

# Truvada (tenofovir+emtricitabine)

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## What is Truvada?

- Truvada is an anti-HIV medication. It is in a category of HIV medicines called nucleoside reverse transcriptase inhibitors (NRTIs). Truvada prevents HIV from altering the genetic material of healthy T-cells. This prevents the cells from producing new virus and decreases the amount of virus in the body.
- Truvada is marketed by Gilead Sciences. It was approved by the U.S. Food and Drug Administration (FDA) for use by people living with HIV in August 2004.
- Truvada is a combination of two drugs: 300mg of Viread® (tenofovir DF) and 200mg of Emtriva® (FTC). Truvada should be prescribed by a healthcare provider for patients who need both of these drugs. Both of these drugs can still be purchased individually for use in combination with other anti-HIV drugs.
- Truvada must be combined with at least one other anti-HIV drug, usually a protease inhibitor (PI) or a non-nucleoside reverse transcriptase inhibitor (NNRTI).

- Both the Viread and the Emtriva in Truvada are active against the hepatitis B virus (HBV), the virus responsible for causing hepatitis B. Although it has not been approved by the FDA for the treatment of hepatitis B, some doctors may prescribe Truvada to treat both hepatitis B and HIV. See *What about side effects?* below for more important information regarding Viread, Emtriva, and hepatitis B.

## What is known about Truvada?

- Truvada is a tablet taken once a day. It can be taken with or without food.
- Truvada should not be any more or less effective than Viread and Emtriva taken as separate pills together. However, it is considered to be a much more convenient way of taking these two anti-HIV drugs.
- See the “What is known about ...” sections of Viread and Emtriva for information about possible drug resistance.

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## What about drug interactions?

- Truvada should not be taken at the same time as Epivir® or other combination tablets that contain Epivir (for example, Epzicom™, Combivir®, or Trizivir®). This is because Epivir is very similar to the Emtriva in Truvada, and it is not believed that combining these two anti-HIV drugs will make a regimen any more effective against the virus.
- HIV-positive people who use Truvada in combination with Videx®/Videx EC® (ddI) must reduce the dose of Videx or Videx EC used. This is because the Viread in Truvada increases the amount of Videx in the bloodstream, which can increase the risk of side effects associated with Videx (e.g., peripheral neuropathy and pancreatitis). The usual dose of Videx or Videx EC is 400mg a day. If these drugs are combined with Truvada, the Videx or Videx EC dose should not exceed 250mg/day. For example, if your doctor has prescribed Truvada and Videx EC, you should be taking one 250mg Videx EC capsule once a day.
- HIV-positive people should also be careful if they use Truvada in combination with Reyataz® (atazanavir), a protease inhibitor used to treat HIV. The Viread in Truvada can decrease Reyataz levels in the bloodstream and Reyataz can increase Viread levels in the bloodstream. Thus, if you are using Reyataz in combination with Truvada, your doctor should also prescribe low doses of Norvir® (ritonavir), another protease inhibitor that can significantly boost the amount of Reyataz in the bloodstream. The correct dose is 300mg Reyataz plus 100mg Norvir, combined with the standard daily dose of Truvada. To make sure that the increased Viread levels do not cause kidney damage (a possible side effect of Viread), blood tests to monitor kidney function should be performed regularly.
- Levels of lopinavir, one of the two protease inhibitors in Kaletra® (lopinavir/ritonavir), can decrease when the drug is combined with Truvada. Kaletra can also increase Viread levels—one of the drugs in Truvada—

in the bloodstream. If Kaletra and Truvada are used together, it is important to watch out for potential side effects of Viread (e.g., kidney problems).

## What about side effects?

- Lactic acidosis, which can be fatal, and severe liver problems have been reported in people taking nucleoside reverse transcriptase inhibitors (NRTIs). Contact your doctor immediately if you experience nausea, vomiting, or unusual or unexpected stomach discomfort; weakness and tiredness; shortness of breath; weakness in the arms and legs; yellowing of the skin or eyes; or pain in the upper stomach area.
- The Viread in Truvada may cause bone problems. In one clinical trial conducted by the manufacturer involving HIV-positive patients who were new to anti-HIV therapy, Viread [combined with Sustiva® and Epivir®] was more likely to cause decreased bone mineral density (osteopenia)—which can lead to osteoporosis—than Zerit® (d4T) [combined with Sustiva and Epivir]. This can increase the risk of bone breakage, including the hip, spine, and wrist. Researchers are currently looking into the seriousness of this possible side effect. If you have a history of bone fracture or are at risk for osteopenia, your doctor may want to consider ordering bone scans on a regular basis while you are taking Truvada. While it's not clear if calcium and vitamin D supplementation can help reverse this side effect, it might be a good idea if you have either osteopenia or osteoporosis and are taking Viread.
- The Viread in Truvada can be problematic for HIV-positive people who have a history of kidney problems (renal impairment). If you have a history of kidney problems, your doctor will need to order a simple laboratory test to measure your “creatinine clearance”—the rate your kidneys remove this protein produced by muscles from the bloodstream. Depending on the results of this test, you may not be able to take Truvada. You may need to take the individual Viread tablets, using a lower dose. It is always impor-

tant to be careful if using Truvada in combination with Vistide® (cidofovir), Cytovene® (ganciclovir), and Valcyte™ (valganciclovir), three treatments for CMV that can also cause kidney problems.

- Anti-HIV drug regimens containing nucleoside reverse transcriptase inhibitors (NRTIs), including Truvada, can cause increased fat levels (cholesterol and triglycerides) in the blood, abnormal body-shape changes (lipodystrophy; including increased fat around the abdomen, breasts, and back of the neck, as well as decreased fat in the face, arms, and legs), and diabetes.
- If you have hepatitis B and HIV and plan to stop taking Truvada, your doctor might want to frequently check your liver enzymes after stopping treatment. This is because the Viread and Emtriva in Truvada are also active against the hepatitis B virus (HBV). If Truvada is stopped abruptly, it can cause liver disease to “flare” and damage the liver.
- See the “What about side effects?” sections of Viread and Emtriva for additional possible side effects.

### Who should not take Truvada?

- Before taking this medication, tell your doctor if you have: kidney disease; liver disease; a history of pancreatitis; decreased activity of your bone marrow (low red blood cells [anemia] or low white blood cells). You may not be able to take Truvada, or you may require a lower dose or special monitoring during treatment if you have any of these conditions.
- Truvada is classified by the FDA as a pregnancy category B drug. All the FDA-approved anti-HIV drugs are classified as either category B or C. Pregnancy category B means that animal studies have failed to demonstrate a risk to the fetus, but there are no adequate and well-controlled studies in pregnant women. Pregnancy category C means that animal studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. HIV-positive women who become

pregnant should discuss the benefits and possible side effects of anti-HIV treatment to help protect their babies from HIV.

- It is not known whether Truvada passes into breast milk and what effect it may have on a nursing baby. To prevent transmission of the virus to uninfected babies, it is recommended that HIV-positive mothers not breast-feed.

### Where can I learn more about clinical trials involving Truvada?

- If you would like to find out if you are eligible for any clinical trials that include Truvada, there is an interactive web site run by amfAR, the American Foundation for AIDS Research.
- Another useful service for finding clinical trials is AIDSinfo.nih.gov, a site run by the US National Institutes of Health. They have “health information specialists” you can talk to at their toll-free number at 1-800-HIV-0440 (1-800-448-0440).

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