WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB196 trade name]*

Isoniazid 100 mg tablets

[TB196 trade name], manufactured at Lupin Limited, Chikalthana, Aurangabad, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 31 October 2012.

[TB196 trade name] is indicated in combination with other tuberculosis medicines for the treatment of tuberculosis due to *Mycobacterium tuberculosis*, and as monotherapy or with other medicines for the prevention of tuberculosis in persons at risk. 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 [TB196 trade name] is the antimycobacterial agent isoniazid. The efficacy and safety of isoniazid are well established based on extensive clinical experience in the treatment of tuberculosis.

For details on the uses 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 in the treatment of tuberculosis the team of assessors advised that [TB196 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB196 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB196 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

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

Initial acceptance	Date	Outcome
Status on PQ list	31 Oct 2012	Listed
Quality	26 Oct 2012	MR
Bioequivalence	15 Aug 2012	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	16 June 2011	MR
FPP	23 Feb 2012	MR
GCP/GLP (re-)inspection	NA	NA
Batch analysis	NA	NA

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

Requalification	17 June 2019