

Important Educational Information about
PrMylan-Emtricitabine/Tenofovir Disoproxil to Reduce the Risk of
Infection with Human Immunodeficiency Virus-1 (HIV-1)

The following brochure was developed to help reduce the risk of HIV-1 infection for
adults taking Mylan-Emtricitabine/Tenofovir Disoproxil.

Mylan-Emtricitabine/Tenofovir Disoproxil can help reduce the risk of HIV-1 infection when used with safer sex practices in:

- HIV-1 negative men who have sex with other men, who are at high risk of getting infected with HIV-1 through sex.
- Male-female sex partners, when one partner who has HIV-1 infection and the other, who does not.

This is sometimes called Pre-Exposure Prophylaxis or PrEP.

Mylan-Emtricitabine/Tenofovir Disoproxil contains 2 medicines, emtricitabine and tenofovir disoproxil fumarate (DF), combined in one pill.

Mylan-Emtricitabine/Tenofovir Disoproxil is for adults age 18 and older. Mylan-Emtricitabine/Tenofovir Disoproxil is not indicated in children under age 18 or adults over age 65.

Considerations when Mylan-Emtricitabine/Tenofovir Disoproxil is used for PrEP:

- Together with your healthcare professional, you need to decide whether Mylan-Emtricitabine/Tenofovir Disoproxil is right for you.
- Mylan-Emtricitabine/Tenofovir Disoproxil can only help reduce your risk of getting HIV-1 **before** you are infected.
- Do not take Mylan-Emtricitabine/Tenofovir Disoproxil to help reduce your risk of getting HIV-1 if:
 - You already have HIV-1 infection.
 - If you are HIV-1 positive, you need to take other medicines with Mylan-Emtricitabine/Tenofovir Disoproxil to treat HIV-1. Mylan-Emtricitabine/Tenofovir Disoproxil by itself is not a complete treatment for HIV-1.
 - You do not know your HIV-1 infection status.
 - You may already be HIV-1 positive and need to take other HIV-1 medicines with Mylan-Emtricitabine/Tenofovir Disoproxil to treat HIV-1.
- Your healthcare professional will run tests to determine that you are HIV-negative before starting PrEP treatment.

Important Warnings and Precautions about Mylan-Emtricitabine/Tenofovir Disoproxil that you should know about

1. Kidney Problems

The most serious side effect from taking Mylan-Emtricitabine/Tenofovir Disoproxil could be harm to your kidneys, including damage to kidney cells, kidney tissue inflammation and kidney failure. Your healthcare professional may monitor your kidney function before starting and while on Mylan-Emtricitabine/Tenofovir Disoproxil therapy. If you have had kidney problems in the past or need to take another drug that can cause kidney problems, additional blood testing may be needed.

2. Hepatitis B virus (HBV) infection

If you are infected with HBV and also taking Mylan-Emtricitabine/Tenofovir Disoproxil, when you stop taking Mylan-Emtricitabine/Tenofovir Disoproxil the flare-ups of HBV infection may return in a worse way.

- Do not stop taking Mylan-Emtricitabine/Tenofovir Disoproxil without your healthcare professional's advice.
- If you stop taking Mylan-Emtricitabine/Tenofovir Disoproxil, tell your healthcare professional immediately about any new, unusual or worsening symptoms that you notice after stopping treatment.
- After you stop taking Mylan-Emtricitabine/Tenofovir Disoproxil, your healthcare professional will still need to check your health and take blood tests for several months to check your liver.
- Mylan-Emtricitabine/Tenofovir Disoproxil is not approved for the treatment of HBV infection.

3. Lactic Acidosis

The class of medicines to which Mylan-Emtricitabine/Tenofovir Disoproxil belongs (NRTIs) can cause a condition, called lactic acidosis, together with an enlarged liver. Lactic acidosis is a rare but serious side effect that has occasionally been fatal. Lactic acidosis is a medical emergency and must be treated in the hospital.

If you notice any of the following symptoms, stop taking Mylan-Emtricitabine/Tenofovir Disoproxil and consult a healthcare professional immediately.

