

**Important Safety Information About Teva-Emtricitabine/Tenofovir to Help Reduce the Risk of Getting Human Immunodeficiency Virus-1 (HIV-1) Infection**

# Pr **TEVA-Emtricitabine/Tenofovir** (Emtricitabine and Tenofovir Tablets)

200 mg / 300 mg

Antiretroviral Agent

**Risk minimization tool for individuals exposed to HIV-1 and at risk of infection**

## **Important Safety Information**

This brochure is for adults taking Teva-Emtricitabine/Tenofovir to help reduce the risk of getting HIV-1 infection.

If you are taking Teva-Emtricitabine/Tenofovir to treat HIV-1, please see the Teva-Emtricitabine/Tenofovir Consumer Information leaflet for other important information.

This material was developed by Teva Canada Limited, as part of the risk minimization plan for Teva-Emtricitabine/Tenofovir. This material is not intended for promotional use.



## About Teva-Emtricitabine/Tenofovir (Emtricitabine and Tenofovir Tablets)

Teva-Emtricitabine/Tenofovir (Emtricitabine and Tenofovir Tablets) is a prescription medicine that is used to help reduce the chance of getting HIV-1 infection in adults when used with safer sex practices in:

- 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.

Teva-Emtricitabine/Tenofovir is for adults age 18 and older.

Teva-Emtricitabine/Tenofovir is not indicated in children under age 18 or adults over age 65.

Teva-Emtricitabine/Tenofovir may 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.

- Teva-Emtricitabine/Tenofovir should be taken **before** you are exposed to HIV-1.
- You need to take Teva-Emtricitabine/Tenofovir every day, not just when you think you have been exposed.
- Just taking Teva-Emtricitabine/Tenofovir may not keep you from getting HIV-1 infection.

**You must be HIV negative to start Teva-Emtricitabine/Tenofovir.**

**You must get tested to make sure that you do not already have HIV-1 infection before PrEP treatment.**

**Do not take Teva-Emtricitabine/Tenofovir unless you are confirmed to be HIV negative.**

**It is very important that you see your healthcare professional regularly while taking Teva-Emtricitabine/Tenofovir.**

## Serious Warnings and Precautions

- The most serious possible side effect is harm to the kidneys, including damage to kidney cells, kidney tissue inflammation and kidney failure.
- Your healthcare professional may monitor your kidney function before beginning and while receiving Teva-Emtricitabine/Tenofovir. Some patients treated with tenofovir disoproxil fumarate (a component of Teva-Emtricitabine/Tenofovir) have had kidney problems.
- Your healthcare professional 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.
- **If you are also infected with the Hepatitis B Virus, “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 Teva-Emtricitabine/Tenofovir.
- Do not stop taking Teva-Emtricitabine/Tenofovir without your healthcare professional’s advice. If you stop taking Teva-Emtricitabine/Tenofovir, tell your healthcare professional immediately about any new, unusual or worsening symptoms that you notice after stopping treatment. After you stop taking Teva-Emtricitabine/Tenofovir, your healthcare professional will still need to check your health and take blood tests to check your liver for several months. Teva-Emtricitabine/Tenofovir is not approved for the treatment of Hepatitis B Virus infection.
- The class of medicines to which Teva-Emtricitabine/Tenofovir belongs (NRTIs) can cause a condition called lactic acidosis, together with an enlarged liver. Non-specific symptoms such as nausea, vomiting and stomach pain might indicate the development of lactic acidosis. This rare but serious side effect has occasionally been fatal. Lactic acidosis occurs more often in women, particularly if they are very overweight. You should consult your healthcare professional immediately if such symptoms occur while you are receiving Teva-Emtricitabine/Tenofovir. The symptoms that may indicate lactic acidosis include: feeling very weak, tired or uncomfortable; unusual or unexpected stomach discomfort; feeling cold; feeling dizzy or lightheaded; suddenly developing a slow or irregular heartbeat. If you notice these symptoms, stop taking Teva-Emtricitabine/Tenofovir and consult a healthcare professional immediately.
- Tenofovir disoproxil fumarate caused harm to the bones of animals. Tenofovir disoproxil fumarate reduced bone density in humans. If you notice bone pain, or suffer a bone fracture, or other bone problem, consult your healthcare professional. If you have bone problems, you may wish to discuss calcium and/or vitamin D supplements with your healthcare professionals.

- Teva-Emtricitabine/Tenofovir should only be used for the PrEP indication if you are HIV negative before and during treatment. 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 Teva-Emtricitabine/Tenofovir treatment.

