

Important Safety Information About Pr MINT-EMTRICITABINE/TENOFOVIR to Help Reduce the Risk of Getting Human Immunodeficiency Virus-1 (HIV-1) Infection

This brochure is for adults taking MINT-EMTRICITABINE/TENOFOVIR to help reduce the risk of getting HIV-1 infection.

If you are taking MINT-EMTRICITABINE/TENOFOVIR to treat HIV-1, please see the MINT-EMTRICITABINE/TENOFOVIR Consumer Information for other important information.

MINT-EMTRICITABINE/TENOFOVIR to help Reduce the Risk of Getting HIV-1 Infection

MINT-EMTRICITABINE/TENOFOVIR (emtricitabine/tenofovir disoproxil fumarate) is a prescription medicine to help reduce the chance of getting HIV-1 infection in adults when used with safer sex practices. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

MINT-EMTRICITABINE/TENOFOVIR, to help reduce the risk of getting HIV-1 infection, is meant for:

- HIV-negative men who have sex with men, who are at high risk for getting HIV-1 infection through sex. Male-female sex partners when one partner has HIV-1 infection and the other does not.
- This is sometimes called Pre-Exposure Prophylaxis or PrEP.

MINT-EMTRICITABINE/TENOFOVIR only works to help reduce the risk of getting HIV-1 infection as part of a complete prevention strategy that includes safer sex practices and regular testing for HIV-1.

- MINT-EMTRICITABINE/TENOFOVIR works better to help reduce the risk of getting HIV-1 infection when the medicines are in your bloodstream **before** you are exposed to HIV-1.
- You need to take MINT-EMTRICITABINE/TENOFOVIR every day, not just when you think you have been exposed.
- Just taking MINT-EMTRICITABINE/TENOFOVIR alone may not keep you from getting HIV-1 infection

You must be HIV negative to start MINT-EMTRICITABINE/TENOFOVIR. You must get tested to make sure that you do not already have HIV-1 infection before PrEP treatment. Do not take MINT-EMTRICITABINE/TENOFOVIR to help reduce the risk of getting HIV-1 infection unless you are confirmed to be HIV negative.

Important information on serious side-effects that you should know about MINT-EMTRICITABINE/TENOFOVIR

MINT-EMTRICITABINE/TENOFOVIR can cause serious side effects, including:

1. Lactic acidosis

Lactic acidosis is a rare, serious and sometimes fatal side effect that can occur while taking MINT-EMTRICITABINE/TENOFOVIR. It is a medical emergency and must be treated in the hospital.

Call your healthcare provider right away if you get these symptoms:

- Weakness or being more tired than usual
- Unusual muscle pain
- Being short of breath or fast breathing
- Nausea, vomiting, and stomach-area pain
- Cold or blue hands and feet
- Feeling dizzy or lightheaded
- Fast or abnormal heartbeats

You may be more likely to get lactic acidosis if you are a woman, are very overweight (obese), or have been taking MINT-EMTRICITABINE/TENOFOVIR for a long time.

2. Severe liver problems.

Severe liver problems can happen in people who take MINT-EMTRICITABINE/TENOFOVIR. In some cases, these liver problems can lead to death. Your liver may become large and tender. You may develop fat in your liver when you take MINT-EMTRICITABINE/TENOFOVIR.

Call your doctor or nurse right away if you get these symptoms:

- Your skin or the white part of your eyes turns yellow
- Dark “tea-colored” urine
- Light-colored stools
- Loss of appetite for several days or longer
- Nausea
- Stomach-area pain

You may be more likely to get severe liver problems if you are very overweight (obese) or have been taking MINT-EMTRICITABINE/TENOFOVIR for a long time.

3. If you also have hepatitis B virus (HBV) infection and take MINT-EMTRICITABINE/TENOFOVIR, your flare-ups of hepatitis B may return in a worse way if you stop taking MINT-EMTRICITABINE/TENOFOVIR.

- Do not stop taking MINT-EMTRICITABINE/TENOFOVIR without first talking to your healthcare provider.
- If your healthcare provider stops MINT-EMTRICITABINE/TENOFOVIR, your healthcare provider will need to watch you closely for several months to check your hepatitis B infection, or give you a medication to treat hepatitis B. MINT-EMTRICITABINE/TENOFOVIR is not approved for the treatment of hepatitis B infection.

Tell your healthcare provider about any new or unusual symptoms you have after you stop taking MINT-EMTRICITABINE/TENOFOVIR.

