RWANDA FDA
Rwanda Food and Drugs Authority

Ref. N°: DD/PVCT/4337 /FDA /2026

SAFETY INFORMATION COMMUNICATION

Medical Product category	Title
Lenacapavir	HIV-1 Pre-Exposure Prophylaxis

1. *Introduction*

Reference is made to Regulations No. DD/PVCT/TRG/002 Rev_1 governing pharmaceutical products and medical devices, particularly Article 23 concerning safety information and communication**(1)**.

Rwanda FDA hereby informs healthcare professionals and the general public about lenacapavir, a novel antiretroviral medicine indicated for HIV-1 pre-exposure prophylaxis (PrEP) for the prevention of HIV-1 infection**(2)**.

Rwanda FDA has registered two formulations of lenacapavir: Lenacapavir Gilead 300 mg film-coated tablets and Lenacapavir Gilead 464 mg solution for injection.
This communication provides key product information, including the approved indication, place in therapy, dosage and administration, contraindications, precautions, and adverse reactions, with the aim of promoting the safe, effective, and rational use of lenacapavir.

2. *Description*

Lenacapavir (Lenacapavir Gilead) is a combined treatment consisting of tablets to be taken by mouth and a solution for injection. Lenacapavir is a multistage, selective inhibitor of HIV-1 capsid function that directly binds to the interface between capsid protein (CA) subunits. Lenacapavir inhibits HIV-1 replication by interfering with multiple, essential steps of the viral lifecycle, including capsid-mediated nuclear uptake of HIV-1 proviral DNA (by blocking nuclear import proteins binding to capsid), virus assembly and release (by interfering with Gag/Gag-Pol functioning, reducing production of CA subunits), and capsid core formation (by disrupting the rate of capsid subunit association, leading to malformed capsids)**(3)**.

3. *Indications*

Lenacapavir is indicated for:

- Pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in adults and adolescents (≥35 kg) at increased risk of HIV-1 infection.

4. *Contraindications*

Lenacapavir is contraindicated in individuals:

- With known hypersensitivity to lenacapavir or to any excipient listed in the product information
- With unknown HIV-1 status
- Receiving concomitant treatment with strong inducers of CYP3A, P-gp, and UGT1A1, including but not limited to:

✓ antimycobacterials: rifampicin
✓ anticonvulsants: carbamazepine, phenytoin
✓ herbal products: St. John's wort (Hypericum perforatum)

5. *Posology and Method of Administration*

Table 1: Dosing schedule for lenacapavir initiation and continuation

Time	
	Dose of lenacapavir: Initiation[a]
Day 1	927 mg subcutaneous injection (2 x 1.5 mL injections[b]) 600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
Every 6 Months (26 weeks) [c] +/- 2 weeks	927 mg subcutaneous injection (2 x 1.5 mL injections[b])

a The complete initiation dosing schedule, consisting of subcutaneous injections and oral tablets, is required; the efficacy of lenacapavir has only been established with this dosing schedule

b Two injections, with the second injection at least 5 centimetres from the first injection

c From the date of the last injection.

6. *Adverse Drug Reactions Associated with use of Lenacapavir*

- Injection site reactions which include swelling, pain, nodule, erythema, induration, pruritus, extravasation, discomfort, mass, haematoma, oedema, and ulcer.
- Nausea
- Immune reconstitution inflammatory syndrome

7. *Information for the Patients and Caregivers*

- Lenacapavir is intended only for individuals confirmed to be HIV-negative
- HIV testing must be performed before initiation and as advised by healthcare providers
- Attend all scheduled 6-month injection appointments without delay
- Do not discontinue or delay treatment without consulting a healthcare professional
- Inform healthcare providers of all concomitant medicines prior to use
- Seek medical attention if symptoms suggestive of HIV infection occur.

8. *Information to Healthcare Professionals*

- Ensure strict confirmation of HIV-negative status prior to initiation and during use
- Adhere strictly to the recommended dosing schedule to maintain therapeutic protection
- Evaluate patients for potential drug–drug interactions prior to prescribing
- Avoid co-administration with strong CYP3A, P-gp, and UGT1A1 inducers
- Initiate full antiretroviral therapy immediately if HIV infection is confirmed during treatment
- Educate patients on adherence and risk-reduction strategies
- Report all suspected adverse drug reactions promptly through national pharmacovigilance systems.

9. *Reporting channel*

Patients and Healthcare Professionals are urged to report any suspected adverse drug event/reaction associated with Lenacapavir medicine or any other medical product to the Rwanda FDA by using an online reporting tool called VigiMobile for medicines, which is available on the Rwanda FDA website at *https://vigiflow-eforms.who-umc.org/rw/adr* or using the online reporting system (PViMS) accessible on *https://pvims.rwandafda.gov.rw/security/landing*

Sincerely,

By Authority delegation

FOR

Dr. Védaste HABYALIMANA
Head of Drugs Department

10. References

1. Rwanda Food and Drugs Authority. Regulations governing pharmacovigilance of pharmaceutical products and medical devices: Rwanda Food and Drugs Authority; 2018. p. 1–18. Available from: https://www.rwandafda.gov.rw/

2. European Medicines Agency. Lenacapavir: product information. Annex I. Amsterdam: European Medicines Agency; 2025. p. 1–73. Available from: https://www.ema.europa.eu/en/documents/outside-eu-product-information/lenacapavir-gilead-product-information_en.pdf

3. Inhibitor L acting HC. Pharmacological outlook of lenacapavir: a novel first-in-class. 2023. p. 495–499. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC10705863/