

PART III: CONSUMER INFORMATION

Pr MYLAN-EFAVIRENZ
(Efavirenz Tablets)
600 mg

This leaflet is Part III of a three-part “Product Monograph” published when Mylan-Efavirenz 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. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What is Mylan-Efavirenz?

- Mylan-Efavirenz is the brand name for the active ingredient efavirenz.
- Mylan-Efavirenz belongs to a class of anti-HIV medicines known as "non-nucleoside reverse transcriptase inhibitors" (NNRTIs or non-nukes).

What the medication is used for:

- Your doctor has prescribed Mylan-Efavirenz for you because you have been infected with HIV. Mylan-Efavirenz must always be taken in combination with other anti-HIV medicines (frequently referred to as "combination therapy").
- When taken with other anti-HIV medicines, efavirenz has been shown to reduce viral load and increase the number of CD4 cells (a type of immune cell in blood). Mylan-Efavirenz may not have these effects in every patient.

Does Mylan-Efavirenz cure HIV or AIDS?

- Mylan-Efavirenz is not a cure for HIV nor Acquired Immunodeficiency Syndrome (AIDS). People taking Mylan-Efavirenz may still develop infections or other illnesses associated with HIV.
- It is very important that you remain under the constant care of your doctor while taking Mylan-Efavirenz.

Does Mylan-Efavirenz reduce the risk of passing HIV to others?

- Mylan-Efavirenz has not been shown to reduce the risk of passing HIV to others through sexual contact or blood contamination. It is important to continue to practice safe sex and not use or share dirty needles.

What it does:

- Mylan-Efavirenz fights Human Immunodeficiency Virus (HIV) infection by reducing the amount of virus in the blood (called "viral load").

When it should not be used:

- Do not take Mylan-Efavirenz if you know you are allergic to any of the ingredients in the Mylan-Efavirenz tablets (See **What the nonmedicinal ingredients are**).

- Mylan-Efavirenz should not be taken with some other medicines that are listed in this pamphlet (see the section entitled **“Drugs that may interact with Mylan-Efavirenz”**).

What the medicinal ingredient is:

Efavirenz

What the nonmedicinal ingredients are:

Mylan-Efavirenz tablets also contain the following inactive ingredients: croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and sodium lauryl sulfate. The film coating contains hypromellose, iron oxide red, iron oxide yellow, polyethylene glycol and titanium dioxide.

What dosage forms it comes in:

Each Mylan-Efavirenz tablet contains 600 mg of efavirenz.

WARNINGS AND PRECAUTIONS

BEFORE TAKING Mylan-Efavirenz

What should I tell my doctor before I start Mylan-Efavirenz?

- Inform your doctor about any past or present medical problems, including liver disease, hepatitis, allergies, severe kidney failure, seizures or mental illness.
- Inform your doctor if you have ever had a previous life-threatening skin reaction (e.g., Stevens-Johnson syndrome).
- Inform your doctor about any medications (prescription and nonprescription), herbal products, vitamins, nutritional supplements that you are currently taking or are planning to take.
- Also inform your doctor about any recreational (street, illicit) drugs that you are currently taking or are planning to take. The effect of combining recreational (street, illicit) drugs or alcohol with Mylan-Efavirenz has not been studied. Because they may interact with each other, speak with your doctor or other healthcare provider before you combine these drugs.
- Inform your doctor if you have or have had a heart rhythm disorder such as an irregular heartbeat, prolongation of the QT interval or any risk factors for Torsade de Pointes (dangerous fluttering of the heart).

What should I consider concerning contraception, pregnancy, or breastfeeding?

