

YEZTUGO® (lenacapavir)

What is expected of me when receiving YEZTUGO?

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_pi.pdf

The short answer

- Stay under the care of a healthcare provider. Get tested for HIV-1 when your healthcare provider tells you. 1
- Follow the dosing plan for YEZTUGO. Missing injections or pills increases your chance of getting HIV-1.¹
- In studies of YEZTUGO, 9 out of 10 people got their injections on time.^{2,3}

Who is YEZTUGO for?1

YEZTUGO is a prescription medicine used for HIV-1 PrEP to reduce the chance of getting HIV-1 from sex 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.

How is YEZTUGO given?¹

YEZTUGO is given as injections and tablets. Your **healthcare provider will give** you **injections under your skin**. You will take the **tablets by mouth**.

On **Day 1**, you will get **2 injections and take 2 tablets** of **YEZTUGO**.



On Day 2, you will take 2 tablets of YEZTUGO.

You will then get **2 injections of YEZTUGO every 6 months** (26 weeks).

What is expected of me when receiving YEZTUGO?¹

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

Some HIV tests can miss HIV-1 in a person who has only recently gotten HIV. If you have flu-like symptoms, you could have recently become HIV-1 positive. Tell your healthcare provider if you had a flu-like illness within the last month before starting YEZTUGO or at any time while receiving it.

While receiving YEZTUGO:



Stay under the care of a healthcare provider.



Get tested for HIV-1 when your healthcare provider tells you.



Tell your healthcare provider right away if you think you were exposed to HIV-1. They may want to do more tests to be sure you do not have HIV-1.



Follow the dosing plan. Return to your healthcare provider for your planned injections of YEZTUGO every 6 months (26 weeks). Missing injections or tablets increases your chance of getting HIV-1.

If you are not able to visit your healthcare provider to get the injections as planned, call them right away to discuss your PrEP options.

Did people get YEZTUGO injections as planned in the research studies?

The **two main studies** of YEZTUGO are called **PURPOSE 1 and PURPOSE 2**. Each study compared how well YEZTUGO and other PrEP medications reduced the chance of getting HIV-1.¹

YEZTUGO was given as oral pills and injections under the skin. The people who got other PrEP medications also got a placebo injection under the skin. The placebo had no drug in it. The study was blinded meaning the people did not know what treatment they were receiving. People received the study drugs on Day 1 and Day 2 followed by study injections every 6 months.^{2,3}

Researchers looked at whether people got their injections on time at week 26 and 52 of the study. "On time" meant they got their next injection no more than 28 weeks after their last injection.^{2,3}

For the group that got YEZTUGO, more than 90% (9 out of 10 people) got their injections on time in the studies. $\frac{2.4}{}$

Glossary

AIDS (acquired immunodeficiency syndrome): most advanced stage of HIV.

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 (acquired immunodeficiency syndrome).

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

References

- 1. Enclosed, Gilead Sciences Inc. YEZTUGO® (lenacapavir) tablets, for oral use. YEZTUGO® (lenacapavir) injection, for subcutaneous use. U.S. Prescribing Information. Foster City, CA.
- 2. 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.
- 3. Kelley CF, Acevedo-Quinones M, Agwu AL, et al. Twice-Yearly Lenacapavir for HIV Prevention in Men and Gender-Diverse Persons. *N Engl J Med.* 2024.
- 4. Kelley CF, Acevedo-Quinones M, Agwu AL, et al. Twice-Yearly Lenacapavir for HIV Prevention in Men and Gender-Diverse Persons [Supplementary Appendix]. *N Engl J Med.* 2024.

More information about YEZTUGO

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: \$\mathbb{T} \cdot 1-866-MEDI-GSI (1-866-633-4474) or \$\frac{1}{2}\$ 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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