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GILEAD | Medical Information

Yeztugo® (lenacapavir) Dosing and Administration

This document is in response to your request for information regarding Yeztugo® (lenacapavir [LEN]) and oral and subcutaneous dosing and administration.

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The full indication, important safety information, and boxed warning are available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_pi.

Summary

Product Labeling[1]

Dosage

The LEN dosing schedule in adults and adolescents weighing at least 35 kg consists of a required initiation dosing (SUBQ injections and oral tablets) followed by once every 6-months continuation dosing (SUBQ injections). LEN oral tablets may be taken with or without food. See Table 1 for dosing schedule.

Administration

- LEN injection is only for SUBQ administration into the abdomen by a healthcare provider. The thigh can be used as an alternative injection site if preferred. Do NOT administer intradermally due to risk of serious injection site reactions.
- SUBQ administered LEN forms a drug depot whereby LEN is slowly released from the site of administration.

Product Labeling[1]

Dosage and Administration

HIV-1 Screening for Individuals Receiving LEN for HIV-1 PrEP

Screen all individuals for HIV-1 infection prior to initiating LEN, prior to each subsequent injection of LEN, and additionally as clinically appropriate, using a test approved or cleared by the FDA for the diagnosis of acute or primary HIV-1 infection. When screening for HIV-1 infection prior to initiating LEN, if an antigen/antibody-specific test is used and provides negative results, then such negative results should be confirmed using an RNA-specific assay, even if the results of the RNA-assay are available after LEN initiation. When screening for HIV-1 infection prior to continuing LEN, negative results from a rapid, point-of-care antigen/antibody test should be confirmed using a more sensitive assay.

Adherence to LEN

Prior to starting LEN, healthcare providers should select individuals who agree to the required testing and every 6 month injection dosing schedule, and counsel individuals about the importance of adherence to scheduled LEN dosing visits to help reduce the risk of acquiring HIV-1 infection and development of resistance.

Recommended Dosage

The LEN dosing schedule in adults and adolescents weighing at least 35 kg consists of a required initiation dosing (SUBQ injections and oral tablets) followed by once every 6-months continuation dosing (SUBQ injections; Table 1). LEN oral tablets may be taken with or without food.

Table 1. Dosing Schedule for LEN Initiation and Continuation in Adults and Adolescents weighing ≥35 kg

Time	Dosage
Dosage of LEN: Initiation[a]	
Day 1	927 mg by SUBQ injection (2 x 1.5 mL injections) and 600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
Dosage of LEN: Continuation	
Every 6-months (26 weeks)[b] +/- 2 weeks	927 mg SUBQ injection (2 x 1.5 mL injections)

[a] The complete initiation dosing schedule, consisting of SUBQ injections and oral tablets, is required; the efficacy of LEN has only been established with this dosing schedule.
[b] From the date of the last injection.

Dosing Schedule for Missed Dose

Missed Oral Initiation Dose

If the Day 2 oral initiation dose (600 mg; Table 1) is missed, it should be taken as soon as possible. Day 1 and Day 2 oral initiation doses should not be taken on the same day.

Anticipated Delayed Injections

During continuation dosing, if the scheduled 6-month injection is anticipated to be delayed by more than 2 weeks, LEN tablets may be taken on an interim basis (for up to 6 months if needed), until injections resume (Table 2).

Table 2. Dosing Schedule for Anticipated Delayed Injections: Weekly Oral Dosage

Time since last injection	Dosage of LEN
26 to 28 weeks	Oral dosage of 300 mg taken once every 7 days.[a] Resume the continuation injection dosage within 7 days after the last oral dose.

[a] Use on an interim basis only (for up to 6 months if needed).

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Missed Injections

Individuals who miss a scheduled injection visit should be clinically reassessed to ensure resumption of LEN remains appropriate and that the individual remains HIV-1 negative. During continuation dosing, if more than 28 weeks have elapsed since the last injection and LEN tablets have not been taken see Table 3 for the dosing schedule after missed injections. Adherence to the injection dosing schedule is strongly recommended.

Table 3. Dosing Schedule after Missed Injections

Time since last injection	Dosage of LEN
More than 28 weeks	Reinitiate with initiation dosing schedule from Day 1 (Table 1) and then continue with continuation injection dosing.

Dose Modifications for Co-administration with Strong or Moderate CYP3A4 Inducers

Supplemental doses of LEN are recommended for individuals initiating therapy with either strong CYP3A4 inducers (Table 4) or moderate CYP3A4 inducers (Table 5).

Strong CYP3A4 inducers may be initiated starting at least 2 days after LEN is first initiated, while moderate CYP3A4 inducers may be started any time after LEN is first initiated.

