WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Lenacapavir Gilead 464 mg solution for injection [1]

Lenacapavir (as sodium) 464 mg solution for injection

Lenacapavir Gilead 464 mg solution for injection was submitted in 2025 by Gilead Sciences Ireland Unlimited Company, to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the management of HIV/AIDS on 06 October 2025.

Information on the site(s) involved in the manufacture of the product and the API is available at the products listing information: https://extranet.who.int/prequal/medicines/ha811

The "Procedure for prequalification of pharmaceutical products[2]" defines specific evaluation mechanisms for products approved by regulatory authorities, which apply similar stringent standards for quality, safety and efficacy as those required by WHO.

The prequalification of this product by the WHO Prequalification Team: Medicines (PQTm), is based on the scientific opinion by the European Medicines Agency (EMA https://www.ema.europa.eu/en/medicines) in line with the "Procedure to enable prequalification of products approved by SRAs for use outside the SRA region."[3].

Hence, no assessment of the data underlying this decision has been undertaken within the WHO Prequalification Programme.

However, according to the Procedure, WHO may request additional data when considered necessary for the safe use of the product in regions relevant for prequalified products and such information may be included in the WHOPAR as a separate piece of information. In order to safeguard product quality throughout its entire intended shelf-life in hot and very humid areas, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant[4].

Based on the submitted stability data WHO PQTm considers the following storage condition appropriate for the product when distributed in regions with zone III, IVa and IVb climatic conditions, based on available stability information:

[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

[2] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs961-annex10-who-procedure-prequalification.pdf?sfvrsn=85029f47_2

[3] https://extranet.who.int/prequal/sites/default/files/document_files/Procedure%20to%20enable%20prequalification%20products%20approved%20by%20SRAs%20for%20use%20outside%20the%20SRA%20region-18%20March%202025_0.pdf

[4] https://extranet.who.int/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

- Do not store above 30°C.
  Store in the original outer carton in order to protect from light.

- The shelf-life at this storage condition is 36 months.

Based on the above, the WHOPAR for Lenacapavir Gilead refers for parts 1, 3, 4, 5, 6 and 8 to the previously issued public assessment report as follows:

WHOPAR part		**Reference[5, 6]**
Part 1	Summary for the Public	https://www.ema.europa.eu/en/documents/outside-eu-summary/lenacapavir-gilead-medicine-overview_en.pdf
Part 3	Package Leaflet	https://www.ema.europa.eu/en/documents/outside-eu-product-information/lenacapavir-gilead-product-information_en.pdf
Part 4	Summary of Product Characteristics	https://www.ema.europa.eu/en/documents/outside-eu-product-information/lenacapavir-gilead-product-information_en.pdf
Part 5	Labelling	https://www.ema.europa.eu/en/documents/outside-eu-product-information/lenacapavir-gilead-product-information_en.pdf
Part 6	Discussion	https://www.ema.europa.eu/en/documents/outside-eu-assessment-report/lenacapavir-gilead-assessment-report_en.pdf
Part 8	Steps taken following Authorisation	https://www.ema.europa.eu/en/opinion-medicine-use-outside-EU/human/lenacapavir-gilead#assessment-history

Parts 2 and 7 of the WHOPAR for Lenacapavir Gilead are included here.

Lenacapavir Gilead contains lenacapavir. Its WHO recommended use is for the management of HIV/AIDS.

Summary of Prequalification Status for Lenacapavir Gilead 464 mg solution for injection

Initial acceptance	**Date**	**Outcome**
Status on PQ list	06 October 2025	listed
Quality	September 2025	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.

[5]https://www.ema.europa.eu/en/partners-networks/international-activities/medicines-assessed-under-eu-m4all-procedure

[6]https://www.ema.europa.eu/en/opinion-medicine-use-outside-EU/human/lenacapavir-gilead
EMEA/H/W/006659