

Truvada[®]

²⁰⁰mg emtricitabine · tenofovir disoproxil fumarate ³⁰⁰mg

Important Safety Information About TRUVADA to Reduce the Risk of Getting Human Immunodeficiency Virus–1 (HIV-1) Infection

This booklet is for adults taking TRUVADA to reduce the risk of getting HIV-1 infection.

If you are taking TRUVADA to treat HIV-1, please see the Medication Guide for other important information.

TRUVADA to Reduce the Risk of Getting HIV-1 Infection

TRUVADA (emtricitabine/tenofovir disoproxil fumarate) is a prescription medicine to 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).

TRUVADA, to reduce the risk of getting HIV-1 infection, is meant for adults who are:

- HIV negative, and
- At high risk for getting HIV-1 infection through sex

TRUVADA only works to 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.

- TRUVADA works better to 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 TRUVADA every day, not just when you think you have been exposed
- Just taking TRUVADA alone may not keep you from getting HIV-1 infection

You must be HIV negative to start TRUVADA. You must get tested to make sure that you do not already have HIV-1 infection. Do not take TRUVADA to reduce the risk of getting HIV-1 infection unless you are confirmed to be HIV negative.

The most important information you should know about TRUVADA

TRUVADA can cause serious side effects, including:

- 1. Too much lactic acid in your blood (lactic acidosis).** Your body normally makes lactic acid, but too much lactic acid can be a serious medical emergency. It can be treated, but it can also lead to death.

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 TRUVADA for a long time.

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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 and tender. You may develop fat in your liver when you take TRUVADA.

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 a woman, are very overweight (obese), or have been taking TRUVADA for a long time.

3. If you also have hepatitis B virus (HBV) infection and take TRUVADA, your hepatitis B may become worse if you stop taking TRUVADA.

- Do not stop taking TRUVADA without first talking with your healthcare provider
- If your healthcare provider stops TRUVADA, 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

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

Before taking TRUVADA to reduce your risk of getting HIV-1 infection

- **You must be HIV negative to start TRUVADA.** 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 TRUVADA or at any time while taking TRUVADA. Symptoms of new HIV-1 infection include:
 - Tiredness
 - Fever
 - Joint or muscle aches
 - Headache
 - Sore throat
 - Vomiting or diarrhea
 - Rash
 - Night sweats
 - Enlarged lymph nodes in the neck or groin

While you are taking TRUVADA to reduce your risk of getting HIV-1 infection:

- **Just taking TRUVADA alone may not keep you from getting HIV-1 infection**

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- **You must continue using safer sex practices** while you are taking TRUVADA to reduce your risk of getting HIV-1 infection
- **You must stay HIV-1 negative to keep taking TRUVADA to reduce your risk of infection**
 - Know your HIV-1 status and the HIV-1 status of your partners
 - 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. Your healthcare provider 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 TRUVADA. Missing doses may increase your risk of getting HIV infection
- If you do become HIV positive, you need more medicine than TRUVADA alone to treat HIV-1 infection. TRUVADA by itself is not a complete treatment for HIV-1 infection
 - If you have HIV-1 and take only TRUVADA, over time your HIV-1 infection may become harder to treat

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

Things you should avoid while taking TRUVADA

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

- 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

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Do not take TRUVADA to reduce the risk of getting HIV-1 infection if...

TRUVADA can only help reduce your risk of getting HIV-1 **before** you are infected. **Do not take TRUVADA to reduce the risk of getting HIV-1 infection if:**

- **You already have HIV-1 infection.** If you are HIV positive, you need to take other medicines with TRUVADA to treat HIV-1. TRUVADA 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 over HIV-1 medicines with TRUVADA to treat HIV-1 infection

Things to tell your healthcare provider before taking TRUVADA

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 TRUVADA can harm your unborn child

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

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 with your healthcare provider.

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- **Are breastfeeding or plan to breastfeed**

- If you become HIV-1 positive while taking TRUVADA, do not breastfeed because the virus can pass to your baby through the breast milk
- Do not breastfeed if you take TRUVADA. TRUVADA 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.

- Tenofovir or emtricitabine (ATRIPLA[®], COMPLERA[®], EMTRIVA, STRIBILD[®], or VIREAD). These medicines contain the same active ingredient as TRUVADA
- Medicines that contain lamivudine (Combivir[®], Epivir[®], Epivir-HBV[®], Epzicom[®], or Trizivir[®])
- Adefovir (HEPSERA[®])

TRUVADA may interact with other medicines. Especially tell your healthcare provider if you take:

- Didanosine (Videx[®] EC)
- Atazanavir (Reyataz[®])
- Darunavir (Prezista[®])
- Lopinavir with ritonavir (Kaletra[®])

Your doctor may need to check you more often or change your dose if you take any of these medicines and TRUVADA.

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 TRUVADA

- Take TRUVADA exactly as prescribed
- Take TRUVADA by mouth, with or without food
- TRUVADA is usually taken 1 time each day. Take TRUVADA at the same time each day to keep TRUVADA blood levels constant
- Do not miss any doses of TRUVADA. Missing a dose lowers the amount of medicine in your blood
- If you miss a dose of TRUVADA, take it as soon as you remember that day. Do not take more than 1 dose of TRUVADA in a day. Do not take 2 doses at the same time to make up for a missed dose. Call your healthcare provider or pharmacist if you are not sure what to do
- Do not change your dose or stop taking TRUVADA without first talking with your healthcare provider. Stay under a healthcare provider's care when taking TRUVADA
- Refill your TRUVADA prescription before you run out of medicine
- If you take too much TRUVADA, call your healthcare provider or go to the nearest hospital emergency room right away
- If you take TRUVADA to reduce your risk of getting HIV-1 infection:
- 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 TRUVADA”** in this booklet
- **Take TRUVADA every day**, not just when you think you have been exposed to HIV-1

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Possible side effects of TRUVADA

TRUVADA may cause serious side effects, including:

- See “The most important information you should know about TRUVADA”
- **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 TRUVADA. Your healthcare provider may tell you to stop taking it if you have kidney problems
- **Bone problems** can happen in some people who take TRUVADA. 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 TRUVADA

Common side effects in people who take TRUVADA to reduce the risk of getting HIV-1 infection 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 TRUVADA. 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 FDA at 1-800-FDA-1088.

How to store TRUVADA

- Store TRUVADA at room temperature between 68°F to 77°F (20°C to 25°C)
- Keep TRUVADA in its original container and keep the container tightly closed
- Do not use TRUVADA if seal over bottle opening is broken or missing

Keep TRUVADA and all other medicines out of reach of children.

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You can find this booklet and other important information about TRUVADA to reduce the risk of getting HIV-1 infection at www.TRUVADAprerequisites.com or call 1-800-445-3235.



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