WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Retrovir 250 mg capsules, hard [1]

Zidovudine 250 mg hard gelatin capsules

Retrovir 250 mg capsules, hard, was submitted in 2001 by Glaxo Wellcome Operations, United Kingdom, to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for treatment of HIV/AIDS on 29 May 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/ha109.

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 Kingdom "Medicines & Healthcare products Regulatory Agency" (MHRA, http://www.mhra.gov.uk) 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 25°C.
- Store in the original package to protect from light and moisture.
- Avoid excursions above 30°C.
- The shelf-life at this storage condition is 60 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

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://products.mhra.gov.uk/search/?search=Retrovir&page=1&doc=Par&rerouteType=0

For details on the uses of this product, for relevant efficacy and safety information see the summary of product characteristics and the patient information leaflet as approved by MHRA https://products.mhra.gov.uk/search/?search=Retrovir&page=1 PL 35728/0002

This WHOPAR for Retrovir is comprised of parts 2, 5 and 7.

Retrovir contains zidovudine. Its WHO recommended use is for the management of HIV/AIDS.

Summary of Prequalification Status for Retrovir 250 mg capsules, hard:

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	29 May 2002	listed	26 August 2020	listed
Dossier Evaluation	April 2002	MR	August 2020	requalified
Status on PQ list			24 February 2025	listed
Dossier Evaluation			February 2025	requalified
PQ: prequalification MR: meets requirements				

The table represents the status of relevant completed activities only.