WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Epivir 10 mg/ml oral Solution [1]

Lamivudine 10 mg/ml oral solution

Epivir 10 mg/ml oral solution, was submitted in 2001 by GlaxoSmithKline Research & Development Limited to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS on 20 March 2002.

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/ha128

The Marketing Authorization was transferred in 2010 to "ViiV Healthcare UK Limited" and to ViiV Healthcare BV in 2018.

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 approval by a stringent regulatory authority (SRA), namely the "European Medicines Agency" (EMA https://www.ema.europa.eu/en/homepage) in line with the "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities" [3].

However, according to the SRA guideline 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:

- Do not store above 30°C. Avoid excursions above 30°C
- The shelf-life at this storage condition is 18 months.
- Discard the oral solution one month after first opening.

[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://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs986-annex5.pdf?sfvrsn=8aae767d_2

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

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

WHOPAR part		**Reference**[5]
Part 1	Summary for the Public	https://www.ema.europa.eu/documents/overview/epivir-epar-summary-public_en.pdf
Part 3	Package Leaflet	https://www.ema.europa.eu/en/documents/product-information/epivir-epar-product-information_en.pdf
Part 4	Summary of Product Characteristics	https://www.ema.europa.eu/en/documents/product-information/epivir-epar-product-information_en.pdf
Part 5	Labelling	https://www.ema.europa.eu/en/documents/product-information/epivir-epar-product-information_en.pdf
Part 6	Discussion	https://www.ema.europa.eu/documents/scientific-discussion/epivir-epar-scientific-discussion_en.pdf
Part 8	Steps taken following Authorization	https://www.ema.europa.eu/documents/procedural-steps-after/epivir-epar-procedural-steps-taken-scientific-information-after-authorisation_en.pdff

This WHOPAR for Epivir is comprised of parts 2 and 7.

Epivir contains lamivudine. Its WHO recommended use is with other antiretroviral medicinal products for the treatment and post-exposure prophylaxisof HIV/AIDS.

Summary of Prequalification Status for Epivir 10 mg/ml oral solution

	Initial Acceptance		**Requalification**		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	20 March 2002	listed	14 Dec 2018	listed	25 Feb 2025	listed
Dossier Evaluation	Sept 2001	MR	Dec 2018	requalified	Feb 2025	requalified

PQ: prequalification
MR: meets requirements

The table represents the status of relevant completed activities only

[5] Epivir | European Medicines Agency (europa.eu)
Agency product number: EMEA/H/C/000107