

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB239 trade name]*

Protonamide 250 mg tablets

[TB239 trade name], manufactured at Micro Labs Ltd, Tamil Nadu, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 25 February 2013.

[TB239 trade name] is indicated for 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 ingredients of [TB239 trade name] is the antimycobacterial agent protonamide.

The efficacy and safety of protonamide 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 protonamide in tuberculosis, the team of assessors advised that [TB239 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB239 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB239 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	25 Feb 2013	listed
Quality	19 Feb 2013	MR
Bioequivalence	01 Feb 2013	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	29 Nov 2012	MR
FPP	20 April 2012	MR
GCP/GLP (re-)inspection	18 May 2012	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.

Requalification	19 December 2019
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* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.