# WHO Prequalification Programme
# WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

## Combivir 150 mg/300 mg film-coated tablets[1]

Lamivudine/Zidovudine 150mg/300mg film-coated tablets

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 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/ha110

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 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].

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:

- 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/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

Based on the above, the WHOPAR for Combivir 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/en/documents/overview/combivir-epar-summary-public_en.pdf |
| Part 3 | Package Leaflet | https://www.ema.europa.eu/en/documents/product-information/combivir-epar-product-information_en.pdf |
| Part 4 | Summary of Product Characteristics | https://www.ema.europa.eu/en/documents/product-information/combivir-epar-product-information_en.pdf |
| Part 5 | Labelling | https://www.ema.europa.eu/en/documents/product-information/combivir-epar-product-information_en.pdf |
| Part 6 | Discussion | https://www.ema.europa.eu/en/documents/scientific-discussion/combivir-epar-scientific-discussion_en.pdf |
| Part 8 | Steps taken following Authorisation | https://www.ema.europa.eu/en/documents/procedural-steps-after/combivir-epar-procedural-steps-taken-and-scientific-information-after-authorisation_en.pdf |

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

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

| | **Initial Acceptance** | | **Requalification** | |
|---|---|---|---|---|
| | **Date** | **Outcome** | **Date** | **Outcome** |
| Status on PQ list | 20 March 2002 | listed | 27 November 2017 | listed |
| Dossier Evaluation | September 2001 | MR | November 2017 | requalified |
| Status on PQ list | | | 24 February 2025 | listed |
| Dossier Evaluation | | | February 2025 | requalified |
| PQ: prequalification<br>MR: meets requirements | | | | |

The table represents the status of relevant completed activities only.

[5] https://www.ema.europa.eu/en/medicines/human/EPAR/combivir
EMEA/H/C/000190