

Patient Information

TRUVADA™ (tru-VAH-dah) Tablets

Generic name: emtricitabine and tenofovir disoproxil fumarate
(em tri SIT uh bean and te NOE fo veer dye sioe PROX ih FYOU-mar-ate)

Read the Patient Information that comes with TRUVADA before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. You should stay under a healthcare provider's care when taking TRUVADA. **Do not change or stop your medicine without first talking with your healthcare provider.** Talk to your healthcare provider or pharmacist if you have any questions about TRUVADA.

What is the most important information I should know about TRUVADA?

• Some people who have taken medicine like TRUVADA (nucleoside analogs) have developed a serious condition called lactic acidosis (buildup of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital. Call your healthcare provider right away if you get the following signs or symptoms of lactic acidosis.

- You feel very weak or tired.
- You have unusual (not normal) muscle pain.
- You have trouble breathing.
- You have stomach pain with nausea and vomiting.
- You feel cold, especially in your arms and legs.
- You feel dizzy or lightheaded.
- You have a fast or irregular heartbeat.

• Some people who have taken medicines like TRUVADA have developed serious liver problems called hepatotoxicity, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). Call your healthcare provider right away if you get the following signs or symptoms of liver problems.

- Your skin or the white part of your eyes turns yellow (jaundice).
- Your urine turns dark.
- Your bowel movements (stools) turn light in color.
- You don't feel like eating food for several days or longer.
- You feel sick to your stomach (nausea).
- You have lower stomach area (abdominal) pain.

• You may be more likely to get lactic acidosis or liver problems if you are female, very overweight (obese), or have been taking nucleoside analog medicines, like TRUVADA, for a long time.

• TRUVADA is not for the treatment of Hepatitis B Virus infection. Patients infected with both Hepatitis B Virus and human immunodeficiency virus (HIV) who take TRUVADA need close medical follow-up for several months after stopping treatment with TRUVADA. Follow-up includes medical exams and blood tests to check for Hepatitis B Virus that could be getting worse. Patients with Hepatitis B Virus infection, who take TRUVADA and then stop it, may get "flare-ups" of their hepatitis. A "flare-up" is when the disease suddenly returns in a worse way than before.

What is TRUVADA?

TRUVADA is a type of medicine called an HIV (human immunodeficiency virus) nucleoside analog reverse transcriptase inhibitor (NRTI). TRUVADA contains 2 medicines, EMTRIVA® (emtricitabine) and VIREAD® (tenofovir disoproxil fumarate, or tenofovir DF) combined in one pill. TRUVADA is always used with other anti-HIV medicines to treat people with HIV infection. TRUVADA is for adults age 18 and older. TRUVADA has not been studied in children under age 18 or adults over age 65.

HIV infection destroys CD4 (T) cells, which are important to the immune system. The immune system helps fight infection. After a large number of T cells are destroyed, acquired immune deficiency syndrome (AIDS) develops.

TRUVADA helps block HIV reverse transcriptase, a chemical in your body (enzyme) that is needed for HIV to multiply. TRUVADA lowers the amount of HIV in the blood (viral load). TRUVADA may also help to increase the number of T cells (CD4 cells). Lowering the amount of HIV in the blood lowers the chance of death or infections that happen when your immune system is weak (opportunistic infections).

TRUVADA does not cure HIV infection or AIDS. The long-term effects of TRUVADA are not known at this time. People taking TRUVADA may still get opportunistic infections or other conditions that happen with HIV infection. Opportunistic infections are infections that develop because the immune system is weak. Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium* complex (MAC) infection. It is very important that you see your healthcare provider regularly while taking TRUVADA.

TRUVADA does not lower your chance of passing HIV to other people through sexual contact, sharing needles, or being exposed to your blood. For your health and the health of others, it is important to always practice safer sex by using a latex or polyurethane condom or other barrier to lower the chance of sexual contact with semen, vaginal secretions, or blood. Never use or share dirty needles.

Who should not take TRUVADA?

Do not take TRUVADA if you are allergic to TRUVADA or any of its ingredients. The active ingredients of TRUVADA are emtricitabine and tenofovir DF. See the end of this leaflet for a complete list of ingredients.

