WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

SYMFI LO[1]

Efavirenz/Lamivudine/Tenofovir disoproxil fumarate,
400mg/300mg/300mg film-coated tablets

SYMFI LO was submitted in 2018 by Mylan Laboratories Limited to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS on 31 October 2018.

Information on the sites involved in the manufacture of the product and the APIs is available at the products listing information: https://extranet.who.int/prequal/medicines/ha721

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 the United States "Food and Drug Administration" (https://www.fda.gov), in line with the "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities" [3].

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

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:

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[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

- Do not store above 30°C. Store in the original container. Protect from light.
- The shelf-life at this storage condition is:
  - 30's White HDPE Bottle – 36 months
  - 30's Blue HDPE Bottle – 24 months
  - 90's Blue HDPE Bottle – 36 months

This WHOPAR refers to the information available at the approving stringent regulatory authority's website resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208255Orig1s000TOC.cfm

For details on the uses of this product, for relevant efficacy and safety information, see the Prescribing Information as approved by USFDA
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208255Orig1s000Lbl.pdf
Application Number: 208255

This WHOPAR for SYMFI LO is comprised of parts 2 and 7.

SYMFI LO contains efavirenz/lamivudine/tenofovir disoproxil fumarate. Its WHO recommended use is for the treatment of HIV/AIDS.

Summary of Prequalification Status for SYMFI LO

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	31 October 2018	listed	29 July 2025	listed
Dossier Evaluation	October 2018	MR	July 2025	requalified
PQ: prequalification MR: meets requirements				

The table represents the status of relevant completed activities only.