YEZTUGO® (lenacapavir)

Have reactions at the needle site happened with use 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: www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_patient_pi.pdf

The short answer[1]

- **Reactions at the needle site were the most common reactions that happened in people** who take YEZTUGO. These may **include lumps, pain, skin hardening, swelling, itching, redness, bruising, and warmth**.
- **Lumps** or bumps at the needle site were the **most common**.
- **None of the reactions at the needle site were serious**. Rarely, improper injection of YEZTUGO by a healthcare professional can lead to serious reactions at the needle site like severe skin damage (necrosis) or open sores (ulcers).
- In studies of YEZTUGO, reactions at the needle site were severe in **less than 1 out of 100 people**.
- These are not all the possible side effects of YEZTUGO. Please contact your healthcare provider for medical advice if you have a reaction at the needle site or any side effect.

What is the most important information I should know about YEZTUGO?[1]

Some medications have important warnings that are designed to alert you of serious or life-threatening risks that come with taking the medication.

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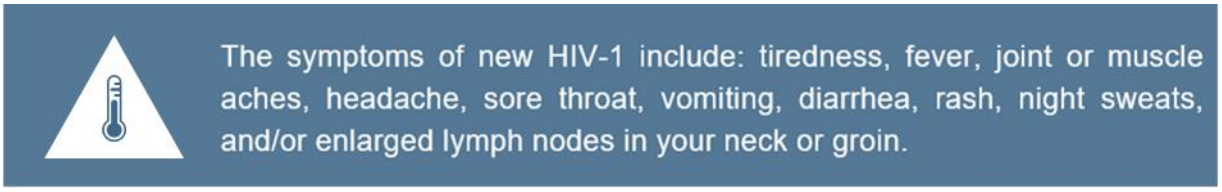
YEZTUGO has an important warning for: Risk of developing resistance to YEZTUGO if you have or get HIV-1 while receiving YEZTUGO. Resistance means that over time your HIV-1 may become harder to treat.

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 just gotten it. 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 gotten HIV-1.



You must stay HIV-1 negative to keep receiving YEZTUGO. Know your HIV-1 status and the HIV-1 status of your partners. Get tested for HIV-1 with each YEZTUGO injection or when your healthcare provider tells you. You should not miss any HIV-1 tests. If you get HIV-1 and continue receiving YEZTUGO because you do not know you have HIV-1, the HIV-1 may become harder to treat.

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

If you get HIV-1, you will need to immediately take other medicines to treat HIV-1. YEZTUGO is not approved for treating HIV-1. If you have HIV-1 and receive only YEZTUGO, over time your HIV-1 may become harder to treat.

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.

Have reactions at the needle site happened with use of YEZTUGO?[1]

Reactions at the needle site are common side effects that happen in most people who take YEZTUGO. These may include:

- a lump or bump
- pain
- skin hardening
- swelling
- itching
- redness
- bruising
- 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**.

Rarely, improper injection of YEZTUGO by a healthcare provider can lead to serious reactions at the needle site like severe skin damage (necrosis) or open sores (ulcer).

These are not all of the possible side effects of YEZTUGO.

Were reactions at the needle site seen in the research studies of YEZTUGO?

The **two main studies** of YEZTUGO used as HIV-1 PrEP 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. It was also given as tablets to start on Day 1 and Day 2.[2,3]

- On Day 1, people took 2 tablets of YEZTUGO and got 2 injections of YEZTUGO.
- On Day 2, people took 2 tablets of YEZTUGO.
- After this, they got 2 injections of YEZTUGO every 6 months (26 weeks).

In **PURPOSE 1**, the safety of YEZTUGO was studied **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]

Reactions at the need site were the most common 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.

None of the reactions at the needle site were serious. The rate of new reactions at the needle site decreased with future injections.

What types of reactions happened at the needle site?[1]

Lumps or bumps at the needle site were the most common. They happened **in just over 60 out of 100 people** in each study.

Other reactions that happened in at least 2 out of 100 people in either study were:

- pain
- skin hardening
- swelling
- redness
- itching
- bruising
- warmth

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How long did the reactions at the needle site last?[1]

The amount of time reactions at the needle site lasted varied with the type of reaction. The researchers reported the amount of time as a median.

Lumps or bumps lasted

- a median of **350 days in PURPOSE 1**
- a median of **297 days PURPOSE 2**

Skin hardening lasted

- a median of **173 days in PURPOSE 1**
- a median of **151 days PURPOSE 2**

Other reactions that were not lumps, bumps, or skin hardening lasted

- a median of **9 days in PURPOSE 1**
- a median of **4 days PURPOSE 2**

Were any of the reactions at the needle site severe?[1]

Most reactions at the needle site were not severe. Less than 1 out of 100 people in each study had severe reactions. These reactions were:

- lumps or bumps and open sores in PURPOSE 1
- open sores, pain, redness, swelling, and irritated skin in PURPOSE 2

Few people stopped YEZTUGO due to reactions at the needle site.

How big were the lumps or bumps at the needle site?[1]

The size of a bumps was measured at its diameter. The diameter can be thought of as a straight line from one side of the bump to the other that passes through the center.

The researchers looked at the diameter of the largest bumps. They reported the size as an average (median). **In both PURPOSE 1 and PURPOSE 2, the median diameter was 3 cm.**

What should I do if I have a reaction at the needle site?[1]

If you have a reaction at the needle site or other side effect, please talk to your healthcare provider for medical advice.

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/safety/medwatch or call 1-800-FDA-1088.

Glossary

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

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.

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).

Median: the middle number in a set of numbers when they are lined up from smallest to largest. Half of the numbers will be above the median and half below.

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.

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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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