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## Emtricitabine and Tenofovir

pronounced as (em tri sit' uh bean) (te noe' fo veer)

### IMPORTANT WARNING:

Emtricitabine and tenofovir should not be used to treat hepatitis B virus infection (HBV; an ongoing liver infection). Tell your doctor if you have or think you may have HBV. Your doctor may test you to see if you have HBV before you begin your treatment with emtricitabine and tenofovir. If you have HBV and you take emtricitabine and tenofovir, your condition may suddenly worsen when you stop taking emtricitabine and tenofovir. Your doctor will examine you and order lab tests regularly for several months after you stop taking emtricitabine and tenofovir to see if your HBV has worsened.

If you are taking emtricitabine and tenofovir to help prevent you from getting HIV, your doctor will test you to see if you have HIV before you begin your treatment. Tell your doctor if you have had any of the following symptoms in the last month or if you have any of the following symptoms while taking emtricitabine and tenofovir to help prevent you from getting HIV: fever, tiredness, joint or muscle pain, rash, night sweats, vomiting, diarrhea, headache, sore throat, swollen neck or groin area. Tell your doctor if you think you may have been exposed to HIV. Emtricitabine and tenofovir does not always prevent HIV. Your doctor will order HIV tests at least every 3 months while you are taking emtricitabine and tenofovir to see if you have become infected with HIV. Emtricitabine and tenofovir should only be used in combination with other medications to treat HIV. If emtricitabine and tenofovir are used alone to treat HIV, your condition may become more difficult to treat.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests before and during your treatment to check your body's response to emtricitabine and tenofovir.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with emtricitabine and tenofovir and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>] ) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risks of taking emtricitabine and tenofovir.

## Why is this medication prescribed?

The combination of emtricitabine and tenofovir (Descovy, Truvada) is used along with other medications to treat HIV in adults and children who weigh at least 37 pounds (17 kg). Emtricitabine and tenofovir (Truvada) is also used along with practicing safer sex (e.g., condom use) to reduce the risk of HIV infection) in high-risk adults and teenagers who weigh at least 77 pounds (35 kg). Emtricitabine and tenofovir are in a class of medications called nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs). They work by slowing the spread of HIV in the body. Although emtricitabine and tenofovir will not cure HIV, these medications may decrease your chance of developing acquired immunodeficiency syndrome (AIDS) and HIV-related illnesses such as serious infections or cancer. Taking these medications along with practicing safer sex and making other lifestyle changes may decrease the risk of getting or transmitting the HIV virus to other people.

## How should this medicine be used?

The combination of emtricitabine and tenofovir comes as a tablet to take by mouth. It is usually taken, with or without food, once a day. Take emtricitabine and tenofovir at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take emtricitabine and tenofovir exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

If you are taking emtricitabine and tenofovir (Truvada), your doctor may prescribe or recommend a calcium and vitamin D supplement to take during your treatment. You should take these supplements as directed by your doctor.

If your child is taking emtricitabine and tenofovir (Truvada), swallow the tablet whole. Tell your doctor if your child is unable to swallow the tablets.

Continue to take emtricitabine and tenofovir even if you feel well. Do not stop taking emtricitabine and tenofovir without talking to your doctor.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking emtricitabine and tenofovir,

- tell your doctor and pharmacist if you are allergic to emtricitabine and tenofovir, any other medications, or any of the ingredients in emtricitabine and tenofovir tablets. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: antiviral medications such as acyclovir (Sitavig, Zovirax), adefovir (Hepsera), cidofovir, ganciclovir (Cytovene), valacyclovir (Valtrex), and valganciclovir (Valcyte); aspirin and other nonsteroidal anti-inflammatory medications (NSAIDs) such as ibuprofen (Advil, Motrin) and naproxen (Aleve,

Naprosyn); gentamicin; other medications for HIV or AIDS including atazanavir (Reyataz, in Evotaz), darunavir (Prezista, in PrezcoBix), didanosine (Videx), emtricitabine (Emtriva, in Atripla, in Complera, in Genvoya, in Odefsey, in Stribild, in Truvada, others), lamivudine (Epivir, in Combivir, in Epzicom, in Trizivir, others), lopinavir and ritonavir (Kaletra), tenofovir (Viread, in Atripla, in Stribild, in Truvada, others); and other HIV medications containing emtricitabine and tenofovir (Atripla, Complera, Emtriva, Genvoya, Odefsey, Stribild, Vemlidy, Viread). If you are taking emtricitabine and tenofovir (Descovy) also tell your doctor if you are taking carbamazepine (Carbatrol, Equetro, Tegretol, others), oxcarbazepine (Oxtellar XR, Trileptal), phenobarbital, phenytoin (Dilantin, Phenytek), rifabutin (Mycobutin), rifampin (Rifadin, Rimactane, in Rifamate, in Rifater), rifapentine (Priftin), ritonavir (Norvir), and tipranavir (Aptivus). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- tell your doctor what herbal products you are taking, especially St. John's wort. You should not take St. John's wort while you are taking emtricitabine and tenofovir (Descovy).
- tell your doctor if you have or have ever had the conditions mentioned in the IMPORTANT WARNING section, bone problems including osteoporosis (a condition in which the bones become thin and weak and break easily) or bone fractures, any type of infection that does not go away or that comes and goes such as tuberculosis (TB; a type of lung infection) or cytomegalovirus (CMV; a viral infection that may cause symptoms in people with weak immune systems), or liver or kidney disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while taking emtricitabine and tenofovir, call your doctor. You should not breastfeed if you are infected with HIV or if you are taking emtricitabine and tenofovir.
- you should know that while you are taking medications to treat HIV infection, your immune system may get stronger and begin to fight other infections that were already in your body. This may cause you to develop symptoms of those infections. If you have new or worsening symptoms during your treatment with emtricitabine and tenofovir, be sure to tell your doctor.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

## What should I do if I forget a dose?

Take the missed dose as soon as you remember it that day. Do not take more than one dose in a day. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Emtricitabine and tenofovir may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- depression
- anxiety
- difficulty falling asleep or staying asleep
- unusual dreams
- pain, burning or tingling in the hands or feet

- heartburn
- weight loss

**Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING or SPECIAL PRECAUTIONS sections, call your doctor immediately or get emergency medical treatment:**

- swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
- hoarseness
- difficulty swallowing or breathing
- decreased urination
- difficult, painful, or frequent urination
- bone pain
- pain in upper right part of stomach
- loss of appetite
- flu-like symptoms
- unusual bleeding or bruising
- weakness
- dark yellow or brown urine
- light-colored bowel movements
- yellowing of the skin or eyes
- feeling cold, especially in the arms or legs
- muscle pain
- fast or irregular heartbeat
- dizziness
- lightheadedness
- stomach pain with nausea and vomiting
- nausea
- vomiting

Emtricitabine and tenofovir may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## What other information should I know?

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

Keep a supply of emtricitabine and tenofovir on hand. Do not wait until you run out of medication to refill your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names of combination products

- Descovy<sup>®</sup> (containing Emtricitabine, Tenofovir)
- Truvada<sup>®</sup> (containing Emtricitabine, Tenofovir)

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