WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Rimactazid 150 mg/75 mg[1]

International Nonproprietary Name (INN):
Isoniazid/Rifampicin 75mg/150mg Tablets

Abstract

Rimactazid 150 mg / 75 mg, manufactured at Sandoz Private Limited MIDC, Plot No. 8 A/2 and 8B, T.T.C Industrial Area, Kalwe Block, Village Dighe, Navi Mumbai- 400 708, India and Sandoz Private Limited, c/o Strides Arcolabs Limited, KRS Gardens, Suragajakkanahalli, Anekal Taluk, Bangalore 562106, India and Sandoz Private Limited, c/o Panacea Biotec Limited, Malpur, Baddi, Tehsil Nalagarh District Solan,173 205 , Himachal Pradesh, India was submitted to be considered for prequalification in 2002 when the product was licensed / registered in Sweden and subsequently accepted for the WHO list of prequalified products for the treatment of tuberculosis on 14 September 2004.

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 of Medicines Programme (PQP) is based on the approval by a stringent regulatory authority (SRA), namely the Swedish Medical Products Agency (http://www.lakemedelsverket.se/) 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, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant.

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.
Store in the original package in order to protect from moisture. Avoid excursions 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 (NMRA) responsibility.

[2] http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS961_Annex10.pdf
[3] http://apps.who.int/prequal/info_general/documents/TRS986/TRS986_ANNEX-5_SRA-Guide.pdf
https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification_February2017_0.pdf

This WHOPAR refers to the information available at the approving stringent regulatory authority in terms of the assessment of the quality, efficacy and safety as well as steps taken after the prequalification. (https://lakemedelsverket.se/LMF/Lakemedelsinformation/?nplid=20020823000029&type=product). (Accessed 27 December 2019

Parts 2a, 2b, 5 and 7 of the WHOPAR for Rimactazid 150 mg / 75 mg are included here.

Rimactazid 150 mg / 75 mg contains isoniazid and rifampicin. Its recommended use is for the treatment of tuberculosis.

The most frequent adverse events observed during treatment with isoniazid and rifampicin were peripheral neuropathy, transient increases of serum transaminases and flushing.
The most serious adverse events of isoniazid are peripheral and central neurotoxic effects, as well as severe and sometimes fatal hepatitis.
The most serious adverse events of rifampicin are hepatotoxicity, particularly cholestatic reactions, and skin reactions. It can also potentiate the hepatotoxicity of the other anti-tuberculosis medications.

The efficacy and safety profile of isoniazid and rifampicin are well established based on the extensive clinical experience in the treatment of tuberculosis.

Summary of Prequalification Status for Rimactazid 150 mg / 75 mg

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	14 Sept 2004	listed	27 June 2019	listed
Dossier Evaluation	31 July 2004	MR	25 June 2019	requalified

MR: meets requirements
The table represents the status of relevant completed activities only.