WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB133 trade name]*

Ethionamide 250 mg tablets

[TB133 trade name], manufactured at Macleods Pharmaceuticals Limited, Kachigam, Daman, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 21 December 2007.

[TB133 trade name] is indicated in combination with other tuberculosis medicines for the treatment of drug-resistant tuberculosis due to *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 [TB133 trade name] is ethionamide.

The efficacy and safety of ethionamide 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 ethionamide in tuberculosis, the team of assessors advised that [TB133 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB133 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB133 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	21 December 2007	listed
Pharmaceutical quality	27 September 2007	MR
Bioequivalence	21 May 2007	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	20 June 2007	MR
GCP/GLP (re-)inspection	20 September 2007	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

Requalification	11 December 2018

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