



YEZTUGO[®] (lenacapavir)

What are the possible side effects of 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: https://www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_patient_pi.pdf

The short answer¹

- The **most common side effects** of YEZTUGO are **reactions at the needle site, headache, and nausea**.
- Reactions at the needles site are the most common reactions that happen in people who take YEZTUGO. In studies of YEZTUGO as HIV-1 PrEP, these reactions were severe in less than 1 out of 100 people. Injecting YEZTUGO into the skin instead of under the skin can lead to serious reactions like death of skin tissue and open sores.
- These are not all the possible side effects of YEZTUGO. Please tell your healthcare provider if you have a side effect. If you have **flu-like symptoms**, please tell them right away. **Flu-like symptoms might be a sign of recent HIV-1**.

Who is YEZTUGO for?¹

YEZTUGO is a prescription medicine that is used for HIV-1 PrEP to reduce the chance of getting HIV-1 from sex in adults and adolescents 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 before you start and while taking YEZTUGO. Do not take YEZTUGO if you already have HIV-1 or you do not know your HIV-1 status



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 are the possible side effects of YEZTUGO?¹

The **most common side effects** of YEZTUGO are:



Reactions at the needle site



Headache



Nausea

Of the side effects listed above, **reactions at the needle site** are the most common in people who take YEZTUGO. These may include:

- a lump
- itching
- pain
- redness

- skin hardening
- bruising
- swelling
- warmth

Lumps or hardened skin at the needle site usually can be felt but not seen. They may take longer than other reactions at the needle site to go away.

Sometimes, **incorrectly injecting YEZTUGO into the skin** instead of under the skin **can lead to serious reactions** at the needle site like death of skin tissue and open sores.

These are not all the possible side effects of YEZTUGO. Tell your healthcare provider if you have any side effects.

What side effects were seen in the research studies of YEZTUGO?

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 in people at risk for HIV-1.¹ YEZTUGO was given as injections under the skin, 2 times in a year.^{2,3}

In PURPOSE 1, the safety of YEZTUGO was studied in 2140 cis women without HIV. In PURPOSE 2, the safety of YEZTUGO was studied in 2183 cis men and gender diverse people without HIV.¹

Side effects that happened in at least 2 out of 100 people in either study were¹:

- reactions at the needle site
- dizziness
- headache
- vomiting
- nausea
- diarrhea

Reactions at the needle site were the most common of these side effects.¹

- 69 out of 100 people in PURPOSE 1 had reactions at the needle site.
- 83 out of 100 people in PURPOSE 2 had reactions at the needle site

- These reactions were severe in less than 1 out of 100 people.

The other side effects listed happened in no more than 7 out of 100 people in either study.¹

Few people stopped YEZTUGO due to side effects.¹

- Less than 1 out of 100 people in PURPOSE 1 stopped YEZTUGO because of side effects.
- 1 out of 100 people in PURPOSE 2 stopped YEZTUGO because of side effects.

What should I do if I think I am having a side effect?¹

If you are having a side effect, please talk to your healthcare provider. **You are encouraged to report side effects of prescription drugs to the FDA.**

Visit <https://www.fda.gov/safety/medwatch> or call 1-800-FDA-1088.

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. If you have flu-like symptoms, you could have recently become infected with HIV-1.



The symptoms of a new HIV-1 infection include: tiredness, fever, joint or muscle aches, headache, sore throat, vomiting, diarrhea, rash, night sweats, and/or enlarged lymph nodes in your neck or groin.

Glossary

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

Cisgender man (or cis man): a man who was considered and assigned as male at birth.

Cisgender woman (or cis woman): a woman who was considered and assigned as female at birth.

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

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 (acquired immunodeficiency syndrome).

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

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: secondary unwanted effect that occurs due to drug therapy.

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.

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:
☎ 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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