WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB403 trade name]*

Pretomanid 200 mg tablets

[TB403 trade name], manufactured at Lupin Limited, Chikalthana, Chhatrapati Sambhajinagar, Maharashtra State, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 09 September 2025.

[TB403 trade name] is indicated for in combination with other tuberculosis medicines for the treatment of drug-resistant tuberculosis due to *Mycobacterium tuberculosis* in adults and adolescents at least 14 years old. 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 [TB403 trade name] is Pretomanid.

The efficacy and safety of Pretomanid is 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 Pretomanid in tuberculosis, the team of assessors advised that [TB403 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB403 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB403 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	09 September 2025	listed
Pharmaceutical quality	26 August 2025	MR
Bioequivalence	29 August 2025	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	04 April 2025	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