doctor. The effect of supplementation with calcium and/or vitamin D**

is unknown.

- Patients who experience dizziness, trouble concentrating or drowsiness should avoid driving or operating machinery.
- **Women should not become pregnant while taking Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate and for 12 weeks after stopping it.** Serious birth defects have been seen in animals and women treated with efavirenz (a component of Mylan-Efavirenz/ Emtricitabine/Tenofovir Disoproxil Fumarate) during pregnancy. It is not known whether efavirenz caused these defects. A reliable form of barrier contraception must always be used even if you or your partner are using other methods of contraception such as the pill or other hormonal therapy (e.g. implants, injections). Mylan-Efavirenz/Emtricitabine/ Tenofovir Disoproxil Fumarate may remain in your blood for a time after therapy is stopped. Therefore, you should continue use of a reliable form of contraception for 12 weeks after stopping treatment with Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate. If you are pregnant or become pregnant while taking Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil, your doctor may register you in the Antiretroviral Pregnancy Registry. The Registry monitors fetal outcomes in pregnant women using antiretroviral medicines.
- A small number of patients taking efavirenz, one of the components of Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate, have had severe depression, strange thoughts, or angry behavior. Some patients have had thoughts of suicide and a few patients have actually committed suicide. These problems tend to occur more often in patients with a history of mental illness. You should contact your doctor immediately if you think you are having these symptoms, so your doctor can decide whether you should continue to take Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate.
- Consult your doctor if you have a rash, since some rashes may be serious.

BEFORE you use Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate talk to your doctor or pharmacist:

If you have ever had a previous life threatening skin reaction (e.g. Stevens-Johnson syndrome).

If you are breast-feeding or plan to breast-feed: Do not breast-feed if you have HIV or are taking Mylan-Efavirenz/ Emtricitabine/Tenofovir Disoproxil Fumarate. HIV can be passed to your baby in your breast milk. All components of Mylan-Efavirenz/ Emtricitabine/Tenofovir Disoproxil Fumarate (efavirenz, emtricitabine and tenofovir DF) can be passed to your baby in your breast milk and may cause harm to your baby. Talk to your doctor about the best way to feed your baby.

If you have other medical conditions: Let your doctor know if you have other medical conditions, especially liver or kidney problems, pancreatitis (inflammation of the pancreas), seizures or mental illness, or have or are at risk for bone disease or bone-related problems.

If you have or have had a heart rhythm disorder such as:

- lengthening of QT interval
- irregular heartbeat
- a heart condition, Torsades de pointes

If you are taking other medicines: Some medicines can interact when taken together, including prescription and non-prescription medicines, herbal products and dietary supplements (see **INTERACTIONS WITH THIS MEDICATION**).

Other Special Warnings: Your blood sugar levels (glucose) or levels of fats (lipids) in your blood may increase with HIV treatment. Your doctor may order blood tests for you.

INTERACTIONS WITH THIS MEDICATION

No drug interaction studies have been done with Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate.

Drugs that must not be taken with Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate:

- **Propulsid™ (cisapride)*, Versed® (midazolam), Halcion® (triazolam), ergot medications (for example Wigraine® and Cafergot®), Hismanal (astemizole)*, Seldane® (terfenadine)*, Vascor® (bepridil)* or Orap® (pimozide).** Taking these medications with Mylan-Efavirenz / Emtricitabine/Tenofovir Disoproxil Fumarate could create the potential for serious or life-threatening side effects.
- Zepatier® (elbasvir/grazoprevir), since Zepatier® may lose its effect.
- Vfend® (voriconazole), since it may lose its effect or may increase the chance of having side effects from efavirenz/emtricitabine/tenofovir disoproxil fumarate.
- **Do not take Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate if you are taking St. John's wort (*Hypericum perforatum*), or products containing St. John's wort.** St. John's wort is an herbal product sold as a dietary supplement. Taking St. John's wort may decrease efavirenz/emtricitabine/ tenofovir disoproxil fumarate levels and may lead to increased viral load and possible resistance to efavirenz or resistance to the class of nonnucleoside reverse transcriptase inhibitors (NNRTIs).