- Tell your doctor if you are pregnant or planning to become pregnant. Birth defects have been reported in the offspring of animals and women treated with efavirenz during pregnancy. It is not known whether efavirenz caused these defects. Women should not become pregnant while taking Mylan-Efavirenz and for 12 weeks after stopping it. If you are pregnant, you should take Mylan-Efavirenz only if you and your doctor decide that the possible benefit to you is greater than the possible risk to your foetus. If you take Mylan-Efavirenz while you are pregnant, talk to your doctor about how you can be included in the antiretroviral pregnancy registry.
- It is currently recommended that women living with HIV should not breastfeed because HIV infection can be passed on

to the baby in breast milk. If you are breastfeeding or thinking about breastfeeding you **should discuss it with** your doctor **as soon as possible**.

- 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 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.

Can children take Mylan-Efavirenz?

- Efavirenz has not been studied in children below 3 years of age.
- Mylan-Efavirenz can be taken by children weighing at least 40 kg and who are able to swallow tablet.

Do not drive or operate machinery until you have determined your response to Mylan-Efavirenz, as this may make you sleepy or dizzy.

Mylan-Efavirenz can cause abnormal blood test results. Your doctor may perform blood tests and will interpret the results.

To find out how to take Mylan-Efavirenz please read carefully the following section “**WHILE TAKING Mylan-Efavirenz**”.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with Mylan-Efavirenz

Mylan-Efavirenz may affect the dosing of other medications including ones for treating HIV infection. For this reason it is very important to:

- Let all healthcare providers know that you are taking Mylan-Efavirenz.
- Inform your doctor and pharmacist about all medications that you are currently taking including those obtained over-the-counter without a prescription and complementary medications (vitamins, nutritional supplements, etc.) and herbal products, particularly St. John’s Wort.
- Consult your doctor or pharmacist before you start any new medication.
- Consult your doctor or pharmacist before you stop any medications that you are currently taking.

Bring all your medications when you see your doctor. Or make a list of their names, how much you take, and how often you take them. This will give your doctor a complete picture of the medications you are taking. Then he or she can decide the best approach for your situation.

You must not take the following medications if you are taking Mylan-Efavirenz. Taking these medications with Mylan-Efavirenz could create the potential for serious and/or life-threatening side effects:

CISAPRIDE^{*z}

MIDAZOLAM

TRIAZOLAM (e.g. HALCION*)

ERGOT MEDICATIONS (e.g. CAFERGOT*)

VORICONAZOLE (e.g. VFEND)

PIMOZIDE (e.g. ORAP*)

ZEPATIER

ST. JOHN’S WORT (*Hypericum perforatum*)

You must not take products containing St. John’s wort (*Hypericum perforatum*) with Mylan-Efavirenz as this may stop Mylan-Efavirenz from working properly and may lead to resistance to Mylan-Efavirenz or resistance to the class of non-nucleoside reverse transcriptase inhibitors (NNRTIs).

^{*z} CISAPRIDE is not marketed in Canada

The following drugs may interact with Mylan-Efavirenz and your doctor will determine whether they can be used or not or may make dosage changes for the other product, or substitute other products, as indicated below:

- Mylan-Efavirenz may be taken with many of the medications commonly used in people with HIV infection. These include the protease inhibitors, such as nelfinavir (Viracept*) and indinavir (Crixivan*), and nucleoside analogue reverse transcriptase inhibitors (NRTIs).
- **Use of Mylan-Efavirenz with saquinavir (Invirase*) is not recommended if you are taking saquinavir as your only protease inhibitor.**
- Use of Mylan-Efavirenz with rifampin is not recommended. Rifampin can reduce blood levels of Mylan-Efavirenz.
- Tegretol* (carbamazepine), Sporanox* (itraconazole), Posaconol* (posaconazole) and REYATAZ (atazanavir sulfate), if this is not the first time you are receiving treatment for your HIV infection, may need to be replaced with another medicine when taken with Mylan-Efavirenz.
- Mylan-Efavirenz reduces the blood levels of clarithromycin (Biaxin*) and is associated with a higher incidence of rash; your doctor may consider giving you an alternative antibiotic.
- If you are taking Mylan-Efavirenz and REYATAZ (atazanavir sulfate), you should also be taking Norvir* (ritonavir).
- Antimalarials such as atovaquone/proguanil, when taken with Mylan-Efavirenz, may reduce the amount of atovaquone/proguanil in your blood which may reduce the anti-malarial activity of these medicines. Atovaquone/proguanil should not be taken with Mylan-Efavirenz; your doctor should consider alternatives to these antimalarial medicines.
- Drugs that may interact with Mylan-Efavirenz to affect the electrical activity of your heart which include but may not be limited to macrolide antibiotics (such as clarithromycin) and antimalarials (artemether/lumefantrine).
- Use of EPCLUSA (sofosbuvir/velpatasvir), VOSEVI (sofosbuvir/velpatasvir/voxilaprevir), and MAVIRET (glecaprevir/pibrentasvir) is not recommended when taking Mylan-Efavirenz.
- Mylan-Efavirenz may interact with etonogestrel contraceptive implants. This means your implant might not work and you could get pregnant. You should use a barrier birth control method like a condom. Talk to your healthcare professional for advice on additional birth control methods.

