

WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Rimactazid 150 mg/75 mg tablets ¹

Isoniazid/Rifampicin 75mg/150mg film-coated tablets

Rimactazid 150 mg/75 mg tablets was submitted in 2002 by Novartis South Africa (Pty) Limited, to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of tuberculosis on 14 September 2004.

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/prequal/medicines/tb085>

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 Team: Medicines (PQTm), is based on the approval by the Swedish Medical Products Agency “LÅKEMEDSVERKET” (<https://www.lakemedelsverket.se/en>), 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 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 25°C.
- Store in the original package in order to protect from moisture.
- The shelf-life at this storage condition is 36 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=8aac767d_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://www.lakemedelsverket.se/sv/sok-lakemedelsfakta/lakemedel/20020823000029/rimactazid-150-mg-75-mg-filmdragerad-tablett>

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 "LÄKEMEDSVERKET"

<https://www.lakemedelsverket.se/sv/sok-lakemedelsfakta/lakemedel/20020823000029/rimactazid-150-mg-75-mg-filmdragerad-tablett> MT16688

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

Rimactazid contains rifampicin and isoniazid. Its WHO recommended use is for the continuation treatment phase of tuberculosis caused by Mycobacterium tuberculosis and for tuberculosis preventive treatment.

Summary of Prequalification Status for Rimactazid 150 mg/75 mg tablets

	Initial Acceptance		Requalification		Requalification	
	Date	Outcome	Date	Outcome	Date	Outcome
Status on PQ list	14 Sept 2004	listed	27 June 2019	listed	04 June 2025	listed
Dossier Evaluation	July 2004	MR	June 2019	requalified	June 2025	requalified
PQ: prequalification MR: meets requirements						

The table represents the status of relevant completed activities only.