*Not marketed in Canada.

It is also important to tell your doctor if you are taking any of the following:

- Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate should not be used with 3TC® Combivir®, COMPLERA®, DESCOVY®, EMTRIVA, GENVOYA®, Heptovir®, HEPSERA®, Kivexa®, ODEFSEY™, Triumeq®, Trizivir®, TRUVADA®, STRIBILD®, VEMLIDY™ or VIREAD. Mylan-Efavirenz/Emtricitabine/ Tenofovir Disoproxil Fumarate also should not be used with Sustiva® unless your doctor decides a dose adjustment is needed (e.g. with rifampin).

- Do not take Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate if you are on other medications that may affect your kidneys and you have not discussed this with your doctor. Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate should not be used at the same time or shortly after didanosine, ganciclovir, vancomycin or aminoglycosides as this may harm the kidneys.
- Reyataz® (atazanavir sulfate), Fortovase®* or Invirase® (saquinavir); or Biaxin® (clarithromycin); **these medicines need to be replaced with another medicine when taken with Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate. If your doctor does prescribe Reyataz and Mylan-Efavirenz/ Emtricitabine/Tenofovir Disoproxil Fumarate together, you may need to be monitored more carefully for side effects.**
- Biaxin® (clarithromycin). Biaxin may interact with efavirenz / emtricitabine / tenofovir disoproxil fumarate to affect the electrical activity of your heart. **Biaxin needs to be replaced with another medicine when taken with Mylan-Efavirenz / Emtricitabine /Tenofovir Disoproxil Fumarate.**
- Celsenti® (maraviroc).
- Crixivan® (indinavir), methadone, Mycobutin® (rifabutin), Zoloft® (sertraline), Wellbutrin® SR, Wellbutrin® XL, or Zyban® (bupropion); **these medicines may need to have their dose changed when taken with Mylan-Efavirenz / Emtricitabine/ Tenofovir Disoproxil Fumarate.**
- Videx® or Videx EC® (didanosine); tenofovir DF (a component of efavirenz/emtricitabine/tenofovir disoproxil fumarate) may increase the amount of didanosine in your blood, which could result in more side effects. **You may need to be monitored more carefully** if you are taking Mylan-Efavirenz/ Emtricitabine/Tenofovir Disoproxil Fumarate and didanosine together. Also, the dose of didanosine may need to be changed.
- Kaletra® (lopinavir/ritonavir) or HARVONI® (ledipasvir/sofosbuvir) may increase the amount of tenofovir DF (a component of Mylan-Efavirenz / Emtricitabine/ Tenofovir Disoproxil Fumarate) in your blood, which could result in more side effects. **You may need to be monitored more carefully** if you are taking Mylan-Efavirenz / Emtricitabine / Tenofovir Disoproxil Fumarate and Kaletra together or Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate and HARVONI together. Also, the dose of Kaletra may need to be changed.
- EPCLUSA® (sofosbuvir/velpatasvir) or VOSEVI® (sofosbuvir/velpatasvir/voxilaprevir) should not be used with Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate as it is expected to decrease the amount of velpatasvir (a component of EPCLUSA and VOSEVI) and voxilaprevir (a component of VOSEVI) in your blood, which may reduce the effectiveness of EPCLUSA or VOSEVI.
- Maviret® (glecaprevir/pibrentasvir) is not recommended when taking Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate.
- Medicines for seizures [for example, Dilantin® (phenytoin), Tegretol® (carbamazepine), or phenobarbital]; your doctor

may want to switch you to another medicine or check drug levels in your blood from time to time.

