Important Safety Information About TRUVADA for a Pre-exposure Prophylaxis (PrEP) Indication

For Uninfected Individuals
TRUVADA for a PrEP indication

TRUVADA (emtricitabine/tenofovir disoproxil fumarate) is a medicine used in combination with safer sex practices to decrease the chance of getting HIV-1 in adults who are at high risk of getting infected with HIV-1 through sex.

TRUVADA is also used with other antiviral medicines to treat HIV-1 in adults and children 12 years and older.

Only take TRUVADA as part of a complete prevention strategy because TRUVADA is not always effective in preventing a person from getting infected with HIV-1.

What is the most important information you should know about taking TRUVADA?

TRUVADA can cause serious side effects. Some of these side effects are:

1. Build-up of lactic acid in your blood (lactic acidosis). This is a serious medical emergency that can lead to death. Lactic acidosis can be hard to identify early because the symptoms could seem like symptoms of other health problems. **Call your healthcare provider right away if you get these symptoms.** They could be signs of lactic acidosis:
   - Feeling very weak or tired
   - Unusual muscle pain
   - Trouble breathing
   - Stomach pain with nausea and/or vomiting
   - Feeling cold, especially in your arms and legs
   - Feeling dizzy or lightheaded
   - Having a fast or irregular heartbeat
2. **Severe liver problems.** Severe liver problems can happen in people who take TRUVADA. In some cases, these liver problems can lead to death. Your liver may become large (hepatomegaly), and you may develop fat in your liver (steatosis) when you take TRUVADA. **Call your healthcare provider right away if you get these symptoms:**

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

You may be more likely to get lactic acidosis or severe liver problems if you are a woman, are very overweight (obese), or have been taking TRUVADA or a medicine like it for a long time.

3. **Worsening of hepatitis B (HBV) infection.** If you have HBV infection, it may flare up and get worse if you take TRUVADA and then stop it. A flare-up is when your HBV infection suddenly comes back worse than before.

- Do not run out of TRUVADA. Refill your prescription before your TRUVADA is all gone
- Do not stop taking TRUVADA without first talking to your healthcare provider
- If you stop taking TRUVADA, your healthcare provider will need to check your health often. Your healthcare provider will also need to do regular blood tests for several months to check your HBV infection

Tell your healthcare provider about any new or unusual symptoms you have after you stop taking TRUVADA.

4. **You should not take TRUVADA for a PrEP indication if you are HIV-1 positive or do not know your status**

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**Before starting TRUVADA for a PrEP indication**

You must be HIV-1 negative and stay HIV-1 negative **before** starting TRUVADA for a PrEP indication. That is why you **must:**

- Get tested to be sure you are HIV-1 negative. It is important that you also get tested at least every 3 months as recommended by your healthcare provider while taking TRUVADA
- Not take TRUVADA to reduce the risk of getting HIV unless you are confirmed to be HIV-1 negative
- Have no symptoms like feeling weak or tired, fever, sweating a lot (especially at night), rash, vomiting, diarrhea, joint or muscle aches, headache, sore throat, or enlarged lymph nodes in your neck or groin
- Be prepared to commit to adopting safer sex practices, such as regular and correct use of condoms, limiting your number of sexual partners, knowing the HIV status of your sexual partners, and regular testing for HIV-1 (at least every 3 months) and other sexually transmitted infections, such as syphilis and gonorrhea
- Make sure you understand the risks and benefits of taking TRUVADA for a PrEP indication as outlined in the TRUVADA Medication Guide and in the Agreement Form, and you have spoken with your healthcare provider about questions and concerns

**After starting TRUVADA for a PrEP indication**

Just taking TRUVADA may not keep you from getting HIV-1. TRUVADA does not always prevent HIV-1.
Here are some things you must do after starting TRUVADA for a PrEP indication:

• You will need to get tested regularly for HIV-1 to make sure that you are still HIV-1 negative. Your healthcare provider will tell you when

• Tell your healthcare provider if you have any of these symptoms: feeling weak or tired, fever, sweating a lot (especially at night), rash, vomiting, diarrhea, joint or muscle aches, headache, sore throat, or enlarged lymph nodes in your neck or groin. These may be signs of HIV-1 infection

• 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 methods to keep from getting HIV-1:
  – Know your HIV-1 status and the HIV-1 status of your partner(s)
  – Get tested regularly for HIV-1. Ask your partner(s) to get tested
  – Get tested for other sexually transmitted infections, such as syphilis and gonorrhea. These infections make it easier for HIV-1 to infect you
  – Do not have risky sex
  – Have fewer sex partners
  – Do not share needles or other drug injection equipment
  – Do not share personal things, like toothbrushes and razors. They can have blood or body fluids on them

• Do not miss any doses of TRUVADA. Missing doses raises the risk of getting HIV-1. TRUVADA for a PrEP indication may not help you decrease the chance of getting HIV-1 if you do not take it exactly as prescribed. Be sure to stick to the TRUVADA daily dosing schedule

• TRUVADA by itself is not a complete treatment for HIV-1. If you already have HIV-1 or get HIV-1 and take TRUVADA by itself without other anti–HIV-1 medicines, you may develop resistance to TRUVADA

• TRUVADA needs to be in your blood to work. You may have to take TRUVADA for a few days before there is enough in your blood for it to help decrease your chance of getting HIV-1. Even after it is in your blood, it is still very important to practice safer sex

TRUVADA for a PrEP indication was tested in adults who were at high risk for getting infected with HIV-1 through sex.

