

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB410 trade name]*

Isoniazid 100 mg dispersible tablets

[TB410 trade name], manufactured at Lupin Limited, Aurangabad, Maharashtra State, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 23 March 2026.

[TB410 trade name] is indicated in combination with other tuberculosis medicines for the treatment of tuberculosis due to *Mycobacterium tuberculosis*, including in regimens for drug-resistant 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 [TB410 trade name] is Isoniazid.

The efficacy and safety of Isoniazid 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 [TB410 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB410 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB410 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	23 March 2026	listed
Pharmaceutical quality	16 March 2026	MR
Bioequivalence	16 March 2026	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	01 March 2023	MR*
FPP	09 May 2025	MR
GCP/GLP (re-)inspection	23 January 2025	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	