tenofovir disoproxil fumarate (Viread)

WHAT IS TENOFOVIR DISOPROXIL FUMARATE?

Tenofovir disoproxil fumarate, also known as tenofovir DF or TDF (brand name Viread), is a drug used as part of antiretroviral therapy (ART). The FDA approved tenofovir DF in 2001 as an antiretroviral drug (ARV) for people with HIV infection. Generic versions have been approved under PEPFAR. Tenofovir DF is manufactured by Gilead Sciences.

Tenofovir DF is a type of drug called a nucleoside reverse transcriptase inhibitor (NRTI). NRTIs bind to and block reverse transcriptase (an HIV enzyme). HIV uses reverse transcriptase to convert its RNA into DNA (reverse transcription). Blocking reverse transcriptase and reverse transcription prevents HIV from replicating.

When used in combination with other ARVs to treat HIV infection, tenofovir DF may help:

- Reduce the amount of HIV in your blood. This is called viral load.
- Increase the number of CD4 cells in your blood that help fight off other infections.

Reducing the amount of HIV and increasing CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting opportunistic infections (OIs) that can happen when your immune system is weak. Read more about viral suppression.

Tenofovir DF does not cure HIV infection or AIDS. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE TENOFOVIR DF?

Tenofovir DF is a prescription HIV medicine used with other ARVs to treat HIV infection in adults and children 2 years old and older who weigh at least 22 pounds (10 kg). The safety and effectiveness of tenofovir DF has not been established in children under 2 years of age and who weigh less than 22 pounds (10kg). Tenofovir DF has not been carefully studied in the elderly (65 years of age and older).

All people living with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. Read more about U.S. ART guidelines.

WHO SHOULD NOT TAKE TENOFOVIR DF?

Do not take tenofovir DF if you are allergic to tenofovir DF or any of the other ingredients in this drug.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING TENOFOVIR DF?

Before you take tenofovir DF, tell your healthcare provider about all of your medical conditions, and in particular if you:

- Have or have had liver problems, including hepatitis B virus (HBV) infection
- Have kidney problems or receive kidney dialysis treatment
- Have bone problems

Talk to your healthcare provider if you are pregnant or plan to become pregnant during treatment with tenofovir DF. There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. Read more about pregnancy and HIV.

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with tenofovir DF. Tenofovir DF can pass to your baby in breastmilk. Do not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. Read more about HIV drug resistance.

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS TENOFOVIR DF TAKEN?

Tenofovir DF is taken by mouth. The recommended dosage of tenofovir DF for adults and children weighing at least 77 pounds (35 kg) is 300 mg once daily, in combination with other ARVs. The recommended dosage for children weighing less than 77 pounds (35 kg) varies based on the child's weight and age. Your healthcare provider will determine the correct dosage.

Tenofovir DF can be taken with or without food.

You need to take tenofovir DF in combination with other ARVs. Your healthcare provider will tell you what medicines to take and how to take them.

Tenofovir DF is also available in several combination medications. Combination HIV medicines contain two or more HIV medicines from one or more drug classes.

- doravirine/lamivudine/tenofovir DF (Delstrigo)
- efavirenz/emtricitabine/tenofovir DF (Atripla)

- efavirenz/lamivudine/tenofovir DF (Symfi)
- elvitegravir/cobicistat/emtricitabine/tenofovir DF (Stribild)
- emtricitabine/rilpivirine/tenofovir DF (Complera)
- emtricitabine/tenofovir DF (Truvada)
- lamivudine/tenofovir DF (Cimduo)

WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary side effects such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of tenofovir DF are nausea, rash, diarrhea, headaches, pain, depression, and weakness.

Tenofovir DF can cause serious side effects including:

Worsening of HBV infection. Your healthcare provider will test you for HBV infection before you start treatment with tenofovir DF. If you have HBV infection and take tenofovir DF, your HBV infection may get worse (flareup) if you stop taking tenofovir DF. A "flare-up" is when your HBV infection suddenly returns in a worse way than before. Do not run out of tenofovir DF. Refill your prescription or talk to your healthcare provider before your tenofovir DF is all gone. Do not stop taking tenofovir DF without first talking to your healthcare provider. If you stop taking tenofovir DF, your healthcare provider will need to check your health often and do blood tests regularly to check your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking tenofovir DF.

New or worse kidney problems, including kidney failure. Your healthcare provider should do blood and urine tests to check your kidneys before you start and during treatment with tenofovir DF. Your healthcare provider may tell you to take tenofovir DF less often or to stop taking tenofovir DF if you get new or worse kidney problems. Read more about HIV and kidney disease.

Immune Reconstitution Inflammatory Syndrome (IRIS). IRIS is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting tenofovir DF.

Bone problems. Bone problems can happen in people who take tenofovir DF. 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 or your child's bones.

Too much lactic acid in your blood (lactic acidosis). Lactic acidosis is a serious but rare medical emergency that can cause death. Tell your healthcare provider right away if you develop any of these symptoms:

- Feel very weak or tired
- Unusual (not normal) muscle pain
- Trouble breathing
- Stomach pain with nausea and vomiting

- Feel cold, especially in your arms and legs
- Feel dizzy or light-headed
- Have a fast or irregular heartbeat

Severe liver problems. In rare cases, severe liver problems can happen that can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). Tell your healthcare provider right away if you get these symptoms:

- Your skin or the white part of your eyes turns yellow (jaundice)
- Dark or "tea-colored" urine
- Light-colored stools (bowel movements)
- Loss of appetite for several days or longer
- Nausea or vomiting
- Pain, aching, or tenderness on the right side of your stomach area

You may be more likely to get lactic acidosis or serious liver problems if you are assigned female at birth (AFAB) or are very overweight (obese).

These are not all the possible side effects of tenofovir DF. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW DOES TENOFOVIR DF REACT WITH OTHER DRUGS?

All ARVs can interact with other drugs or supplements you are taking. These interactions can change the amount of each drug or substance in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take tenofovir DF with other medicines.

Co-administration of tenofovir DF with atazanavir (Reyataz) may decrease atazanavir concentrations. When co-administered with tenofovir DF, use atazanavir with ritonavir (Norvir).

Co-administration of tenofovir DF with certain protease inhibitors (PIs) or certain drugs to treat hepatitis C virus (HCV) infection increases tenofovir DF concentrations. Your healthcare provider will monitor for evidence of tenofovir DF toxicity.

MORE INFORMATION

Download the full Prescribing Information

Download the Patient Information leaflet

Apply for the Gilead Advancing Access Program

Reviewed June 2024