Before taking MINT-EMTRICITABINE/TENOFOVIR for PrEP:

- **You must be HIV negative to start MINT-EMTRICITABINE/TENOFOVIR.** You must get tested to make sure that you do not already have HIV-1 infection.
- Many HIV-1 tests can miss HIV-1 infection in a person who has recently become infected. If you have flu-like symptoms, you could have recently become infected with HIV-1. Tell your healthcare provider if you had a flu-like illness within the last month before starting MINT-EMTRICITABINE/TENOFOVIR or at any time while taking MINT-EMTRICITABINE/TENOFOVIR. Symptoms of new HIV-1 infection include:
 - tiredness
 - fever
 - joint or muscle aches
 - headache
 - sore throat
 - vomiting or diarrhea
 - rash
 - sweating a lot (especially at night)
 - enlarged lymph nodes in the neck or groin

While you are taking MINT-EMTRICITABINE/TENOFOVIR for PrEP:

- **Just taking MINT-EMTRICITABINE/TENOFOVIR alone may not keep you from getting HIV-1 infection. MINT-EMTRICITABINE/TENOFOVIR does not always prevent HIV.**
- **You must continue using safer sex practices** while you are taking MINT-EMTRICITABINE/TENOFOVIR to reduce your risk of getting HIV-1 infection.
- **You must stay HIV-1-negative to keep taking MINT-EMTRICITABINE/TENOFOVIR for PrEP:**
 - Know your HIV-1 status and the HIV-1 status of your partner(s).
 - Get tested for HIV-1 at least every 3 months or when your healthcare provider tells you.
 - Get tested for other sexually transmitted infections such as syphilis and gonorrhea. These infections make it easier for HIV-1 to infect you.
 - 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 information and support to help reduce risky sexual behavior.
 - Have fewer sex partners.
 - Do not miss any doses of MINT-EMTRICITABINE/TENOFOVIR. Missing doses may increase your risk of getting HIV infection.
 - If you do become HIV positive, you need more medicine than MINT-EMTRICITABINE/TENOFOVIR alone to treat HIV-1 infection. MINT-EMTRICITABINE/TENOFOVIR by itself is not a complete treatment for HIV-1 infection.
 - If you have HIV-1 and take only MINT-EMTRICITABINE/TENOFOVIR, over time your HIV-1 infection may become harder to treat

See the section “**Things you should avoid while taking MINT-EMTRICITABINE/TENOFOVIR**” and talk to your healthcare provider for more information about how to prevent HIV-1 infection.

Things you should avoid while taking MINT-EMTRICITABINE/TENOFOVIR

There are things you should avoid while taking MINT-EMTRICITABINE/TENOFOVIR that can increase your risk of getting infected with HIV-1. While taking MINT-EMTRICITABINE/TENOFOVIR:

- Do NOT have any kind of sex without protection. Always practice safer sex. Use latex or non-latex condoms, except lambskin, to reduce 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 share or reuse needles or other injection equipment.

Ask your healthcare provider if you have any questions about how to prevent getting infected with HIV-1.

Do not take MINT-EMTRICITABINE/TENOFOVIR for PrEP if:

MINT-EMTRICITABINE/TENOFOVIR can only help reduce your risk of getting HIV-1 **before** you are infected.

Do not take MINT-EMTRICITABINE/TENOFOVIR for PrEP if:

- **You already have HIV-1 infection.** If you are HIV-positive, you need to take other medicines with MINT-EMTRICITABINE/TENOFOVIR to treat HIV-1. MINT-EMTRICITABINE/TENOFOVIR 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-positive. You need to take other HIV-1 medicines with MINT-EMTRICITABINE/TENOFOVIR to treat HIV-1 infection.

Things to tell your healthcare provider before taking MINT-EMTRICITABINE/TENOFOVIR

Tell your healthcare provider if you:

- Have liver problems, including hepatitis B virus infection
- Have kidney problems or receive kidney dialysis treatment
- Have bone problems
- Have any other medical conditions
- **Are pregnant or plan to become pregnant.** It is not known if MINT-EMTRICITABINE/TENOFOVIR can harm your unborn child.

If you are a female who is taking MINT-EMTRICITABINE/TENOFOVIR to reduce the risk of getting HIV-1 infection and you become pregnant while taking MINT-EMTRICITABINE/TENOFOVIR, talk to your healthcare provider to decide if you should keep taking MINT-EMTRICITABINE/TENOFOVIR.

Pregnancy Registry: A pregnancy registry collects information about your health and the health of your baby. There is a pregnancy registry for women who take medicines to treat or prevent HIV-1 during pregnancy.

For more information about the registry and how it works, talk to your healthcare provider.

