

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB348 trade name]*

Isoniazid 100mg Dispersible Tablets

[TB348 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 16 March 2020.

[TB348 trade name] is indicated in combination with other anti-tuberculosis agents for the treatment of tuberculosis and prevention of tuberculosis caused by *Mycobacterium 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 of [TB348 trade name] is isoniazid.

The efficacy and safety profile of isoniazid is well established based on extensive clinical experience in treatment and prevention 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 [TB348 trade name] for treatment and prevention of tuberculosis, the team of assessors advised that [TB348 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB348 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB348 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	16 March 2020	listed
Quality	05 March 2020	MR
Bioequivalence	10 March 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	23 November 2018	MR
FPP	10 April 2019	MR
GCP/GLP (re-)inspection	15 December 2017	MR
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	

The table represents the status of relevant completed activities only.

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