WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Isoniazid/Rifampicin 150 mg/150 mg Tablets*

International Nonproprietary Name (INN)
Isoniazid/Rifampicin

Abstract

Isoniazid/Rifampicin 150mg/150mg Tablets, manufactured at Lupin Limited, Aurangabad, India was included in the WHO list of prequalified products for the treatment of tuberculosis on 29 January 2013.

Isoniazid/Rifampicin 150mg/150mg Tablets is indicated for the treatment of tuberculosis. Detailed information on the use of this product is described in the Summary of Product Characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredients (APIs) of Isoniazid/Rifampicin 150mg/150mg Tablets are the antimycobacterial agents isoniazid and rifampicin. The APIs are well-established and documented 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 safety concerns with isoniazid are peripheral and central neurotoxic effects, as well as severe and sometimes fatal hepatitis.

The most serious safety concerns with 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 is well-established based on extensive clinical experience in the treatment of tuberculosis.

On the basis of data submitted and public information on the use of isoniazid and rifampicin conbination in antituberculosis therapy the team of assessors advised that Isoniazid/Rifampicin 150mg/150mg Tablets is of acceptable quality, efficacy and safety to allow inclusion of Isoniazid/Rifampicin 150mg/150mg Tablets in the list of prequalified medicinal products.

* 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.

Summary of Prequalification Status for Isoniazid/Rifampicin 150mg/150mg Tablets:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	29 Jan 2013	listed				
Dossier Evaluation						
Quality	25 Jan 2013	MR				
Bioequivalence	10 Dec 2012	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API 1	16 June 2011	MR				
API 2	18 Feb 2011	MR				
FPP	NA	MR[i]				
GCP (re-)inspection	NA	MR[ii]				
GCP/GLP inspection	NA	MR[iii]				

MR: Meets Requirements
NA: not applicable, not available

[i] For further details regarding the inspection status reference is made to part 7 of this WHOPAR
[ii] For further details regarding the inspection status reference is made to part 7 of this WHOPAR
[iii] For further details regarding the inspection status reference is made to part 7 of this WHOPAR