WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Retrovir 100 mg/10 ml oral solution[1]

Zidovudine 50mg/5mL oral solution

Retrovir 100 mg/10 ml oral solution was submitted in 2001 by Glaxo Wellcome Operations, Middlesex, United Kingdom, to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for 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/pqweb/medicine/2385

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 30°C. Do not freeze.
- Keep the bottle in the outer carton to protect from light.
- The shelf-life at this storage condition is 24 months.
- Discard the oral solution 1 month after first opening of the bottle."

[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%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 35728/0004

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

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

The efficacy and safety profile zidovudine is well established based on the extensive clinical experience in the treatment of HIV infected patients

Summary of Prequalification Status for Retrovir 100 mg/10 ml oral solution:

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	20 March 2002	listed	05 March 2019	listed
Dossier Evaluation	September 2001	MR	28 January 2019	requalified

PQ: prequalification
MR: meets requirements

The table represents the status of relevant completed activities only.