WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB352 trade name]*

Ethionamide 125 mg Dispersible Tablets

[TB352trade name], manufactured at Micro Labs Limited, Tamil Nadu, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 23 July 2019.

[TB352trade name] is indicated for tuberculosis treatment. 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 [TB352trade 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 [TB352trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB352trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB352trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	23 July 2019	Listed
Quality	01 March 2019	MR
Bioequivalence	11 March 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	07 July 2017	MR
FPP	10 April 2019	MR
GCP/GLP (re-)inspection	18 December 2017	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.