WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB333 trade name]*

Ethionamide 125 mg Dispersible Tablets

[TB333 trade name], manufactured at Macleods Pharmaceuticals Limited, Daman, Gujarat, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 30 May 2017.

[TB333 trade name] is indicated for the treatment of 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 [TB333 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 [TB333 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB333 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB333 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	30 May 2017	listed
Quality	30 May 2017	MR
Bioequivalence	03 Oct 2016	MR
GMP (re-)inspection		
API	19 Nov 2015	MR
API	12 Aug 2016	MR
FPP	23 May 2014	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.