

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB359 trade name]*

Isoniazid 100mg dispersible tablets

[TB359 trade name], manufactured at Macleods Pharmaceuticals Limited, Baddi, Himachal Pradesh India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 02 March 2021.

[TB359 trade name] is indicated in combination with other anti-tuberculosis agents for the treatment of multi-drug resistant 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(s) of [TB359 trade name] is isoniazid.

The efficacy and safety of isoniazid is well established based on extensive clinical experience in the 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 isoniazid in tuberculosis, the team of assessors advised that [TB359 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB359 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB359 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	02 March 2021	listed
Quality	17 February 2021	MR
Bioequivalence	22 February 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	23 November 2018	MR
API	01 February 2019	MR
API	March 2019	MR*:
FPP	21 September 2020	MR
GCP/GLP (re-)inspection	01 September 2020	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 tables represent the status of relevant completed activities only.

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