

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB409 trade name]*

Linezolid 150 mg dispersible tablets

[TB409 trade name], manufactured at Lupin Limited, Jammu, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 05 July 2025.

[TB409 trade name] is currently indicated in combination with other tuberculosis medicines for the treatment of drug-resistant 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 [TB409 trade name] is linezolid.

The efficacy and safety of linezolid are well established based on extensive clinical experience in the treatment of drug-resistant tuberculosis caused by *Mycobacterium 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 linezolid, the team of assessors advised that [TB409 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB409 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB409 trade name]:

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

Initial acceptance	Date	Outcome
Status on PQ list	05 July 2025	listed
Pharmaceutical quality	10 June 2025	MR
Bioequivalence	18 June 2025	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	13 March 2025	MR*
FPP	12 July 2024	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		

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