

# Tenofovir (Viread)

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## What is Viread?

- Viread is an anti-HIV medication. It is in a category of HIV medicines called nucleotide reverse transcriptase inhibitors. Viread 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.
- Viread, manufactured by Gilead Sciences, was approved by the U.S. Food and Drug Administration for the treatment of HIV in 2001.
- Nucleotide analogues, such as Viread, are very similar to nucleoside analogues (e.g., Retrovir® (AZT), Zerit® (d4T), and Epivir® (3TC)). The only difference is that nucleotide analogues, unlike nucleoside analogues, are chemically preactivated and thus require less processing in the body for them to become active.

## What is already known about Viread?

- The dose is one 300mg pill, taken once a day.
- Viread can be taken either with or without food.

- The manufacturer of Viread is currently developing a pill that will contain both Viread and Emtriva™ (emtricitabine). For people who require these two drugs, the two-in-one pill will make both drugs easier to take. It is expected that this pill will be available in September or October 2004.
- Viread is not approved for children younger than 18 years of age.
- Studies have demonstrated that Viread is effective for the treatment of HIV when combined with other anti-HIV drugs, usually at least one other nucleoside reverse transcriptase inhibitor (NRTI) and either a protease inhibitor or non-nucleoside reverse transcriptase inhibitor (NNRTI). Viread should not be taken alone (as monotherapy) or with just one other anti-HIV drug.
- The United States Department of Health and Human Services (DHHS) lists Viread as a “preferred” NRTI for HIV-positive people starting anti-HIV treatment for the first time, when used in combination with Epivir® (3TC) and the NNRTI Sustiva® (efavirenz). An “alternative” option specified by the DHHS is to combine Viread with

Sustiva and the NRTI Emtriva® (emtricitabine). In the future, Viread will likely be studied in combination with other anti-HIV drugs and the DHHS list of alternative and preferred uses for Viread will likely expand.

- Viread is active against many strains of HIV resistant to Retrovir® (AZT), Zerit® (d4T), Videx®/Videx EC® (ddI), Hivid® (ddC), and Ziagen® (abacavir). There is also some data from studies indicating that HIV that has become resistant to Epivir® (3TC) may be even more sensitive to Viread. The drug is also active against virus containing the Q151M mutation—a single mutation that results in high-level resistance to multiple nucleoside analogues.
- Viread may be less active against strains of HIV that contain the K65R mutation in its reverse transcriptase gene. To figure out if your virus has this mutation, your doctor can order a genotypic drug-resistance test.
- Viread is also active against the hepatitis B virus (HBV), which can cause hepatitis (inflammation of the liver). Many patients are using Viread, along with Epivir (which is approved for the treatment of both HIV and HBV), as a part of their anti-HIV drug combinations to treat both viral infections. One study has demonstrated that Viread helped control HBV and HIV reproduction in a group of patients infected with both viruses. Additional studies testing Viread as a treatment for HBV and HIV in patients infected with both viruses are under way.

#### What about drug interactions?

- HIV-positive people who use Viread in combination with Videx®/Videx EC® (ddI) must reduce the dose of Videx or Videx EC used. This is because Viread 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 Viread, the Videx or Videx EC dose should not exceed 250mg/day. For example, if your doctor has

prescribed Viread 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 Viread in combination with Reyataz™ (atazanavir), a protease inhibitor used to treat HIV. Viread 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 Viread, 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 Viread. 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 Viread. Kaletra can also increase Viread levels in the bloodstream. If Kaletra and Viread are used together, it is important to watch out for potential side effects of Viread (e.g., kidney problems).

#### What is known 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.
- Viread 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 Viread. 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.

- Viread 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, your Viread dose may need to be decreased. It is always important to be careful if using Viread 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 NRTIs, including Viread, 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.
- Nausea, vomiting, diarrhea, and flatulence (intestinal gas) are the most likely short-term side effects of Viread.

### Who should not take Viread?

- Viread 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 Viread 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 of Viread?

- If you would like to find out if you are eligible for any clinical trials that include Viread, 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 U.S. 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).



For more treatment information, call Project Inform's toll-free National HIV/AIDS Treatment Information Hotline at 1-800-822-7422.

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