

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB391 trade name]*

Linezolid 150 mg dispersible tablets

[TB391 trade name], manufactured at Macleods Pharmaceuticals Ltd, Pithampur, Madhya Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 14 November 2022.

[TB391 trade name] is indicated for 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 [TB391 trade name] is linezolid.

The efficacy and safety of linezolid is 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 [TB391 trade name] in tuberculosis, the team of assessors advised that [TB391 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB391 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB391 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	14 November 2022	listed
Quality	01 November 2022	MR
Bioequivalence	04 November 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	31 August 2020	MR*
FPP	19 November 2021	MR
GCP/GLP (re-)inspection	09 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 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.