WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Sinerdol ISO, capsules, 300 mg/150 mg[1]

International Nonproprietary Name (INN):
Isoniazid/Rifampicin 150mg/300mg Capsules

Abstract

Sinerdol ISO, capsules, 300 mg/150 mg manufactured at Antibiotice SA was submitted to be considered for prequalification in 2013 when the product was licensed / registered in at least one of the ICH regions and subsequently accepted for the WHO list of prequalified products for treatment of tuberculosis on 28 Feb 2013.

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 WHO Prequalification of Medicines Programme (PQP) is based on the approval by a stringent regulatory authority (SRA), namely the Romanian Authority "Agentia Nationalia A Medicamentului" (www.anm.ro), 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 WHO Prequalification Programme.

Based on the above, 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. Detailed information on the SRA-approved use of this product is described in the Summary of Product Characteristics (SmPC), which is a company authorized English translation of the Romanian SmPC and can be found in this WHOPAR. The most recent authorized Romanian product information can be requested from the Romanian Medicines Regulatory Agency. (www.anm.ro)

Parts 2a, 2b, 3, 4, 5 and 7 of the WHOPAR for Sinerdol ISO, capsules, 300mg/150 mg are included here.

Sinerdol ISO, capsules, 300 mg/150 mg contain rifampicin and isoniazid. It's 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.

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[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's (NMRA) responsibility Throughout this WHOPAR the proprietary name is given as an example only.
[2] http://apps.who.int/prequal/info_general/documents/TRS961/TRS961_Annex10.pdf
[3] http://apps.who.int/prequal/info_general/documents/TRS986/TRS986_ANNEX-5_SRA-Guide.pdf

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/Rifampicin is well established based on the extensive clinical experience in the treatment of tuberculosis.

Summary of Prequalification Status for Sinerdol ISO, capsules, 300 mg/150 mg

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list i.e. date of listing	28 Feb 2013	listed				
Dossier Evaluation	20 Feb 2013	MR				

MR: meets requirements

The table represents the status of relevant completed activities only.