WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Rifabutin Capsules, USP 150mg [1]

Rifabutin 150 mg hard gelatin capsules

Rifabutin Capsules, USP 150mg was submitted in 2014 by Lupin Ltd. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS related conditions on 17 November 2014.

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/ha640

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:

[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 25°C. Avoid excursions above 30°C.
- Store in the original bottle and keep the bottle tightly closed to protect from moisture. Protect from light.
- The shelf-life at this storage condition is 24 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/scripts/cder/daf/index.cfm FDA application no:.090033)

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/scripts/cder/daf/index.cfm?event=BasicSearch.process
The prescribing information as certified to be FDA approved text also is included in this WHOPAR. Since a separate Patient Information Leaflet is not available, part 3 is not included in this WHOPAR.

This WHOPAR for Rifabutin Capsules USP 150 mg is comprised of parts 2, 4, 5 and 7.

Rifabutin Capsules contains rifabutin. Its WHO recommended use is for TB treatment in HIV/AIDS infected patients who require an antiretroviral therapy containing a boosted protease inhibitor.

Summary of Prequalification Status for Rifabutin Capsules, USP 150mg

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	17 November 2014	listed	02 October 2024	listed
Dossier Evaluation	November 2014	MR	October 2024	requalified
PQ: prequalification MR: meets requirements				

The table represents the status of relevant completed activities only.