

YEZTUGO® (yez-TOO-go) (lenacapavir) tablets, for oral use	PATIENT INFORMATION YEZTUGO® (yez-TOO-go) (lenacapavir) injection, for subcutaneous use
<p>What is the most important information I should know about YEZTUGO?</p> <p>Important information for people who receive YEZTUGO to reduce their risk of getting human immunodeficiency virus-1 (HIV-1), also called pre-exposure prophylaxis or “PrEP”:</p> <p>Before receiving YEZTUGO to reduce your risk of getting HIV-1:</p> <ul style="list-style-type: none"> • 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-1 tests can miss HIV-1 infection in a person who has recently acquired HIV-1. If you have flu-like symptoms, you could have recently acquired HIV-1. Tell your healthcare provider if you had a flu-like illness within the last month before starting YEZTUGO or at any time while receiving YEZTUGO. Symptoms of a new HIV-1 infection include: <ul style="list-style-type: none"> ○ tiredness ○ joint or muscle aches ○ sore throat ○ rash ○ enlarged lymph nodes in the neck or groin ○ fever ○ headache ○ vomiting or diarrhea ○ night sweats <p>While you are receiving YEZTUGO:</p> <ul style="list-style-type: none"> • YEZTUGO does not prevent other sexually transmitted infections (STIs). <ul style="list-style-type: none"> ○ Practice safer sex by using a latex or polyurethane condom to reduce the risk of getting STIs. ○ Get tested for other STIs such as syphilis, chlamydia, and gonorrhea. • You must stay HIV-1 negative to keep receiving YEZTUGO. <ul style="list-style-type: none"> ○ Know your HIV-1 status and the HIV-1 status of your partners. ○ Ask your partners with HIV-1 if they are taking anti-HIV-1 medicine and have an undetectable viral load. An undetectable viral load is when the amount of virus in the blood is too low to be measured in a lab test. To maintain an undetectable viral load, your partners must keep taking HIV-1 medicine as prescribed. Your risk of getting HIV-1 is lower if your partners with HIV-1 are taking effective treatment. ○ 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. ○ Get information and support to help reduce sexual behaviors associated with the risk of getting HIV-1. ○ Follow the YEZTUGO dosing schedule, which includes returning to a healthcare provider for your scheduled injections every 6 months. Missing YEZTUGO injections or tablets increases your risk of getting HIV-1 (see “How should I receive YEZTUGO”). • If you get HIV-1, you will need to immediately take other medicines to treat HIV-1. YEZTUGO is not approved for treatment of HIV-1. <p>If you have HIV-1 and receive only YEZTUGO, over time your HIV-1 may become harder to treat.</p>	
<p>What is YEZTUGO?</p> <p>YEZTUGO is a prescription medicine that is used for HIV-1 PrEP to reduce the risk of getting HIV-1 in adults and adolescents who weigh at least 77 pounds (at least 35 kg).</p> <p>HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).</p> <p>It is not known if YEZTUGO is safe and effective in children weighing less than 77 pounds (less than 35 kg).</p>	

Do not receive YEZTUGO if you:

- **already have HIV-1.** If you already have HIV-1, you will need to take other medicines to treat HIV-1. YEZTUGO is not approved for treatment of HIV-1.
- **do not know your HIV-1 status.** You may already have HIV-1. If you have HIV-1, you will need to take other medicines to treat it. YEZTUGO can only help reduce your risk of getting HIV-1 **before** you get it.

What should I tell my healthcare provider before receiving YEZTUGO?**Before receiving YEZTUGO, tell your healthcare provider about all your medical conditions, including if you:**

- are pregnant or plan to become pregnant. Tell your healthcare provider if you become pregnant while or after receiving YEZTUGO.
Pregnancy Registry: There is a pregnancy registry for individuals who receive YEZTUGO during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. A small amount of YEZTUGO is present in breast milk. Talk to your healthcare provider about the best way to feed your baby while you are receiving YEZTUGO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines may interact with YEZTUGO. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with YEZTUGO.
- **Do not start a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to receive YEZTUGO with other medicines.
- YEZTUGO may affect certain other medicines for up to 9 months after your last injection.