The following medicine should not be taken with Mylan-Efavirenz since it contains efavirenz, the active ingredient in Mylan-Efavirenz:

- ATRIPLA (efavirenz, emtricitabine, tenofovir disoproxil fumarate).
- Your doctor may need to adjust the dose of the following medications when taken with Mylan-Efavirenz:
 - Crixivan* (indinavir)
 - Methadone
 - Zoloft* (sertraline)
 - Wellbutrin SR, Wellbutrin XL or Zyban (bupropion)
 - Kaletra* (lopinavir/ritonavir) Lopinavir and ritonavir combination should not be taken once daily with Mylan-Efavirenz. Your doctor may suggest an alternate dosing regimen.
 - Celsenti* (maraviroc)
 - Mycobutin* (rifabutin)
 - The cholesterol-lowering medicines Lipitor* (atorvastatin), Pravachol* (pravastatin), and Zocor* (simvastatin)
 - Calcium channel blockers such as Cardizem* or Tiazac* (diltiazem), Covera HS, Isoptin SR or Tarka (verapamil), and others.
 - Immunosuppressants such as Neoral* (cyclosporin), Advagraf* or Prograf* (tacrolimus), Rapamune* or Torisel* (sirolimus)
 - Hepatitis C antiviral agents
 - Antimalarials such as Coartem*[#] and Riamet*[#] (artemether/lumefantrine)
 - Anthelmintics such as Biltricide* (praziquantel). Your doctor may have to consider increasing the dose of praziquantel.

Not marketed in Canada

- The effect of combining alcohol or recreational (street, illicit) drugs with Mylan-Efavirenz has not been studied. Because they may interact with each other, speak with your doctor or other healthcare provider before you combine these drugs.

PROPER USE OF THIS MEDICATION

WHILE TAKING Mylan-Efavirenz

Usual Dose

- The dose of Mylan-Efavirenz for adults and children weighing more than 40 kg (88 lbs) is 600 mg once-a-day (one 600 mg tablet).
- You should take Mylan-Efavirenz on an empty stomach, preferably at bedtime. Taking Mylan-Efavirenz with food increases the level of efavirenz in the blood and may increase the possibility of side effects.
- Your doctor or pharmacist will give you instructions for proper dosage.

What should I remember to do or avoid while taking Mylan-Efavirenz?

- Swallow Mylan-Efavirenz with water.
- Do not chew the tablets.
- Taking Mylan-Efavirenz at bedtime may improve the tolerability of the nervous system side effects.

- It is important to take Mylan-Efavirenz as your doctor prescribes. Do not change the dose on your own.
- Mylan-Efavirenz should not be used alone to treat HIV. Mylan-Efavirenz should always be taken with other anti-HIV medications in order to prevent the virus from becoming resistant to your drug treatment.
- You should not stop taking Mylan-Efavirenz without first consulting with your doctor.
- If you are unsure of what to do or need help in planning the best times to take your medications, ask your doctor or other healthcare provider.
- If you think it would be useful, ask a friend or family member to remind you to take your medications.
- When your Mylan-Efavirenz supply starts to run low, get more from your doctor or pharmacist. This is very important because the amount of virus may start to increase if Mylan-Efavirenz is stopped for even a short time. The virus may then become harder to treat.
- Remember, Mylan-Efavirenz has been prescribed just for you. Never give your medications to others to try.
- Do not use your current supply of Mylan-Efavirenz after the end of the month and year shown by the “expiry date” on the bottle.