## Side Effects And What To Do About Them

**The most common side effects of Teva-Emtricitabine/Tenofovir are:**

- Diarrhea
- Nausea
- Vomiting
- Dizziness
- Headache

Other side effects include:

- Stomach pain
- Indigestion
- Inflammation of the pancreas
- Sleeping problems
- Abnormal dreams
- Weakness
- Pain
- Shortness of breath
- Allergic reaction (including swelling of the face, lips, tongue or throat)
- Rash
- Flatulence (intestinal gas)
- Skin discoloration (small spots or freckles) may also happen with Teva-Emtricitabine/Tenofovir

## Serious Side Effects And What To Do About Them

**Teva-Emtricitabine/Tenofovir can cause serious side effects, including:**

### **Kidney Problems**

- 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**

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

**Talk to your healthcare provider right away if you get these symptoms:**

- Feeling very weak or tired
- Unusual muscle pain
- Stomach pain with nausea and vomiting
- Feeling cold especially in arms and legs
- Being short of breath
- Feeling dizzy or lightheaded
- Fast or irregular heartbeats

Lactic acidosis occurs more often in women, particularly if they are overweight or have been taking nucleoside analog medicines, like Teva-Emtricitabine/Tenofovir for a long time.

### **Severe liver problems**

Severe liver problems can happen in people who take Teva-Emtricitabine/Tenofovir. Your liver may become large and tender. You may develop fat in your liver when you take Teva-Emtricitabine/Tenofovir.

**Talk with your healthcare professional if you get these symptoms:**

- Jaundice (Your skin or the white part of your eyes turns yellow)
- Urine turns dark
- Bowel movements (stools) turn light in color
- Loss of appetite for several days or longer
- Nausea
- Lower stomach pain

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

**If you also have hepatitis B virus (HBV) infection and take Teva-Emtricitabine/Tenofovir, your flare-ups of hepatitis B may return in a worse way if you stop taking Teva-Emtricitabine/Tenofovir.**

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

Tell your healthcare professional immediately about any new, unusual or worsening symptoms you have after you stop taking Teva-Emtricitabine/Tenofovir.

For a complete list of possible side effects, please consult the **Consumer Information** leaflet. If you experience any side effects that are not listed here, or in your **Consumer Information** leaflet, contact your healthcare professional.

**Before taking Teva-Emtricitabine/Tenofovir for PrEP:**

- **You must be HIV negative to start Teva-Emtricitabine/Tenofovir.** You must get tested to make sure that you do not already have HIV-1 infection.
- Tell your healthcare provider if you had a flu-like illness within the last month before starting Teva-Emtricitabine/Tenofovir or at any time while taking Teva-Emtricitabine/Tenofovir. Symptoms of new HIV-1 infection include:
  - 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

**While you are taking Teva-Emtricitabine/Tenofovir for PrEP:**

- **Just taking Teva-Emtricitabine/Tenofovir may not keep you from getting HIV-1 infection. Teva-Emtricitabine/Tenofovir does NOT always prevent HIV.**
- **You must still 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 to keep you from getting HIV:**
  - Know your HIV-1 status and the HIV-1 status of your partner(s).
  - Get tested for HIV-1 at least every 3 months, as recommended by your healthcare provider. Ask your partners 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 Teva-Emtricitabine/Tenofovir. Missing doses may increase your risk of getting HIV infection.
- Do not take Teva-Emtricitabine/Tenofovir 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 Teva-Emtricitabine/Tenofovir to treat HIV-1.
  - Teva-Emtricitabine/Tenofovir by itself is not a complete treatment for HIV-1 infection.

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

## Things you should avoid while taking Teva-Emtricitabine/Tenofovir

There are things you should avoid while taking Teva-Emtricitabine/Tenofovir that can increase your risk of getting infected with HIV-1 or spreading HIV infection to other people:

- Do NOT share or reuse needles or other injection equipment.
- Do NOT share personal items that can have blood or body fluids on them, such as toothbrushes and razor blades.
- 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.

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

### Do not take Teva-Emtricitabine/Tenofovir for PrEP if:

Teva-Emtricitabine/Tenofovir can only help reduce your risk of getting HIV-1 **before** you are infected. **Do not take Teva-Emtricitabine/Tenofovir for PrEP if:**

- **You already have HIV-1 infection.** If you are HIV-positive, you need to take other medicines with Teva-Emtricitabine/Tenofovir to treat HIV-1. Teva-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 Teva-Emtricitabine/Tenofovir to treat HIV-1 infection.

## Things to tell your healthcare provider before taking Teva-Emtricitabine/Tenofovir

### Tell your healthcare provider if you:

- **Are pregnant or planning to become pregnant**
  - Pregnant mothers should not take Teva-Emtricitabine/Tenofovir unless specifically directed by your healthcare professional. If you are a female who is taking Teva-Emtricitabine/Tenofovir to prevent HIV infection (PrEP) and you become pregnant while taking Teva-Emtricitabine/Tenofovir, talk to your healthcare provider about whether you should continue taking Teva-Emtricitabine/Tenofovir.
- **Pregnancy Registry:** There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this Antiretroviral Pregnancy Registry.



