Lenacapavir (LEN, Sunlenca)

Updated: September 30, 2025
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Formulations

Tablet: 300 mg

Single-Use Vial for Subcutaneous (SQ) Injection: 463.5 mg/1.5 mL suspension

For additional information, see Drugs@FDA or DailyMed.

Dosing Recommendations

Child and Adolescent Dose

- The safety and efficacy of using lenacapavir (LEN) in children and adolescents has not been established.

Adult Dose

- Approved for use in heavily treatment-experienced adults with multidrug resistant HIV-1 infection who are experiencing virologic failure on their current antiretroviral (ARV) regimen due to resistance, intolerance, or safety considerations. LEN is used in combination with an optimized background regimen.
- Approved for use as HIV pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents weighing ≥35 kg who are at risk for HIV-1 acquisition. Individuals must have a negative HIV-1 test prior to initiating. See Initiation Option 1 below.

Initiation Option 1

- Day 1: 927 mg by SQ injection (two 1.5-mL SQ injections in the abdomen) and 600 mg orally (two 300-mg tablets)
- Day 2: 600 mg orally (two 300-mg tablets)

Initiation Option 2

- Day 1: 600 mg orally (two 300-mg tablets)
- Day 2: 600 mg orally (two 300-mg tablets)
- Day 8: 300 mg orally (one 300-mg tablet)
- Day 15: 927 mg by SQ injection (two 1.5 mL SQ injections in the abdomen)

Maintenance

- 927 mg by SQ injection (two 1.5 mL SQ injections in the abdomen) every 26 weeks +/- 2 weeks from date of last injection

Selected Adverse Events

- Injection site reaction
- Nausea
- Headache

Special Instructions

- If LEN is discontinued, initiate an alternative, fully suppressive ARV regimen ≤28 weeks after the final injection of LEN to avoid virologic resistance.

Metabolism/Elimination

- Minor metabolism by cytochrome P450 3A4 and uridine diphosphate glucuronosyltransferase 1A1.
- Major route of elimination is unchanged drug in feces.

Dosing in Patients With Hepatic Impairment

- No dosage adjustments were recommended for adults with mild (Child-Pugh-Turcotte Class A: score 5–6) or moderate (Child-Pugh-Turcotte Class B: score 7–9) hepatic impairment.

Dosing in Patients With Renal Impairment

- Creatinine clearance (CrCl) ≥15 mL/minute: No dosage adjustment is required.
- CrCl <15 mL/minute: No dosage adjustments are provided in the manufacturer's prescribing information (i.e., not studied).[1]
- Dialysis: No dosage adjustments are required. Not expected to be significantly removed by dialysis due to high protein binding. There is one published case report of a patient with estimated glomerular filtration rate 4 mL/min on hemodialysis who received LEN, fostemsavir, and lamivudine, with resultant viral suppression sustained over 1 year.[2]