Table 4. Dosing Recommendations for Individuals Receiving LEN and Initiating Therapy with Strong CYP3A Inducers[a]

<table>
<tr><th rowspan="2">Maintain Scheduled Continuation Injection Dosing</th><th colspan="2">Schedule of Supplemental Doses of LEN</th></tr>
<tr><th>Time</th><th>Dosage</th></tr>
<tr><td rowspan="4">Continue to administer once every 6-months scheduled continuation dosing of LEN 927 mg SUBQ (2 x 1.5 mL injections; Table 1), plus administer supplemental doses of LEN as shown in this table</td><td>On day strong CYP3A inducer is initiated (which should be at least 2 days after LEN is first initiated)</td><td>Supplemental dosage: Step 1
927 mg SUBQ (2 x 1.5 mL injections)
And
600 mg orally (2 x 300 mg tablets)</td></tr>
<tr><td>On day after strong CYP3A inducer is initiated</td><td>Supplemental dosage: Step 2
600 mg orally (2 x 300 mg tablets)</td></tr>
<tr><td>If strong CYP3A inducer is co-administered for longer than 6 months</td><td>Subsequent supplemental dosage
Every 6-months[b] from initiation of strong CYP3A inducer, continue to administer supplemental doses of LEN as described above in Steps 1 and 2.</td></tr>
<tr><td colspan="2">After stopping the strong CYP3A inducer, continue the once every 6-months scheduled continuation injection dosing of LEN (Table 1).</td></tr>
</table>

[a] Dosing recommendations are not available for the initiation of LEN in individuals already receiving strong CYP3A inducers, nor in individuals receiving the weekly oral dosage of LEN (Table 2).
[b] 26 weeks +/- 2 weeks.

Table 5. Dosing Recommendations for Individuals Receiving LEN and Initiating Therapy with Moderate CYP3A Inducers[a]

Maintain Scheduled Continuation Injection Dosing	Schedule of Supplemental Doses of LEN	
	Time	**Dosage**
Continue to administer once every 6-months scheduled continuation dosing of LEN 927 mg SUBQ (2 x 1.5 mL injections; Table 1), plus administer supplemental doses of LEN as shown in this table	On day moderate CYP3A inducer is initiated	**Supplemental dosage** 463.5 mg SUBQ (1 x 1.5 mL injections)
	If moderate CYP3A inducer is co-administered for longer than 6 months	**Subsequent supplemental dosage** Every 6-months[b] from initiation of moderate CYP3A inducer, continue to administer supplemental doses of LEN as described above.
	After stopping the moderate CYP3A inducer, continue the once every 6-months scheduled continuation injection dosing of LEN (Table 1).	

[a] Dosing recommendations are not available for the initiation of LEN in individuals already receiving moderate CYP3A inducers, nor in individuals receiving the weekly oral dosage of LEN (Table 2).
[b] 26 weeks +/- 2 weeks.

Preparation and Administration of SUBQ Injection

LEN injection is only for SUBQ administration into the abdomen by a healthcare provider. The thigh can be used as an alternative injection site if preferred. Do NOT administer intradermally due to risk of serious injection site reactions.

Use aseptic technique when preparing the injections. Visually inspect the solution in the vials and prepared syringe for particulate matter and discoloration prior to administration. LEN injection is a yellow solution. Do not use LEN injection if the solution is discolored or if it contains particulate matter. Once the solution is withdrawn from the vials, the SUBQ injections should be administered as soon as possible.

The Withdrawal Needle Injection Kit contains withdrawal needles that may be supplied with or without a safety shield. The presence or absence of a safety shield does not change how LEN injection is prepared.

Refer to the figure below for the relevant injection kit.

The injection kit components are for singly use only. Two 1.5 mL injections are required for a complete dose.

