WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB397 trade name][*]

Pretomanid 200 mg tablets

[TB397 trade name], manufactured at Macleods Pharmaceuticals Limited, Pithampur, Dist.: Dhar, Madhya Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of drug-resistant tuberculosis on 28 October 2024.

[TB397 trade name] is indicated in combination for 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 [TB397 trade name] is Pretomanid.

The efficacy and safety of pretomanid are well established based on extensive clinical experience in the treatment of drug-resistant 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 [TB397 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB397 trade name] in the list of prequalified medicinal products.

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

Summary of prequalification status for [TB397 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	28 October 2024	listed
Pharmaceutical quality	11 October 2024	MR
Bioequivalence	18 October 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	26 June 2023	MR
FPP	19 November 2021	MR
GCP/GLP (re-)inspection	10 February 2023	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
NA: not applicable, not available
PQ: prequalification