- **Are breastfeeding or planning to breastfeed.** Do not breastfeed if you are taking Teva-Emtricitabine/Tenofovir or have HIV. Teva-Emtricitabine/Tenofovir 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.
- **Have other medical conditions, especially liver, bone and kidney problems.**

**Tell your healthcare provider about all the medicines you take**, including prescription and non-prescription medicines, and dietary supplements.

Do not take Teva-Emtricitabine/Tenofovir if:

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

Teva-Emtricitabine/Tenofovir may interact with other medicines. Especially tell your healthcare provider if you take:

- didanosine (Videx, Videx EC<sup>®</sup>)
- atazanavir (Reyataz<sup>®</sup>)
- lopinavir with ritonavir (Kaletra<sup>®</sup>)
- darunavir (Prexista<sup>®</sup>)
- ledipasvir and sofosbuvir (HARVONI<sup>®</sup>)
- sofosbuvir/velpatasvir (EPCLUSA)
- sofosbuvir/velpatasvir/voxilaprevir (VOSEVI<sup>™</sup>)
- non-steroidal anti-inflammatory drugs (NSAIDS)

Teva-Emtricitabine/Tenofovir should not be used with or soon after cidofovir, acyclovir, valacyclovir, ganciclovir, valganciclovir, aminoglycosides, or nonsteroidal anti-inflammatory drugs (NSAIDS), due to potential harm to the kidneys.

## Other special warnings:

Blood sugar levels (glucose) or levels of fats (lipids) in blood may increase with HIV treatment. Your doctor may order blood tests for you.

It is a good idea to keep a complete list of all the medicines that you take. Make a new list when medicines are added or stopped. Give copies of this list to all your healthcare providers every time you visit your healthcare professional or fill a prescription.

### How to take Teva-Emtricitabine/Tenofovir

- Take Teva-Emtricitabine/Tenofovir exactly as prescribed.
- Take Teva-Emtricitabine/Tenofovir by mouth, with or without food.
- Teva-Emtricitabine/Tenofovir is usually taken 1 time each day.
- Do not miss any doses of Teva-Emtricitabine/Tenofovir.
  - If you miss a dose of Teva-Emtricitabine/Tenofovir and it is less than 12 hours from the time you usually take Teva-Emtricitabine/Tenofovir, then take the dose. If more than 12 hours has passed from the time you usually take Teva-Emtricitabine/Tenofovir, then wait until the next scheduled daily dose.
  - **Do not** take more than 1 dose of Teva-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 treatment or stop taking Teva-Emtricitabine/Tenofovir without first talking with your healthcare provider. Stay under a healthcare provider's care when taking Teva-Emtricitabine/Tenofovir.
- Refill your Teva-Emtricitabine/Tenofovir prescription before you run out of medicine.
- If you take too much Teva-Emtricitabine/Tenofovir, contact your healthcare professional, hospital emergency department or Regional Poison Control, even if there are no symptoms.
- You must also use other methods to reduce your risk of getting infected with HIV-1. See section "Things you should avoid while taking Teva-Emtricitabine/Tenofovir".
- Take Teva-Emtricitabine/Tenofovir every day, not just when you think you have been exposed to HIV-1.

When your Teva-Emtricitabine/Tenofovir supply starts to run low, get more from your healthcare professional. This is very important because protection from infection might decrease if you stop taking Teva-Emtricitabine/Tenofovir, even for a short time.

### **How to store Teva-Emtricitabine/Tenofovir**

- Store Teva-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 Teva-Emtricitabine/Tenofovir in its original container and keep the container tightly closed.
- Do not use Teva-Emtricitabine/Tenofovir if seal over bottle opening is broken or missing.

**Keep Teva-Emtricitabine/Tenofovir and all other medicines out of reach and sight of children.**

## Reporting side effects

You can report any suspected side effects associated with the use of Teva-Emtricitabine/Tenofovir by contacting:

- **Teva Canada Limited** at 1-800-268-4127 option 3 (English), 1-877-777-9117 (French), Telefax: 1-416-335-4472; or

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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/reportdeclaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Teva-Emtricitabine/Tenofovir is indicated in combination with safer sex practices for PrEP to reduce the risk of sexually acquired HIV-1 infection in adults at high risk.

- Do not pass it to others. It may harm them even if it seems to you that their medical condition is similar. Return any unused capsules to the pharmacy.
- Reports on pregnancy during treatment with Teva-Emtricitabine/Tenofovir should be reported immediately by telephone to Teva Canada Ltd. at 1 800 268-4127 ext. 3 or visiting [druginfo@tevacanada.com](mailto:druginfo@tevacanada.com).

The above contacts can be also used for reporting side effects during the treatment with Teva-Emtricitabine/Tenofovir.

**For further information, read the entire Consumer Information leaflet carefully before using the medicine.** If you have further questions, contact your doctor or pharmacist.

Reference: 1. Teva-Emtricitabine/Tenofovir Product Monograph. Teva Canada Limited. April 11, 2019.