- Feeling very weak, tired or uncomfortable
- Unusual or unexpected stomach discomfort
- Nausea, vomiting, and stomach-area pain
- Feeling cold

- Feeling dizzy or lightheaded
- Suddenly developing a slow, or irregular heartbeat

You may be more likely to get lactic acidosis if you are female and overweight (obese) or have been taking nucleoside analog medicines, like Mylan-Emtricitabine/Tenofovir Disoproxil, for a long time.

4. Bone Problems

Tenofovir DF can reduce bone density in humans. If you notice bone pain, suffer a bone fracture, or other bone problems, consult your healthcare professional. If you already have bone problems, you may wish to discuss calcium and/or vitamin D supplements with your healthcare professional.

5. Body Fat Changes

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.

6. HIV Status

Mylan-Emtricitabine/Tenofovir Disoproxil should only be used for the PrEP indication if you are HIV-negative before and during treatment. You must get tested to be sure you are HIV-negative. Discuss with your healthcare professional if you have had a recent flu-like illness. Your healthcare professional will run tests to confirm that you are HIV negative before and during Mylan-Emtricitabine/Tenofovir Disoproxil treatment.

Before Mylan-Emtricitabine/Tenofovir Disoproxil treatment for PrEP

You must get tested to be sure you are HIV-negative. It is important that you also get tested at least every 3 months as recommended by your healthcare provider while taking Mylan-Emtricitabine/Tenofovir Disoproxil.

Do not take Mylan-Emtricitabine/Tenofovir Disoproxil to reduce the risk of getting HIV unless you are confirmed to be HIV-negative.

Tell your healthcare provider if you had any of the following symptoms within the last month before you start Mylan-Emtricitabine/Tenofovir Disoproxil or at any time while taking Mylan-Emtricitabine/Tenofovir Disoproxil:

- tiredness
- fever
- sweating a lot (especially at night)
- rash
- vomiting or diarrhea
- joint or muscle aches
- headache
- sore throat
- enlarged lymph nodes in the neck or groin

These may be signs of HIV infection and you may need to have a different kind of test to diagnose HIV. If you are already taking Mylan-Emtricitabine/Tenofovir Disoproxil to prevent HIV-1 infection (PrEP), your healthcare provider may tell you to stop taking Mylan-Emtricitabine/Tenofovir Disoproxil until an HIV test confirms that you do not have HIV-1 infection.

Just taking Mylan-Emtricitabine/Tenofovir Disoproxil may not keep you from getting HIV. Mylan-Emtricitabine/Tenofovir Disoproxil does NOT always prevent HIV.

You must also use other prevention methods from getting HIV.

- Know your HIV-1 status and the HIV-1 status of your partner(s).
- While taking Mylan-Emtricitabine/Tenofovir Disoproxil, get tested at least every 3 months for HIV, as recommended by your healthcare provider. Ask your partner(s) to get tested.
- If you think you were exposed to HIV-1, tell your healthcare provider right away. They may want to do more tests to be sure you are still HIV-negative.
- Get tested for other sexually transmitted infections such as syphilis and gonorrhea. These infections make it easier for HIV to infect you.
- Get information and support to help reduce risky sexual behavior.
- Have fewer sex partners.

- Do not miss any doses of Mylan-Emtricitabine/Tenofovir Disoproxil. Missing doses may increase your risk of getting HIV-1 infection.

Let your healthcare professional know if:

- **You have other medical conditions, especially:**
 - Liver problems
 - Kidney problems
 - Bone problems
- **You are taking other medicines.**
 - Some medicines can interact when taken together, including prescription and nonprescription medicines and dietary supplements.
- **You are taking didanosine.**
 - Taking didanosine and Mylan-Emtricitabine/Tenofovir Disoproxil may cause serious reactions including lactic acidosis (too much acid in the blood), pancreatitis (inflamed pancreas) and nerve damage (neuropathy).

Mylan-Emtricitabine/Tenofovir Disoproxil should not be used with or soon after cidofovir, acyclovir, valacyclovir, ganciclovir, valganciclovir, aminoglycosides, or non-steroidal anti-inflammatory drugs (NSAIDs), due to potential harm to the kidneys.