When you should not take TRUVADA for a PrEP indication

Do not take TRUVADA to help prevent HIV-1 infection...

• If you have been tested for HIV-1 and have found out you are infected

• If you are already taking ATRIPLA® (efavirenz/emtricitabine/tenofovir disoproxil fumarate), COMPLERA® (emtricitabine/rilpivirine/tenofovir disoproxil fumarate), Complivir® (lamivudine/zidovudine), EMTRIVA® (emtricitabine), Epivir® or Epivir-HBV® (lamivudine), Epzicom® (abacavir sulfate/lamivudine), Trizivir® (abacavir sulfate/lamivudine/zidovudine), or VIREAD® (tenofovir disoproxil fumarate). These medicines have the same or similar active ingredients as TRUVADA

• Do not take TRUVADA with HEPSERA® for hepatitis B virus (HBV)
Things to tell your healthcare provider

Tell your healthcare provider if you...

- **Are pregnant or plan to become pregnant.** There is an increased risk of HIV-1 infection during pregnancy. It is not known if TRUVADA can harm your unborn child. You and your healthcare provider will need to decide if TRUVADA is right for you. If you use TRUVADA while you are pregnant, talk to your healthcare provider about joining the TRUVADA Antiviral Pregnancy Registry.

- **Are breast-feeding.** You should not breast-feed if you have HIV-1 because you may pass HIV-1 to your baby. Also, the components of TRUVADA (emtricitabine/tenofovir disoproxil fumarate) can pass into your breast milk, and it is not known if this will harm your baby. If you are a woman who has or will have a baby, talk with your healthcare provider about the best way to feed your baby.

- **Have kidney problems or get kidney dialysis treatment**

- **Have bone problems**

- **Have liver problems, including hepatitis B virus infection**

Your healthcare provider needs to know what other medicines you take

- Make sure you tell your doctor if you take didanosine (VIDEX EC), atazanavir (REYATAZ), or lopinavir with ritonavir (KALETRA) because the doses of these medications may need to change.

Tell your healthcare provider about all of the medicines you take. That means prescription and non-prescription medicines, vitamins, and herbal supplements. TRUVADA may affect the way other medicines work, and other medicines may affect how TRUVADA works.

Show a list of all your medicines to your healthcare provider or pharmacist when you get a new medicine.

Possible side effects of TRUVADA

TRUVADA may cause these serious side effects:

- **New or worse kidney problems**, including kidney failure. If you have had kidney problems in the past or need to take another medicine that can cause kidney problems, your healthcare provider may need to do blood tests to check your kidneys while you are taking TRUVADA.

- **Bone problems.** Bone problems, like bone pain, softening, or thinning (which may lead to fractures), can occur. Your healthcare provider may need to do tests to check your bones.

- **Changes in body fat.** These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the main part of your body (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.

- **Changes in your immune system (immune reconstitution syndrome).** This can occur if you have active HIV-1 infection and take TRUVADA.

Complete management to lower the risk of acquiring HIV-1

Use TRUVADA for a PrEP indication only as part of a complete prevention strategy that includes other prevention measures, such as safer sex practices, because TRUVADA is not always effective in preventing the acquisition of HIV-1.
Common side effects of TRUVADA

No new side effects emerged in the iPrEx and Partners PrEP clinical trials. The most common reported with the use of TRUVADA alone in these clinical trials include abdominal pain, headache, and decreased weight.

The most common side effects of EMTRIVA or VIREAD, the medicines in TRUVADA, when used with other anti–HIV-1 medicines are:

- Diarrhea
- Dizziness
- Nausea
- Headache
- Fatigue
- Abnormal dreams
- Problems sleeping
- Rash
- Depression
- Vomiting

These are not all of the possible side effects of TRUVADA. For more information, ask your healthcare provider or pharmacist.

Talk with your healthcare provider

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

Call your doctor for medical advice about side effects. You may also report side effects to FDA at 1-800-FDA-1088.

Please see the Full Prescribing Information with Medication Guide, including “What is the most important information I should know about TRUVADA?” that goes with this brochure.

Make sure you understand the risks and benefits of taking TRUVADA for a PrEP indication as outlined in the TRUVADA Medication Guide and in the Agreement Form, and you have spoken with your healthcare provider about questions and concerns.