

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB323 trade name]*

Linezolid 600 mg tablets

[TB323 trade name], manufactured at Micro Labs Limited, Bengaluru, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 31 October 2018.

[TB323 trade name] is indicated in combination with other antituberculosis agents 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 [TB323 trade name] is antibacterial agent linezolid. The efficacy and safety of linezolid are well established based on extensive clinical experience in the treatment of bacterial infections.

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 in the treatment of tuberculosis, the team of assessors advised that [TB323 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB323 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB323 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	31 October 2018	listed
Quality	3 October 2018	MR
Bioequivalence	16 October 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 August 2016	MR
FPP	10 December 2015	MR
GCP/GLP (re-)inspection	NA	NA
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.