GILEAD | Medical Information

YEZTUGO® (lenacapavir)

Has YEZTUGO been studied in cis women?

This information is provided in response to your question. It is not treatment advice on how to use YEZTUGO. Please discuss this question and others you have about your medical condition or treatment with your healthcare provider.

Download the YEZTUGO Patient Information for more details, including approved use(s) and important warnings: www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_patient_pi.pdf

The short answer

- YEZTUGO is **approved to help reduce the chance of getting HIV-1** through sex in adults and teenagers who weigh at least 77 pounds (35 kg). **PrEP** is known as **pre-exposure prophylaxis**, and is a **medicine taken ahead of time to reduce the chance of getting HIV from sex**.[1]
- YEZTUGO is approved for **cis women**.
- The PURPOSE 1 study is still going on, and the main results have been published. In a study called PURPOSE 1, **YEZTUGO was compared with DESCOVY and TRUVADA**. TRUVADA is also approved for PrEP in cis women.[2] DESCOVY is not approved for PrEP in cis women.[3]
- In the study, **YEZTUGO prevented 100% of new HIV cases at the time the results were looked at**. The **most common side effects** were **reactions at the site where the shot was given**.[1]

Who is YEZTUGO for?[1]

YEZTUGO is a prescription medicine that is used for HIV PrEP to reduce the chance of getting HIV-1 in adults and teenagers who weigh at least 77 pounds (35 kg). HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

You must be HIV-negative to start YEZTUGO. You must get tested to make sure that you do not already have HIV-1.

Talk to a healthcare provider about your chance of getting HIV and if YEZTUGO is right for you. If you do not have a healthcare provider, the PrEP Locator website (https://www.PrEPLocator.org) can help you find a healthcare provider in your area who has experience prescribing PrEP medications.

What is the PURPOSE 1 study?

PURPOSE 1 is a study comparing different PrEP medications. PrEP stands for "pre-exposure prophylaxis," or a **medicine taken ahead of time to reduce the chance of getting HIV from sex.** The study includes **women who have been considered female** since birth, also called **cis women**. The women did not have HIV at the start of the study.[1]

What is the study plan in PURPOSE 1?

The researchers **compared YEZTUGO** with **DESCOVY** and **TRUVADA for PrEP**.[1] YEZTUGO and TRUVADA are approved as PrEP in cis women.[1,2] DESCOVY is not approved for PrEP in cis women.[3] The medications were assigned by chance. The women did not know what treatment they got, and neither did the researchers. Each of the women also got a treatment that had no drug called a **placebo**. Placebo is used to help disguise the true treatment each woman received.

2134 HIV-negative cis women got **YEZTUGO** shots 2 times a year. The women also took a daily placebo pill.[1,4]

2136 HIV-negative cis women took 1 **DESCOVY** pill every day. The women also got placebo shots 2 times a year.[4]

1068 HIV-negative cis women took 1 **TRUVADA** pill every day. The women also got placebo shots 2 times a year.[1,4]

Who is taking part in the PURPOSE 1 Study?[1,4]

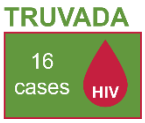
The women in the PURPOSE 1 study were **16 to 26 years old** and almost all of them were Black. **32 pregnant women were part of the study** and received YEZTUGO.

What are the main results of the PURPOSE 1 Study?[1,4,5]

After **half of the women** had been **in the study for at least 1 year**, the researchers looked at the number of new cases of HIV. There were **55 new cases of HIV in all the women**, but **none in the YEZTUGO group**.

There were **0 new cases of HIV in the YEZTUGO** group of 2134 women. **100%** of them were still free of HIV.

There were **39 new cases of HIV** in the **DESCOVY** group of 2136 women. 98.2% of them were still free of HIV.



There were **16 new cases of HIV** in the **TRUVADA** group of 1068 women. 98.5% of them were still free of HIV.

The researchers also studied different numbers of women and lengths of treatment. The results give the data as the number of new cases of HIV per 100 person-years. This translates to the **number of new cases if 100 women were treated for 1 year**.

They compared those numbers with the number of new cases expected with no PrEP.

- With **YEZTUGO**, there were **0 cases of HIV per 100 women treated for 1 year**.
- With **DESCOVY**, there were **2.02 cases of HIV per 100 women treated for 1 year**.
- With **TRUVADA**, there were **1.69 cases of HIV per 100 women treated for 1 year**.
- With **no PrEP**, there would be **2.41 cases of HIV per 100 women treated for 1 year**.

What side effects did patients have in the PURPOSE 1 Study?[4]

The women in the PURPOSE 1 study were usually able to tolerate the study treatment. Less than 5% of the women had serious or severe side effects.

