WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB173 trade name]*

Isoniazid 100 mg tablets

[TB173 trade name], manufactured at Micro Labs Limited, Hosur, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 1 November 2010.

[TB173 trade name] is indicated with other tuberculosis medicines for the treatment of tuberculosis due to *Mycobacterium tuberculosis*, including in regimens for drug-resistant tuberculosis. It is also indicated as monotherapy or with other medicines for the prevention of tuberculosis in persons at risks. 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 of [TB173 trade name] is the antimycobacterial agent isoniazid. The efficacy and safety of isoniazid is well established based on extensive clinical experience in the treatment of tuberculosis.

For details on the use of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of isoniazid for treatment of tuberculosis, the team of assessors advised that [TB173 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB173 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB173 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	1 November 2010	listed
Quality	14 October 2010	MR
Bioequivalence	23 September 2010	MR
Safety, Efficacy	NA	NA
GMP (re-)inspection		
API	15 September 2010	MR
FPP	21 May 2009	MR
GCP/GLP (re-)inspection	16 July 2010	MR

API: active pharmaceutical ingredient	GMP: good manufacturing practice [quality standard]
FPP: finished pharmaceutical product	MR: meets requirements
GCP: good clinical practice [quality standard]	MR*: desk review (based on recent inspection reports)
GLP: good laboratory practice [quality standard]	NA: not applicable, not available
	PQ: prequalification

The table represents the status of relevant completed activities only.

Requalification	6 May 2020

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.