

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Combivir 150 mg/300 mg film-coated tablets¹

Lamivudine/Zidovudine 150mg/300mg Tablets

The innovator product Combivir 150 mg/300 mg film-coated tablets, was submitted in 2001 by Glaxo Wellcome Operations to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS on 18 March 2002.

Information on the site(s) involved in the manufacture of the product and the APIs is available at the products listing information (<https://extranet.who.int/pqweb/medicine/2382>)

The “Procedure for prequalification of pharmaceutical products²” 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 of Medicines Programme (PQP) is based on the approval by a stringent regulatory authority (SRA), namely the “European Medicines Agency” (EMA <http://www.ema.europa.eu/ema/>) 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, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant⁴.

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
- The shelf-life at this storage condition is 24 months.

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/pqweb/sites/default/files/documents/48 Stability data SRA FPPs_March2016_newtempl.pdf](https://extranet.who.int/pqweb/sites/default/files/documents/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf)

This WHOPAR 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/combivir-epar-summary-public_en.pdf
Part 3	Package Leaflets	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000368/WC500039043.pdf
Part 4	Summaries Product Characteristics	https://www.ema.europa.eu/documents/product-information/combivir-epar-product-information_en.pdf
Part 5	Labelling	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000368/WC500039043.pdf
Part 6	Discussion	https://www.ema.europa.eu/documents/scientific-discussion/combivir-epar-scientific-discussion_en.pdf
Part 8	Steps taken following Authorisation	https://www.ema.europa.eu/documents/procedural-steps-after/combivir-epar-procedural-steps-taken-scientific-information-after-authorisation_en.pdf

This WHOPAR for Combivir is comprised of parts 2 and 7

Summary of Prequalification Status for Combivir 150 mg/300 mg film-coated tablets

	Initial Acceptance		Requalification	
	Date	Outcome	Date	Outcome
Status on PQ list	18 March 2002	listed	27 November 2017	listed
Dossier Evaluation	06 September 2001	MR	08 November 2017	requalified

PQ: prequalification

MR: meets requirements

The table represents the status of relevant completed activities only

*Formerly ViiV Healthcare UK Ltd, UK

⁵ <https://www.ema.europa.eu/en/medicines/human/EPAR/combivir>

Agency product number: EMEA/H/C/000190