

Box 3: Dosing, Preparation, and Administration of Subcutaneous Lenacapavir as Pre-Exposure Prophylaxis [a]

How supplied:

- Injection: 463.5 mg/1.5 mL (309 mg/mL) in 2 single-dose vials, 2 vial access devices, 2 disposable syringes, and 2 injection safety needles for subcutaneous (SC) injection (22 gauge, ½ inch)
- Tablets: 300 mg x 4 tablets
- Oral lenacapavir (LEN) tablets should be stored at room temperature, between 68° and 77° F, in their original packaging.
- SC LEN vials should be stored at room temperature, between 68° and 77° F, with excursions permitted at 59° to 86° F. Vials should be kept in their original carton until just before use to protect from light. Do not shake the vial before injection.

Initiation dose:

- Day 1: 927 mg (3 mL) LEN by SC injection (two 1.5 mL injections in separate areas) plus 600 mg LEN orally (two 300 mg tablets)
- Day 2: 600 mg LEN orally (two 300 mg tablets)

Continuation dose:

- Every 6 months (26 weeks), plus or minus 2 weeks, from the date of the last injection: 927 mg (3 mL) LEN by SC injection (two 1.5 mL injections in separate areas)

Preparation and administration:

- Use of ice packs before and after and analgesics after injections significantly decreases discomfort from injection site reactions (ISRs).
- Once the solution has been drawn into the syringes, administer as soon as possible. Discard solution if not used within 4 hours.
- SC LEN injections are administered at a 90° angle to decrease the risk of ISRs, placing the 2 injections on the opposite side of the body. The U.S. Food and Drug Administration lists the preferred site of administration as the abdomen, but the lateral thigh, upper arm, and buttocks are also acceptable sites based on patient preference.
- SC LEN is not appropriate for self-injection and should be administered by a healthcare professional.

Note:

- a. See [prescribing information](#).