- **Are breastfeeding or plan to breastfeed.**
 - If you become HIV-1 positive while taking MINT-EMTRICITABINE/TENOFOVIR, do not breastfeed because the virus can pass to your baby through the breast milk.
 - Do not breastfeed if you take MINT-EMTRICITABINE/TENOFOVIR. MINT-EMTRICITABINE/TENOFOVIR can pass to your baby in your breast milk.
 - Talk with your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Do not take MINT-EMTRICITABINE/TENOFOVIR if:

- You are already taking 3TC[®], ATRIPLA[®], Combivir[®], COMPLERA[®], EMTRIVA[®], Heptovir[®], Kivexa[®], STRIBILD[®], Triumeq[®], Trizivir[®] or VIREAD[®] because these medicines contain the same or similar ingredients
- you are also taking HEPSERA[®] (adefovir) to treat your HBV infection

MINT-EMTRICITABINE/TENOFOVIR may interact with other medicines. Especially tell your healthcare provider if you take:

- didanosine (Videx, Videx EC[®])
- atazanavir (Reyataz[®])
- lopinavir with ritonavir (Kaletra[®])
- darunavir (Prezista[®])
- ledipasvir and sofosbuvir (HARVONI[®])
- non-steroidal anti-inflammatory drugs (NSAIDS)

Your doctor may need to check you more often or change your dose if you take any of these medicines and MINT-EMTRICITABINE/TENOFOVIR.

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How to take MINT-EMTRICITABINE/TENOFOVIR

- Take MINT-EMTRICITABINE/TENOFOVIR exactly as prescribed.
- Take MINT-EMTRICITABINE/TENOFOVIR by mouth, with or without food.
- MINT-EMTRICITABINE/TENOFOVIR is usually taken 1 time each day. Take MINT-EMTRICITABINE/TENOFOVIR at the same time each day to keep MINT-EMTRICITABINE/TENOFOVIR blood levels constant.
- Do not miss any doses of MINT-EMTRICITABINE/TENOFOVIR. Missing a dose lowers the amount of medicine in your blood.
- If you miss a dose of MINT-EMTRICITABINE/TENOFOVIR and it is less than 12 hours from the time you usually take MINT-EMTRICITABINE/TENOFOVIR, then take the dose. If more than 12 hours has passed from the time you usually take MINT-EMTRICITABINE/TENOFOVIR, then wait until the next scheduled daily dose. **Do not** take more than 1 dose of MINT-EMTRICITABINE/TENOFOVIR 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.
- Do not change your dose or stop taking MINT-EMTRICITABINE/TENOFOVIR without first talking with your healthcare provider. Stay under a healthcare provider's care when taking MINT-EMTRICITABINE/TENOFOVIR.
- Refill your MINT-EMTRICITABINE/TENOFOVIR prescription before you run out of medicine.
- If you take too much MINT-EMTRICITABINE/TENOFOVIR, call your healthcare provider or go to the nearest hospital emergency room right away, even if there are no symptoms.
- If you take MINT-EMTRICITABINE/TENOFOVIR for PrEP:
 - you must also use other methods to reduce your risk of getting infected with HIV-1. See the section **"Things you should avoid while taking MINT-EMTRICITABINE/TENOFOVIR"** in this booklet.
 - **Take MINT-EMTRICITABINE/TENOFOVIR every day**, not just when you think you have been exposed to HIV-1.

Possible side effects of MINT-EMTRICITABINE/TENOFOVIR

MINT-EMTRICITABINE/TENOFOVIR may cause serious side effects, including:

- See “Important information on serious side-effects that you should know about MINT-EMTRICITABINE/TENOFOVIR?”
- **New or worse kidney problems**, including kidney failure. If you have had kidney problems in the past or take medicines that can cause kidney problems, your healthcare provider may do blood tests to check your kidneys before you start and while you are taking MINT-EMTRICITABINE/TENOFOVIR. Your healthcare provider may tell you to stop taking it if you have kidney problems.
- **Bone problems** can happen in some people who take MINT-EMTRICITABINE/TENOFOVIR. Bone problems include bone pain, or softening or thinning of bones, which may lead to fractures. Your healthcare provider may need to do tests to check your bones.
- **Changes in body fat** can happen in people who take HIV medicines. The exact cause and long-term health effects of these problems are not known. The changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the middle of your body (trunk), and loss of fat from the legs, arms, and face.

Common side effects of MINT-EMTRICITABINE/TENOFOVIR

Common side effects in people who take MINT-EMTRICITABINE/TENOFOVIR for PrEP include: stomach-area (abdomen) pain, headache, and decreased weight.

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all of the possible side effects of MINT-EMTRICITABINE/TENOFOVIR. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may also report side effects to Health Canada at 1-866-234-2345 or online at www.healthcanada.gc.ca/medeffect.

How to store MINT-EMTRICITABINE/TENOFOVIR

- Store MINT-EMTRICITABINE/TENOFOVIR at room temperature between 15 °C to 30 °C
- 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 MINT-EMTRICITABINE/TENOFOVIR in its original container and keep the container tightly closed.
- Do not use MINT-EMTRICITABINE/TENOFOVIR if seal over bottle opening is broken or missing.

Keep MINT-EMTRICITABINE/TENOFOVIR and all other medicines out of reach and sight of children.