WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Sinerdol 150 mg hard capsules [1]

Rifampicin 150 mg hard capsules

Sinerdol 150 mg hard capsules was submitted in 2013 by Antibiotice SA. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for treatment of tuberculosis on 28 February 2013.

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/tb268

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 Romanian "National Agency for Medicines and Medical Devices of Romania" (Agentia Nationalia a Medicamentului (https://www.anm.ro/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 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. Protect from moisture.

- The shelf-life at this storage condition is 48 months.

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[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 Stability data SRA FPPs_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://nomenclator.anm.ro/medicamente, (CoD CIM W41998001 / W41998002)

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.

The English language version of the patient information leaflet, the summary of product characteristics and the labelling, as certified to be "National Agency for Medicines and Medical Devices of Romania" approved texts, are included in this WHOPAR.

This WHOPAR for Sinerdol is comprised of parts 2, 3. 4. 5 and 7.

Sinerdol contains rifampicin. Its WHO recommended use is for the treatment and prevention of tuberculosis as well as leprosy.

Summary of Prequalification Status for Sinerdol 150 mg hard capsules

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	28 February 2013	listed	02 May 2023	listed
Dossier Evaluation	February 2013	MR	April 2023	requalified
PQ: prequalification MR: meets requirements				

The table represents the status of relevant completed activities only.