Overdose:

If you think you, or a person you are caring for, have taken too much Mylan-Efavirenz, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

- If you forget to take Mylan-Efavirenz, **do not double your next dose**. Take the missed dose as soon as possible, and then carry on with your regular dosing schedule.
- Try not to miss a dose. With anti-HIV medications, missing doses or not taking them properly may allow the amount of HIV in your body to increase. HIV may then become resistant. This means that the virus changes or mutates causing a medication to lose its effect.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

- Mylan-Efavirenz, like all medications, affects different people in different ways. Any medication may have unintended or unwanted effects, so-called side effects. Some people may develop side effects, others may not.
- The most notable side effects of efavirenz are rash and nervous system symptoms that include dizziness, insomnia (difficulty falling asleep), drowsiness, reduced ability to concentrate, and abnormal dreaming. These side effects are generally mild to moderate and tend to disappear after you have taken efavirenz for a few weeks.
- Some of these side effects such as dizziness will likely be less noticeable if you take Mylan-Efavirenz before going to bed. Be sure to tell your doctor if any of these side effects continue or if they bother you.

- A small number of patients 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.
- Dizziness, trouble concentrating, and drowsiness have been reported with efavirenz. If you notice any of these symptoms, you should avoid potentially hazardous tasks such as driving or operating machinery.
- You should consult your doctor if you have a rash since some rashes may be serious. However, most cases of rash disappear without any change in your treatment.
- Rash seems to be more common in children than in adults treated with efavirenz.
- Some patients taking efavirenz 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 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Autoimmune disease (when the immune system attacks healthy body tissue) may also occur after you start taking medicines for HIV infection. Examples of this include the following conditions: Grave's disease, Guillain-Barre syndrome, polymyositis or autoimmune hepatitis. Autoimmune disorders may occur many months after the start of treatment. Look for any symptoms such as:
 - fever, redness, rash or swelling
 - fatigue
 - joint or muscle pain
 - numbness or weakness beginning in the hands and feet and moving up towards the trunk of the body
 - palpitations (chest pain) or rapid heart rate
 - bulging eyes, light sensitivity, or vision changes
 - yellowing of the skin
 - difficulty talking, chewing, or swallowing

If you notice any of these symptoms, tell your doctor immediately.

Other side effects

- Other common side effects that have been reported include tiredness, nausea, diarrhea and headache. These may be from Mylan-Efavirenz or from other medications that you are taking.
- Tell your doctor or other healthcare provider if you notice these or any other side effects not mentioned in the pamphlet that continue or if they bother you.

Remember do not stop taking Mylan-Efavirenz without speaking to your doctor first. He or she may be able to help you manage these side effects without stopping your anti-HIV medications.

Serious side effects and what to do about them				
Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
Common	Serious psychiatric events Symptoms: <ul style="list-style-type: none"> • Severe depression • Thoughts of suicide • Strange thoughts • Angry behavior • Catatonia (unable to move or speak normally) 		✓	
	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 			✓
	Liver failure Symptoms: <ul style="list-style-type: none"> • Jaundice (skin or the white part of eyes turn yellow) • Urine turns dark • Bowel movements (stools) turn light in colour • Loss of appetite for several days or longer • Feeling sick to your stomach (nausea) • Lower stomach pain 		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

HOW TO STORE IT

Mylan-Efavirenz should be stored between 15°C and 30°C.

As with all medications, Mylan-Efavirenz should be kept out of the reach and sight of children.

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 at 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

If you want more information about Mylan-Efavirenz:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.mylan.ca or by calling 1-844-596-9526.

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