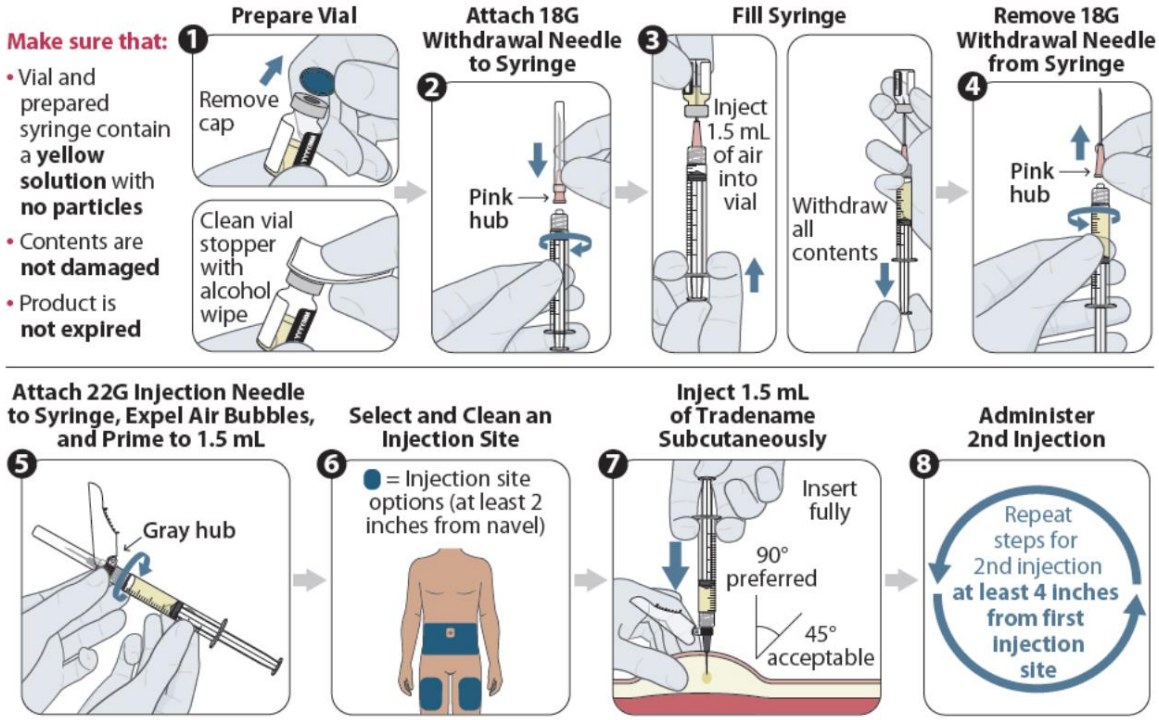
Withdrawal Needle Injection Kit (withdrawal needle without safety shield)

Figure 1 identifies the components for use in the administration steps for the Withdrawal Needle Injection Kit (withdrawal needle supplied without a safety shield), and the administration steps are provided in Figure 2. The 18-gauge needle is for withdrawal only in this kit.

Figure 1. LEN Withdrawal Needle Injection Kit Components (withdrawal needle without safety shield)



Figure 2. LEN Injection Steps for Withdrawal Needle Injection Kit (withdrawal needle without safety shield)



Administer the second injection at least 4 inches apart from the first injection site. If administering in the abdomen, ensure injections are at least 2 inches away from the navel.

SUBQ administered LEN forms a drug depot whereby LEN is slowly released from the site of administration.

Withdrawal Needle Injection Kit (withdrawal needle with safety shield)

Figure 3 identifies the components for use in the administration steps for the Withdrawal Needle Injection Kit (withdrawal needle supplied with a safety shield), and the administration steps are provided in Figure 4. The 18-gauge safety needle is for withdrawal only in this kit.

Figure 3. LEN Withdrawal Needle Injection Kit Components (withdrawal needle with safety shield)