- Sporanox[®] (itraconazole) and Posanol[®] (posaconazole) may need to be replaced by another medicine when taken with Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate.
- The cholesterol-lowering medicines Lipitor[®] (atorvastatin), Pravachol[®] (pravastatin sodium), and Zocor[®] (simvastatin).
- Rifadin[®] (rifampin) or the rifampin-containing medicines Rofact[®] and Rifater[®].
- Calcium channel blockers such as Cardizem[®] or Tiazac[®] (diltiazem), Covera HS[®], Isoptin[®] SR or Tarka[®] (verapamil), and others.
- Immunosuppressants such as Neoral[®] (cyclosporine), Advagraf[®] or Prograf[®] (tacrolimus), Rapamune[®] or Torisel[®] (sirolimus).
- Hepatitis C antiviral agents such as Galexos[®] (simeprevir).
- Antimalarials such as Coartem[®]* and Riamet[®] (artemether/lumefantrine). These medicines may interact with efavirenz/emtricitabine/tenofovir disoproxil fumarate to affect your heart. Malarone[®] (atovaquone/proguanil) (an antimalarial).
- The effect of combining alcohol or recreational (street, illicit) drugs with efavirenz has not been studied. Because they may interact with each other, speak with your doctor before you combine Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate with these drugs.

*Not marketed in Canada.

These are not all the medicines that may cause problems if you take Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate. Be sure to tell your doctor about all the medicines you take.

Keep a complete list of all the prescription and nonprescription medicines as well as any herbal medicines that you are taking, how much you take and how often you take them. Make a new list when medicines or herbal medicines are added or stopped, or if the dose changes. Give copies of this list to all your doctors and pharmacists **every** time you visit them or fill a prescription. This will give your doctor a complete picture of the medicines you use. Then he or she can decide the best approach for the situation.

PROPER USE OF THIS MEDICATION

Stay under a doctor's care when taking Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate. Do not change your treatment or stop treatment without first talking with your doctor.

Take Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate every day exactly as your doctor prescribed it. Follow the directions from your doctor, exactly as written on the label. Set up a dosing schedule and follow it carefully.

When your Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate supply starts to run low, get more from your doctor or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate and become harder to treat.

Only take medicine that has been prescribed specifically for you. Do not give Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate to others or take medicine prescribed for someone else.

Do not use if seal over bottle opening is broken or missing.

Usual Adult Dose:

- The usual dose of Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate is one tablet orally (by mouth) once a day.
- Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate should be taken on an empty stomach. Taking Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate at bedtime may make some side effects less bothersome.

Overdosage:

In case of drug overdose, contact your healthcare practitioner (e.g. doctor), hospital emergency department or regional poison control centre, even if there are no symptoms.

Missed Dose:

It is important that you do not miss any doses. If you miss a dose of Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate, take it as soon as you remember that day. **Do not** take more than 1 dose of Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate in a day. **Do not** take 2 doses at the same time. Call your doctor or pharmacist if you are not sure what to do.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects of SUSTIVA, EMTRIVA and VIREAD are:

- Nervous system symptoms such as dizziness, trouble sleeping, drowsiness, trouble concentrating, unusual dreams
- Headache
- Diarrhea
- Nausea
- Vomiting
- Rash
- Flatulence (intestinal gas)
- Tiredness
- Itching
- Allergic reaction (including swelling of the face, lips, tongue or throat)

IMPORTANT: PLEASE READ

- Abdominal pain

Other side effects may include pancreatitis (inflammation of the pancreas) and shortness of breath.

Skin discoloration (small spots or freckles) may also happen with efavirenz/emtricitabine/tenofovir disoproxil fumarate.

A small number of patients taking efavirenz, one of the components of efavirenz/emtricitabine/tenofovir disoproxil fumarate, have had severe depression, strange thoughts, or angry behavior. Some patients have had thoughts of suicide and a few patients have actually committed suicide. These problems tend to occur more often in patients with a history of mental illness. Contact your doctor immediately if you think you are having these symptoms so your doctor can decide whether you should continue to take Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate.

Changes in body fat have been seen in some patients taking antiretroviral therapy. These changes may include increased amounts 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.

Some patients have experienced serious liver problems including liver failure, resulting in transplantation or death. Most of these serious side effects occurred in patients with a chronic liver disease such as a hepatitis infection, but there have also been a few reports in patients without any existing liver disease.