What should I tell my healthcare provider before taking TRUVADA?

Tell your healthcare provider if you:

- are pregnant or planning to become pregnant. We do not know 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 how you can be on the TRUVADA Antiviral Pregnancy Registry.
- are breast-feeding. You should not breast feed if you are HIV-positive because of the chance of passing the HIV virus to your baby. Also, it is not known if TRUVADA can pass into your breast milk and if it can 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 are undergoing kidney dialysis treatment.
- have bone problems.
- have liver problems including HBV infection.

• Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take:

- COMBIVIR®, EMTRIVA®, EPIVIR®, EPIVIR-HBV®, EPZICOM™, TRIZIVIR®, or VIREAD. TRUVADA should not be used with those medicines.
- Drugs that contain didanosine (VIDEX®, VIDEX EC®). Tenofovir DF (a component of TRUVADA) may increase the amount of VIDEX in your blood. You may need to be followed more carefully if you are taking TRUVADA and VIDEX together.
- REYATAZ™ (atazanavir sulfate) or KALETRA® (lopinavir/ritonavir). These medicines may increase the amount of tenofovir DF (a component of TRUVADA) in your blood, which could result in more side effects. You may need to be followed more carefully if you are taking TRUVADA and REYATAZ or KALETRA together.

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 of your healthcare providers and pharmacist every time you visit your healthcare provider or fill a prescription.

How should I take TRUVADA?

- Take TRUVADA exactly as your healthcare provider prescribed it. Follow the directions from your healthcare provider, exactly as written on the label.
- The usual dose of TRUVADA is 1 tablet once a day. TRUVADA is always used with other anti-HIV medicines. If you have kidney problems, you may need to take TRUVADA less often.
- TRUVADA may be taken with or without a meal. Food does not affect how TRUVADA works. Take TRUVADA at the same time each day.
- If you forget to take 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. Call your healthcare provider or pharmacist if you are not sure what to do. It is important that you do not miss any doses of TRUVADA or your anti-HIV medicines.
- When your TRUVADA supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to TRUVADA and become harder to treat.
- 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.
- If you take too much TRUVADA, call your local poison control center or emergency room right away.

What should I avoid while taking TRUVADA?

- Do not breast-feed. See "What should I tell my healthcare provider before taking TRUVADA?"
- Avoid doing things that can spread HIV infection since TRUVADA doesn't stop you from passing the HIV infection to others.
 - Do not share needles or other injection equipment.
 - Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.
 - Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom or other barrier to reduce the chance of sexual contact with semen, vaginal secretions, or blood.
- COMBIVIR, EMTRIVA, EPIVIR, EPIVIR-HBV, EPZICOM, TRIZIVIR, or VIREAD. TRUVADA should not be used with these medicines.

What are the possible side effects of TRUVADA?

TRUVADA may cause the following serious side effects (See "What is the most important information I should know about TRUVADA?"):

- Lactic acidosis (buildup of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital. Call your doctor right away if you get signs of lactic acidosis. (See "What is the most important information I should know about TRUVADA?")
- Serious liver problems (hepatotoxicity), with liver enlargement (hepatomegaly) and fat in the liver (steatosis). Call your healthcare provider right away if you get any signs of liver problems. (See "What is the most important information I should know about TRUVADA?")
- "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 TRUVADA. Your healthcare provider will monitor your condition for several months after stopping TRUVADA if you have both HIV and HBV infection. TRUVADA is not for the treatment of Hepatitis B Virus infection.
- Kidney problems. If you have had kidney problems in the past or take other medicines that can cause kidney problems, your healthcare provider should do regular blood tests to check your kidneys.
- Changes in bone mineral density (thinning bones). It is not known whether long term use of TRUVADA will cause damage to your bones. If you have had bone problems in the past, your healthcare provider may need to do tests to check your bone mineral density or may prescribe medicines to help your bone mineral density.

Other side effects with TRUVADA when used with other anti-HIV medicines include:

- Changes in body fat have been seen in some patients taking TRUVADA and other anti-HIV medicines. 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 at this time.