- **You are pregnant or planning to become pregnant.**
 - If you are a female who is taking Mylan-Emtricitabine/Tenofovir Disoproxil to prevent HIV-1 infection and you become pregnant while taking Mylan-Emtricitabine/Tenofovir Disoproxil, talk to your healthcare provider about whether you should continue taking Mylan-Emtricitabine/Tenofovir Disoproxil.

Pregnancy Registry: There is a registry for women who take antiviral medicines during pregnancy. The purpose of this registry is to collect information about your health and the health of your baby. Talk to your healthcare provider about how you can take part in this Antiretroviral Pregnancy Registry.

- **You are breastfeeding or planning to breastfeed.**
 - Do not breastfeed if you take Mylan-Emtricitabine/Tenofovir Disoproxil or have HIV. Mylan-Emtricitabine/Tenofovir Disoproxil can pass to your baby in your breast milk. You should not breastfeed because of the risk of passing HIV to your baby.
 - Talk with your healthcare provider about the best way to feed your baby.

During Mylan-Emtricitabine/Tenofovir Disoproxil treatment for PrEP

- Just taking Mylan-Emtricitabine/Tenofovir Disoproxil may not keep you from getting HIV. Mylan-Emtricitabine/Tenofovir Disoproxil does **NOT** always prevent HIV.
- **You must practice safer sex at all times. Do not have any kind of sex without protection.** Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.
- **You must also use other prevention methods from getting HIV.**
 - Know your HIV-1 status and the HIV-1 status of your partner(s).
 - Get tested at least every 3 months for HIV-1, as recommended by your healthcare provider.
 - Ask your partner(s) to get tested.
 - If you think you were exposed to HIV-1, tell your healthcare provider right away. They may want to do more tests to be sure you are still HIV negative.
 - Get tested for other sexually transmitted infections such as syphilis and gonorrhea. These infections make it easier for HIV-1 to infect you.
 - Get information and support to help reduce risky sexual behavior.
 - Have fewer sex partners.
 - Do not miss any doses of Mylan-Emtricitabine/Tenofovir Disoproxil. Missing doses may increase your risk of getting HIV infection.

Things to avoid while taking Mylan-Emtricitabine/Tenofovir Disoproxil

Avoid doing things that can increase your risk of getting infected with HIV or spreading HIV infection to other people.

- Do NOT have any kind of sex without protection. Always practice safer sex by using latex or polyurethane condom to lower the chance of contact with semen, vaginal fluids, or blood.
- Do NOT share personal items that can have blood or body fluids on them, such as toothbrushes and razor blades.
- Do NOT reuse or share needles or other injection equipment.

Ask your healthcare provider if you have any questions about how to prevent getting infected with HIV infection or spreading HIV infection to other people.

Do not take Mylan-Emtricitabine/Tenofovir Disoproxil for PrEP if:

- **You already have HIV-1 infection.** If you are HIV-positive, you need to take other medicines with Mylan-Emtricitabine/Tenofovir Disoproxil to treat HIV-1. Mylan-Emtricitabine/Tenofovir Disoproxil by itself is not a complete treatment for HIV-1 infection.
- **You do not know your HIV-1 infection status.** You may already be HIV-1 positive. You need to take other HIV-1 medicines with Mylan-Emtricitabine/Tenofovir Disoproxil to treat HIV-1 infection.

Some medicines can interact when taken together, including prescription and non-prescription medicines and dietary supplements. Let your healthcare provider know if you are taking these or any other medications:

- Didanosine (VIDEX, VIDEX EC[®])
- Atazanavir sulfate (REYATAZ[®])
- Lopinavir /ritonavir (KALETRA[®])
- Darunavir (PREZISTA[®])
- Ledipasvir/sofosbuvir (HARVONI[®])
- Sofosbuvir/velpatasvir (EPLCUSA[®])
- Sofosbuvir/velpatasvir/voxilaprevir (VOSEVI[®])
- Non-steroidal anti-inflammatory drugs (NSAIDs)

Do NOT take Mylan-Emtricitabine/Tenofovir Disoproxil if:

