

# FDA Approves First Medication to Reduce HIV Risk

**P**eople diagnosed with HIV—the human immunodeficiency virus that without treatment develops into AIDS—take antiviral medications to control the infection that attacks their immune system.

Now, for the first time, adults who do not have HIV but are at risk of becoming infected can take a medication to reduce the risk of sexual transmission of the virus.

The Food and Drug Administration (FDA) has approved the new use of Truvada—to be taken once daily and used in combination with safer sex practices—to reduce the risk of sexually acquired HIV-1 infection in adults who do not have HIV but are at high risk of becoming infected. (HIV-1 is the most common form of HIV.)

In two large clinical trials, daily use of Truvada was shown to significantly reduce the risk of HIV infection

- by 42 percent in a study sponsored by the National Institutes of Health (NIH) of about 2,500 HIV-negative gay and bisexual men and transgender women, and
- by 75 percent in a study sponsored by the University of Washington of about 4,800 heterosexual couples in which one partner was HIV positive and the other was not.

Debra Birnkrant, M.D., director of the Division of Antiviral Products at FDA, explains that Truvada works to prevent HIV from establishing itself and multiplying in the body. She notes that while this is a new approved use, Truvada is not a new product. It was approved by FDA in 2004 for use in

combination with other medications to treat HIV-infected adults and children over 12 years old.

“In the 80s and early 90s, HIV was viewed as a life-threatening disease; in some parts of the world it still is. Medical advances, along with the availability of close to 30 approved individual HIV drugs, have enabled us to treat it as a chronic disease most of the time,” Birnkrant says.

“But it is still better to prevent HIV than to treat a life-long infection of HIV,” she says.

Birnkrant stresses that Truvada is meant to be used as part of a comprehensive HIV prevention plan that includes consistent and correct condom use, risk reduction counseling, regular HIV testing, and treatment of any other sexually-transmitted infections. Truvada is not a substitute for safer sex practices, she says.

## Person Must Be HIV Negative

Truvada, produced by Gilead Sciences Inc., is a combination of two antiretroviral medications used to treat HIV—tenofovir disoproxil fumarate and emtricitabine. When Truvada is used as a treatment for HIV rather than a preventive, the patient also takes a third drug, Birnkrant says. Which of the other approved HIV drugs is added depends on the needs of the patient.

Before this medicine is prescribed, Birnkrant says there are several factors



that a person and his or her health care professional must consider in weighing the risk versus the benefit:

- The person must be tested to ensure that he or she is HIV negative.
- Flu-like symptoms—such as fever or muscle aches—are a red flag because they could indicate the presence of early, acute HIV infection, even if test results are negative. There is a window of four to five weeks with some tests, and up to three months with others, in which the antibodies that indicate HIV infection do not appear in the blood.

# *“It is still better to prevent HIV than to treat a life-long infection of HIV.”*

- Safety concerns tied to Truvada have to do with its effect on the bones and kidneys. While effects observed in clinical trials were mild and reversible with discontinuation of the medication, people with a history of bone or kidney ailments should be regularly monitored to ensure their continued health.
- It is recommended that the person also be tested for hepatitis B because worsening of hepatitis B infections has been reported in those who have both HIV-1 and hepatitis B when treatment with Truvada was stopped.


## **Infection Rates Unchanged**

To help prescribers and other health care professionals advise uninfected people considering taking Truvada, the medicine is being approved with a Risk Evaluation and Mitigation Strategy (REMS). The goals of the


REMS are to inform prescribers and potential users of Truvada of the importance of taking the medication every day, the importance of regular HIV testing and the importance of using Truvada in combination with other measures known to reduce the risk of HIV infection. As part of the REMS, a voluntary training and education plan will be made available to potential prescribers. This program includes a medication guide and safety brochure for the prospective Truvada users that would detail the risks, recommended screening tests and key information to share with a health care professional.

About 1.2 million Americans have HIV. The body’s immune system is devastated by AIDS, leaving those who have it vulnerable to deadly infections. Each year, about 50,000 adults and adolescents in the U.S. are newly diagnosed with HIV.

The overall rate of HIV infection has

remained stable at least since 2004. “The rates of new HIV infections have not significantly changed for a long time,” says Birnkrant. “From FDA’s standpoint, this is not acceptable for a serious disease.” 

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