The most common side effects of EMTRIVA or VIREAD when used with other anti-HIV medicines are: dizziness, diarrhea, nausea, vomiting, headache, rash, and gas. Skin discoloration (small spots or freckles) may also happen with TRUVADA.

These are not all the side effects of TRUVADA. This list of side effects with TRUVADA is not complete at this time because TRUVADA is still being studied. If you have questions about side effects, ask your healthcare provider. Report any new or continuing symptoms to your healthcare provider right away. Your healthcare provider may be able to help you manage these side effects.

How do I store TRUVADA?

- Keep TRUVADA and all other medicines out of reach of children.
- Store at room temperature up to 25°C (77°F).
- Keep TRUVADA in its original container and keep the container tightly closed.
- Do not keep medicine that is out of date or that you no longer need. If you throw away medicines away make sure that children will not find them.

General information about TRUVADA:

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use TRUVADA for a condition for which it was not prescribed. Do not give TRUVADA to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about TRUVADA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about TRUVADA that is written for health professionals. For more information, you may also call 1-800-GILEAD-5 or access the TRUVADA website at www.TRUVADA.com.

Do not use TRUVADA if seal over bottle opening is broken or missing.

What are the ingredients of TRUVADA?

Active Ingredients: emtricitabine and tenofovir DF

Inactive Ingredients: Croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and pregelatinized starch (gluten free). The tablets are coated with Opadry II light Blue Y-30-10671-A containing FD&C Blue #2 aluminum lake, hypromellose, lactose monohydrate, titanium dioxide, and triacetin.

Rx Only

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Para todos

Anti-gay al sesgo en la subida del televisor latino

GLAAD ha levantado alarmas cerca de dos demostraciones de la charla de la televisión de la lengua del español en la difusión de Liberman.

"pecado Censura" y "El Show de María Laria de José Luis," promueve el abuso verbal de y la violencia física contra lesbiana, gay, gente bisexual y del transgénero (LGBT), GLAAD dice.

El perro guardián de los medios de LGBT dijo que el abuso, y la violencia se extendió el enero. 3 difusiones de un nuevo "pecado Censura" demostración y un reestreno de José Luis de "El Show de María Laria."

Los anfitriones José Luis González y María Laria han permitido de largo que los miembros de las audiencias utilicen los insultos homofóbicos y ellos mismos haber hecho las observaciones

insensibles y difamatorias sobre la gente de LGBT. Ambos programas difunden regularmente epítetos difamatorios tales como "pañales [faggot]," "joto [faggot]," "maricón [faggot]," "marimacha [dique]," y otros. Otros comentarios hechos en las demostraciones incluyen "a persona bisexual son alguien que no ha reconocido todavía que él es gay," "la gente es confusa cuando ella es homosexual," "usted debe tomar una prueba del SIDA porque todos estos individuos tienen SIDA," y "usted hombre, transvestite o cosa. Apenas no sé cuáles usted es."

Durante el enero. 3 vuelven a efectuar, María Laria goaded a miembro del jurado del transgénero para levantar su falda para verificar si la mujer había experimentado un cambio del sexo y después había reído sobre él. Además de la irrisión cruel de las huéspedes de LGBT, las demostraciones de la charla han tomado a abuso una medida más lejos permitiendo violencia física, GLAAD dicho. González y Laria permiten que los miembros y los miembros del jurado de las audiencias batan, golpee e insultese. En el enero. 3 "Pecado Censura De José Luis," un golpe del miembro de las audiencias y arrastrado un hombre gay a través de la longitud entera de la etapa antes de González señaló a sus protectores para pararlo. Esto ocurrió después del hombre, una huésped en la demostración, confesó su amor para un amigo masculino.

"El 'pecado Censura' y 'El Show de María Laria' de José Luis está promoviendo prejudicar, odio y violencia hacia la gente de LGBT," dijo a gente de GLAAD de director Mónica Taher de los medios del color. "éste es una de las razones que tenemos tan muchos crímenes del odio contra la gente de LGBT en la comunidad de Latino."