The **most common side effect** was a **reaction at the site where the shot was given**. Reactions happened with both YEZTUGO injections and placebo injections. They were almost twice as common with YEZTUGO than the placebo.

69% of the women who got YEZTUGO had reactions at the needle site.

- Most of the reactions were bumps called **nodules** under the skin. Other reactions at the site were **pain and swelling**.

35% of women who got placebo shots had reactions at the needle site.

- About two-thirds were **pain** at the site. Nodules under the skin and swelling were less common.

Very few of these reactions were severe, and none were thought to be serious. **Four women in the YEZTUGO group stopped** their study treatment because of reactions at the needle site. None of the reactions in the placebo group led to stopped study medication.

Other side effects that happened in **at least 2 out of 100 people** in the YEZTUGO group were **headache, diarrhea and nausea. Dizziness and vomiting** happened in **at least 4 out of 100 people**.

Nausea was **more common** in the **DESCOVY** and **TRUVADA** groups than in the **YEZTUGO group**:

- YEZTUGO: 5% of patients
- DESCOVY: 11% of patients
- TRUVADA: 13% of patients

Vomiting was also **more common** in the **DESCOVY** and **TRUVADA** groups than in the **YEZTUGO** group:

- YEZTUGO: 4% of patients
- DESCOVY: 11% of patients
- TRUVADA: 7% of patients

Did patients skip any pills in the PURPOSE 1 Study?[4]

The researchers measured blood levels of the medicine in some of the women. These levels showed that the DESCOVY and TRUVADA groups often skipped their PrEP pills. **Those who took PrEP pills every day were less likely to get a new case of HIV** compared to those who skipped pills.

Glossary

Cis woman: a woman who was considered and assigned as female at birth.

DESCOVY: a tablet that contains emtricitabine and tenofovir alafenamide. It is approved in combination with other medicines to treat HIV infection. It is also approved as PrEP for people who are at risk for HIV, but not for cis women.

Diarrhea: frequent, loose watery stools, which can cause dehydration and may require hospitalization and treatment.

Headache: a continuous pain in the head; pain in the head.

HIV (Human Immunodeficiency Virus): HIV is a virus that attacks the body's immune system. If HIV is not treated, it can lead to AIDS.

Nausea: feeling sick to the stomach; stomach discomfort and the feeling of wanting to vomit.

Person-year: treatment for 1 person for 1 year.

Pre-exposure prophylaxis (PrEP): means routinely taking prescription medicine before you're exposed to HIV to help reduce your chances of getting it.

Side effect: unwanted effect that happens due to a drug.

TRUVADA: a tablet that contains emtricitabine and tenofovir disoproxil fumarate. It is approved to treat HIV infection and as PrEP for people who are at risk for HIV.

References

1. Enclosed, Gilead Sciences Inc. TRADENAME® (lenacapavir) tablets, for oral use. TRADENAME® (lenacapavir) injection, for subcutaneous use. U.S. Prescribing Information. Foster City, CA.
2. Enclosed. Gilead Sciences Inc, TRUVADA® (emtricitabine/tenofovir disoproxil fumarate) tablets, for oral use. U.S. Prescribing Information. Foster City, CA.
3. Enclosed. Gilead Sciences Inc, DESCOVY® (emtricitabine and tenofovir alafenamide) tablets, for oral use. U. S. Prescribing Information. Foster City, CA.
4. Bekker LG, Das M, Abdool Karim Q, et al. Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women. *N Engl J Med.* 2024;391(13):1179-1192.
5. Bekker LG, Das M, Abdool Karim Q, et al. Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women [Supplementary Appendix]. *N Engl J Med.* 2024:1-69.

Approved for Use on 18 Jun 2025

If you would like more detailed information about YEZTUGO, please visit: www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_pi.pdf.

This is the US FDA-approved Prescribing Information, including the Patient Labeling, for YEZTUGO. It will tell you about the uses, warnings, and other important safety information about YEZTUGO.

Important note

Gilead Sciences, Inc. is providing this letter in response to your unsolicited request for medical information. Some of the information included in this letter may not be covered in the US FDA-approved Prescribing Information for YEZTUGO. Gilead Sciences, Inc. does not intend this letter to be used as medical advice and does not promote use of YEZTUGO in a way that has not been approved by the FDA. Please discuss this question and others you may have about your medical condition or treatment with your healthcare provider.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:
☎1-866-MEDI-GSI (1-866-633-4474) or 🖱 www.patient.askgileadmedical.com/

Reporting side effects

Please report all adverse events to:
Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

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