ALI-LENA

Generic name: Lenacapavir sodium injection

Brand Name: ALI-LENA

Composition:

Lenacapavir.....463.5mg/1.5ml

Indications:

- Lenacapavir, a human immunodeficiency virus type 1 (HIV-1) capsid inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 whose current antiretroviral regimen is failing due to resistance, intolerance, or safety considerations.

Dosage:

- ALI-LENA can be initiated using one of the two recommended dosage regimens in Table 1 and Table 2 below. Maintenance dosing is administered by subcutaneous injection every 6 months regardless of the initiation regimen. Healthcare providers should determine the appropriate initiation regimen for the patient. ALI-LENA oral tablets may be taken with or without food.

Table 1 Recommended Treatment Regimen for ALI-LENA Initiation and Maintenance, Option 1

Treatment Time	
Dosage of ALI-LENA: Initiation	
Day 1	927 mg by subcutaneous injection (2×1.5 mL injections) 600 mg orally (2×300 mg tablets)
Day 2	600 mg orally (2×300 mg tablets)
Dosage of ALI-LENA: Maintenance	
Every 6 months (26 weeks)* +/-2 weeks	927 mg by subcutaneous injection (2×1.5 mL injections)

*From the date of the last injection.

Table 2 Recommended Treatment Regimen for ALI-LENA Initiation and Maintenance, Option 2

Treatment Time	
Dosage of ALI-LENA: Initiation	
Day 1	600 mg orally (2×300 mg tablets)
Day 2	600 mg orally (2×300 mg tablets)
Day 8	300 mg orally (1×300 mg tablets)
Day 15	927 mg by subcutaneous injection (2×1.5 mL injections)
Dosage of ALI-LENA: Maintenance	
Every 6 months (26 weeks)* +/-2 weeks	927 mg by subcutaneous injection (2×1.5 mL injections)

*From the date of the last injection.

- Recommended Dosing Schedule for Missed Dose
  - Planned Missed Injections:

    During the maintenance period, if a patient plans to miss a scheduled 6-month injection visit by more than 2 weeks, ALI-LENA tablets may be taken for up to 6 months until injections resume. Refer to Table 3 below for the recommended dosage after planned missed injections.

Table 3 Recommended Dosage after Planned Missed Injections: Weekly Oral Maintenance

Time since Last Injection	**Recommendation**
26 to 28 weeks	Maintenance oral dosage of 300 mg taken once every 7 days for up to 6 months. Resume the maintenance injection dosage within 7 days after the last oral dose.

  - Unplanned Missed Injections:

    Patients who miss a scheduled injection visit should be clinically reassessed, including consideration of lenacapavir resistance testing, to ensure resumption of therapy remains appropriate. During the maintenance period, if more than 28 weeks have elapsed since the last injection and ALI-LENA tablets have not been taken, see Table 4 below for the recommended dosage after unplanned missed injections. Adherence to the injection dosing schedule is strongly

recommended.

Table 4 Recommended Dosage after Unplanned Missed Injections

Time since Last Injection	Recommendation
More than 28 weeks	Reinitiate with Option 1 (Table 1) or Option 2 (Table 2) and then continue with maintenance injection dosing.

- Preparation and Administration of Subcutaneous Injection:
  - ALI-LENA injection is only for subcutaneous administration into the abdomen by a healthcare provider. Do NOT administer intradermally due to risk of serious injection site reactions.
  - Use aseptic technique. Visually inspect the solution in the vials and prepared syringe for particulate matter and discoloration prior to administration. ALI-LENA injection is a yellow solution. Do not use ALI-LENA injection if the solution is discolored or if it contains particulate matter. Once the solution is withdrawn from the vials, the subcutaneous injections should be administered as soon as possible.
  - The injection kit components are for single use only. Two 1.5 mL injections are required for a complete dose.

Contraindications:

- Concomitant administration of Lenacapavir is contraindicated with strong CYP3A inducers.

Warning:

- Immune reconstitution syndrome: May necessitate further evaluation and treatment.
- Residual concentrations of lenacapavir may remain in systemic circulation for up to 12 months or longer. Counsel patients regarding the dosing schedule; non-adherence could lead to loss of virologic response and development of resistance.
- May increase exposure and risk of adverse reactions to drugs primarily metabolized by CYP3A initiated within 9 months after the last subcutaneous dose of ALI-LENA.
- If discontinued, initiate an alternative, fully suppressive antiretroviral regimen where possible no later than 28 weeks after the final injection of ALI-LENA. If virologic failure occurs, switch to an alternative regimen if possible.
- Injection site reactions may occur, and nodules and indurations may be persistent. Improper administration (intradermal injection) has been associated with serious injection site reactions.

Adverse Effects:

- Most common adverse reactions (incidence greater than or equal to 3%, all grades) are nausea and injection site reactions.

Dosage form: The injection solution is sterile, preservative-free, clear, and yellow with no visible particles.

Expiry date: 24 months from the date of manufacture.

Packaging: 1.5ml/vial，2 vials/Box.

Storage:

- Store at 20 °C-25 °C, excursions permitted to 15 °C-30 °C.
- Keep the vials in the original carton until just prior to preparation of the injections in order to protect from light.
- Once the solution has been drawn into the syringes, the injections should be administered as soon as possible.
- Discard any unused portion of the solution

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