How will I receive and take YEZTUGO?

- YEZTUGO consists of injections and tablets.
 - **YEZTUGO injections** will be given to you by a healthcare provider under the skin (subcutaneous injection). The injection can be given in your stomach-area (abdomen) or upper leg (thigh).
 - Take **YEZTUGO tablets** by mouth, with or without food.
- Your dosing schedule will start as follows:
 - On Day 1, you will receive 2 YEZTUGO injections and take 2 YEZTUGO tablets.
 - On Day 2, you will take 2 YEZTUGO tablets.
- After completing the start of your dosing schedule, you will receive 2 YEZTUGO injections every 6 months (26 weeks) from the date of your last injection.
- Stay under the care of a healthcare provider while receiving YEZTUGO. **It is important that you attend your scheduled appointments to receive your injections of YEZTUGO.**
- If you miss taking your tablets on Day 2, take them as soon as possible. Your Day 1 and Day 2 tablets should not be taken on the same day.
- If you miss or need to delay your scheduled every 6 months injection of YEZTUGO by more than 2 weeks, call your healthcare provider right away to discuss your PrEP options.
 - If you need to delay your scheduled YEZTUGO injection appointment, there is the option to temporarily take YEZTUGO tablets. You will take 1 YEZTUGO tablet by mouth 1 time every 7 days, until your injections resume.
 - It is important to continue receiving YEZTUGO as scheduled. Missing YEZTUGO injections or tablets may increase your risk of getting HIV-1.
- If you stop receiving YEZTUGO, talk to your healthcare provider about other options to reduce the risk of getting HIV-1.
- If you take too many YEZTUGO tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of YEZTUGO?

The most common side effects of YEZTUGO are injection site reactions, headache, and nausea.

Injection site reactions are common side effects experienced by most people who take YEZTUGO. These reactions where you receive the injection may include a lump or bump, pain, skin hardening, swelling, itching, redness, bruising, or warmth. If you develop a lump or hardened skin at the injection site, it may be felt but not seen and may take longer to go away than other injection site reactions.

Rarely, improper injection of YEZTUGO by a healthcare provider can lead to serious injection site reactions like severe skin damage (necrosis) or open sores (ulcer). Tell your healthcare provider if you have any injection site reactions or other side effects.

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

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store YEZTUGO tablets?

- Store YEZTUGO tablets at room temperature between 68 °F to 77 °F (20 °C to 25 °C).
- YEZTUGO bottle contains a desiccant packet to help keep your medicine dry (protect it from moisture). Keep the desiccant packet in the bottle. **Do not eat the desiccant packet.**
- Keep YEZTUGO tablets in their original bottle.
- Keep the bottle tightly closed.
- YEZTUGO bottle has a child resistant cap closure.

Keep YEZTUGO and all medicines out of reach of children.

General information about the safe and effective use of YEZTUGO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use YEZTUGO for a condition for which it was not prescribed. Do not give YEZTUGO to other people. It may harm them. You can ask your pharmacist or healthcare provider for information about YEZTUGO that is written for health professionals.

What are the ingredients in YEZTUGO?

Active ingredient: lenacapavir sodium

Inactive ingredients:

YEZTUGO tablets: copovidone, croscarmellose sodium, magnesium stearate, mannitol, microcrystalline cellulose, and poloxamer 407. The tablets are film-coated with a coating material containing iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

YEZTUGO injection: polyethylene glycol 300 and water for injection.

Manufactured and distributed by: Gilead Sciences, Inc. Foster City, CA 94404

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For more information, call 1-800-445-3235 or go to www.YEZTUGO.com.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Issued: 6/2025