- You are on other medications that may affect your kidneys and have not discussed this with your healthcare professional.
- You have or are at known risk for any type of bone disease or bone related problems and have not discussed this with your healthcare professional.
- You are allergic to Mylan-Emtricitabine/Tenofovir Disoproxil or any of its ingredients (emtricitabine and tenofovir DF).
- You are already taking 3TC[®], ATRIPLA[®], COMBIVIR[®], COMPLERA[®], DESCOVY[®], EMTRIVA[®], GENVOYA[®], ODEFSEY[®], HEPTOVIR[®], KIVEXA[®], STRIBILD[®], TRIUMEQ[®], TRIZIVIR[®], VEMLIDY[®], or VIREAD[®] because these medicines contain the same or similar ingredients.
- You are also taking HEPSERA[®] (adefovir) to treat your HBV infection.

Keep a current list of all the medicines that you take. It is a good idea to provide a copy of this list every time you visit your healthcare professional or fill a prescription.

Proper Use of Mylan-Emtricitabine/Tenofovir Disoproxil

- Take Mylan-Emtricitabine/Tenofovir Disoproxil as prescribed by your doctor.
- Only take medicine that has been prescribed specifically for you.
- Do not give Mylan-Emtricitabine/Tenofovir Disoproxil to others or take medicine prescribed for someone else.
- Take Mylan-Emtricitabine/Tenofovir Disoproxil orally, with or without a meal.
- Take Mylan-Emtricitabine/Tenofovir Disoproxil once-daily.
- If you think you have taken too much Mylan-Emtricitabine/Tenofovir Disoproxil, contact your doctor, pharmacist, hospital emergency department or Regional Poison Control Centre, even if you have no symptoms.
- Do not miss any doses of Mylan-Emtricitabine/Tenofovir Disoproxil.
- If you miss a dose and it is less than 12 hours from the time you usually take your Mylan-Emtricitabine/Tenofovir Disoproxil, then take the dose. If more than 12 hours has passed from the time you usually take the medication, then wait until the next scheduled daily dose.
- Call your healthcare professional if you are not sure what to do.
- Do not take more than 1 dose in a day.
- Do not take 2 doses at the same time.
- Do not change or stop your treatment without first talking with your healthcare professional.
- Maintain adequate supply of Mylan-Emtricitabine/Tenofovir Disoproxil and refill prescription as needed to avoid running out of your medication.
- Do not use the medication if seal is broken or missing.

Common side effects of Mylan-Emtricitabine/Tenofovir Disoproxil

The most common side effects of Mylan-Emtricitabine/Tenofovir Disoproxil include:

- Diarrhea
- Nausea
- Vomiting
- Dizziness
- Headache

Talk to your healthcare provider if you experience any one of the following side effects:

- Increased thirst or increased/decreased urinations as well as increased thirst
- Swollen legs and/or feet
- Feeling very weak, listless and/or tired
- Unusual muscle pain
- Stomach pain with nausea and vomiting
- Feeling cold especially in arms and legs
- Feeling dizzy or lightheaded
- Fast or irregular heartbeat
- Jaundice (skin or the white part of eyes turns yellow)
- Urine turns dark
- Stool turns light in color
- Loss of appetite for several days or longer
- Feeling sick to your stomach (nausea)
- Lower stomach pain

Muscle pain, muscle weakness, bone pain and softening of the bone (infrequently contributing to fractures) have also been reported.

This is not a complete of side effects. If you have questions about side effects, ask your healthcare professional.

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 at <https://www.canada.ca/en/healthcanada/services/drugshealth-products/medeffect-canada> or by calling toll-free at 1-866-234-2345.

How to store Mylan-Emtricitabine/Tenofovir Disoproxil

- Keep Mylan-Emtricitabine/Tenofovir Disoproxil out of children's reach and sight.
- Store Mylan-Emtricitabine/Tenofovir Disoproxil tablets at room temperature between 15 °C to 30 °C. Protect from moisture. 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. Return it to the nearest pharmacy and make sure that children will not find them.
- Keep Mylan-Emtricitabine/Tenofovir Disoproxil in its original container and keep the container tightly closed.

Visit <https://www.viatris.ca/en-ca/products/branded-specialty> for more details about Mylan-Emtricitabine/Tenofovir Disoproxil educational materials.