Changes in your immune system (Immune Reconstitution Inflammatory 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, or you could develop an autoimmune disease in which your immune system reacts against your own body [e.g. Grave's disease (which affects the thyroid gland), Guillain-Barre syndrome (which affects the nervous system) or polymyositis (which affects the muscles)] and it may develop at any time, sometimes months after the start of HIV therapy. Sometimes symptoms can be severe, so if you develop high temperature (fever), joint or muscle pain, redness, rash, swelling or fatigue, or any new symptoms, contact your doctor right away.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptoms / Effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
Common	Effect: Serious psychiatric events Symptoms: <ul style="list-style-type: none"> • Severe depression • Thoughts of suicide • Strange thoughts • Angry behavior 		✓ ✓ ✓ ✓	
	Effect: Serious psychiatric events Symptoms: <ul style="list-style-type: none"> • Catatonia (cannot move or talk for some time) 		✓	
Uncommon	Effect: Severe skin rash Symptoms: <ul style="list-style-type: none"> • Blisters or peeling of the skin • Blisters or peeling of the mouth, lips and throat • Fever and general ill feeling. 			✓ ✓ ✓
	Effect: Lactic acidosis Symptoms: <ul style="list-style-type: none"> • Feeling very weak or tired • Unusual muscle pain • Stomach pain with nausea and vomiting • Feeling cold, especially in arms and legs • Feeling dizzy or lightheaded • Irregular heartbeat 		✓ ✓ ✓ ✓ ✓ ✓	
Rare	Effect: Hepatotoxicity (severe liver problems) with hepatomegaly (liver enlargement) and steatosis (fat in the liver) Symptoms: <ul style="list-style-type: none"> • Jaundice (skin or the white part of eyes turns yellow) • Urine turns dark • Bowel movements (stools) turn light in 		✓ ✓ ✓	

IMPORTANT: PLEASE READ

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

Symptoms / Effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
color • Loss of appetite for several days or longer • Feeling sick to your stomach (nausea) • Lower stomach pain		✓ ✓ ✓	
Effect: Flare-ups of hepatitis B virus infection following drug discontinuation Symptoms: • Jaundice (skin or the white part of eyes turns yellow) • Urine turns dark • Bowel movements (stools) turn light in color • Loss of appetite for several days or longer • Feeling sick to your stomach (nausea) • Lower stomach pain		✓ ✓ ✓ ✓ ✓	
Effect: Kidney problems Symptoms: • You may have increased or decreased urination as well as increased thirst • You may have swelling of your legs and feet • You may feel listless and tired		✓ ✓ ✓	

Lactic acidosis is a medical emergency and must be treated in the hospital. You may be more likely to get lactic acidosis or serious liver problems if you are very overweight (obese) or have been taking nucleoside analog medicines, like Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate, for a long time.

Muscle pain, muscle weakness, bone pain and softening of the bone (infrequently contributing to fractures) have also been reported due to tenofovir DF (a component of Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate).

There have been other side effects in patients taking SUSTIVA, EMTRIVA or VIREAD. This is **not** a complete list of side

effects. If you have questions about side effects, ask your doctor, nurse, or pharmacist. You should report any new or continuing symptoms to your doctor right away. Your doctor may be able to help you manage these side effects.

HOW TO STORE IT

- Keep Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate and all other medications out of reach and sight of children.
- Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate should be stored at 15° -30° C (59- 86°F). It should remain stable until the expiration date printed on the label.
- Do not keep your medicine in places that are too hot or cold.
- Do not keep medicine that is out of date or that you no longer need. If you throw any medicines away, make sure that children will not find them.
- Keep Mylan-Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate in its original container and keep the container tightly closed.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online by mail or by fax; or
- Calling toll-free 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document can be found at: www.mylan.ca

The full product monograph prepared for health professionals can be obtained by contacting the sponsor, Mylan Pharmaceuticals ULC at: 1-844-596-9526

This leaflet was prepared by Mylan Pharmaceuticals ULC Etobicoke, Ontario M8Z 2S6

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Mylan Pharmaceuticals ULC
Etobicoke, ON M8Z 2S6

1-800-575-1379

www.mylan.ca

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