WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Isoniazid 300 mg Tablets*

International Nonproprietary Name (INN):
Isoniazid

Abstract

Isoniazid 300 mg Tablets, manufactured at Micro Labs Limited, Hosur, Tamil Nadu, India was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 1 November 2010.

Isoniazid 300 mg 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 ingredient (API) of Isoniazid 300 mg Tablets is the antimycobacterial agent isoniazid. The API is well-established and documented for the treatment of tuberculosis.

The most frequent adverse events observed during treatment were peripheral neuropathy and transient increases of serum transaminases.The most important adverse effects of isoniazid are peripheral and central neurotoxic effects, as well as severe and sometimes fatal hepatitis.

The efficacy and safety profile of Isoniazid 300 mg Tablets 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 in antituberculosis, the team of assessors advised that Isoniazid 300 mg Tablets is of acceptable quality, efficacy and safety to allow inclusion of Isoniazid 300 mg Tablets in the list of prequalified medicinal products.

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* Trade names are not prequalified by WHO. This is under local DRA responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Summary of Prequalification Status for Isoniazid 300 mg Tablets:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	1 Nov 10	listed				
Dossier Evaluation						
Quality	14 Oct 10	MR				
Bioequivalence	23 Sept 10	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	15 Sept 10	Accepted (based on a risk/benefit assessment)				
FPP	21 May 09	MR				
GCP (re-)inspection	16 July 10	MR				
Batch Analysis	NA	NA				

MR: Meets Requirements
NA: Not applicable, not available