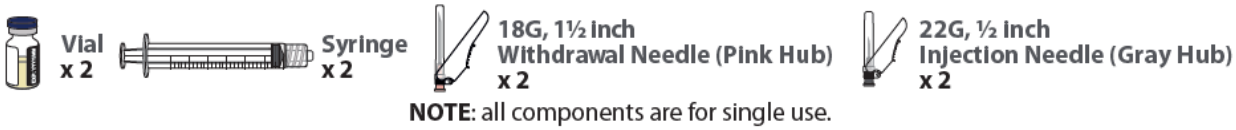
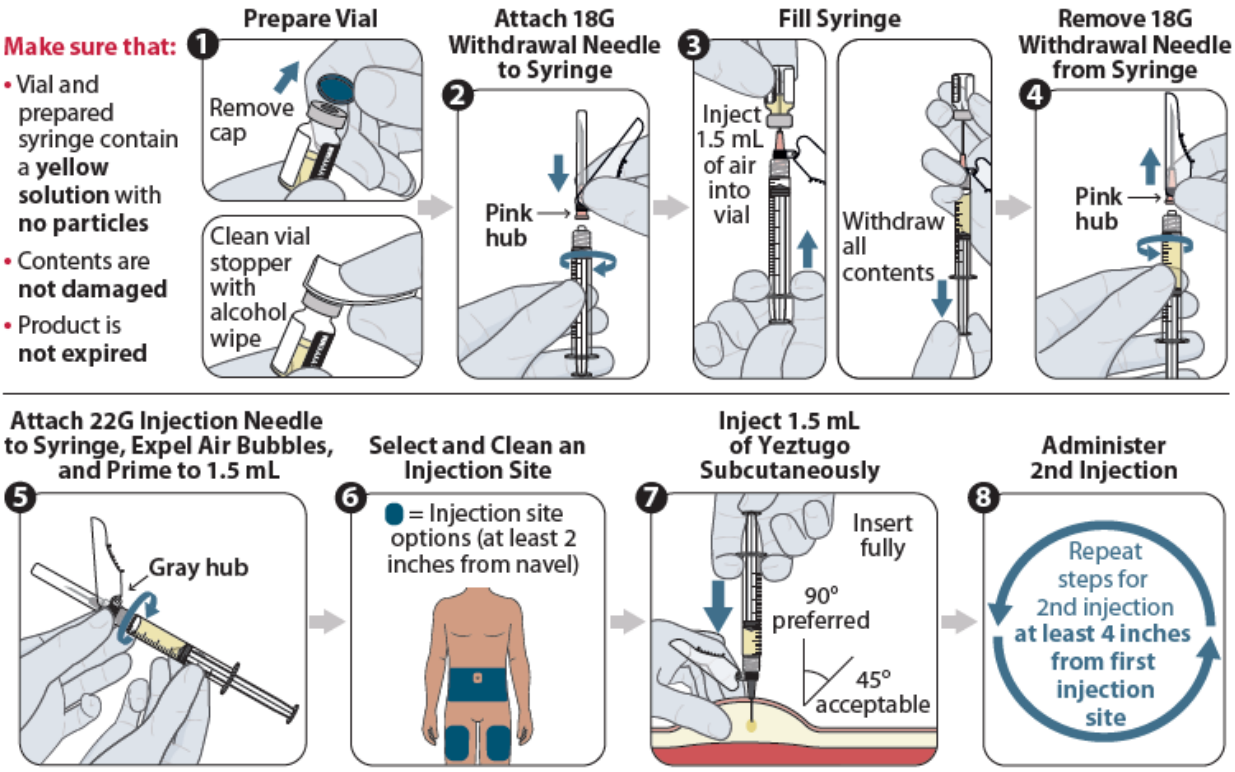


Figure 4. LEN Injection Steps for Withdrawal Needle Injection Kit (withdrawal needle with safety shield)



Clinical Considerations

SUBQ Injection technique for administration[1-3]

Healthcare provider administration is required.

LEN is administered by SUBQ injection in the abdomen or thigh by a healthcare provider at two separate injection sites, at least 4 inches apart from each other. When injecting in the abdomen, ensure injection is at least 2 inches from the navel.

When injecting LEN, it is important that the drug is injected deep into the SUBQ, or fatty tissue. Injecting too superficially may increase the chance of an injection site reaction.[2]

With one hand, gently pinch a fold of skin where injection is to be given.

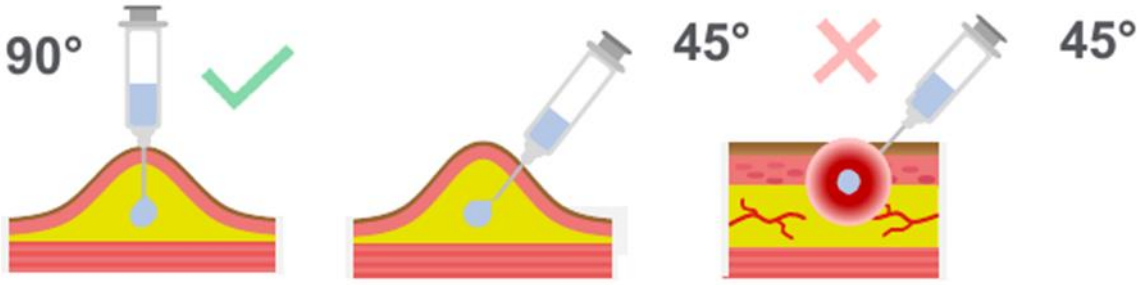
With the other hand, insert the needle into the pinched skin at a 45° to 90° angle. A 90° angle is preferred when feasible, to ensure LEN is deposited into the SUBQ tissue deeper.

The needle should be fully inserted. Caution should be taken not to inadvertently withdraw the needle while injecting.

Pause for several seconds after the injection is complete prior to withdrawing the needle to ensure that the full dose has been administered.

Repeat this process for the second dose.

Figure 5. SUBQ Injection Techniques



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. Kroger A, Bahta L, Long S, Sanchez P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). Available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf. Accessed: 22 October 2026.
3. Gilead Sciences Inc. Data on File.

Abbreviations

ISR=injection site reaction LEN=lenacapavir SUBQ=subcutaneous(ly)

Product Label

For the full indication, important safety information, and boxed warning, please refer to the Yeztugo US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_pi.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎1-866-MEDI-GSI (1-866-633-4474) or 🖱 www.askgileadmedical.com

Adverse Event Reporting

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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