WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB242 trade name][*]

Ethionamide 250 mg tablets

[TB242 trade name], manufactured at Micro Labs Ltd, Tamilnadu, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 19 December 2012.

[TB242 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 [TB242 trade name] is the antimycobacterial agent ethionamide. The efficacy and safety of ethionamide are 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 the treatment of tuberculosis, the team of assessors advised that [TB242 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB242 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB242 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	19 Dec 2012	listed
Quality	5 Oct 2012	MR
Bioequivalence	10 Aug 2012	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	17 Dec 2012	MR
FPP	20 April 2012	MR
GCP/GLP (re-)inspection	18 May 2012	MR
Batch Analysis	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.

Requalification	30 Sept 2019