WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB243trade name]*

Pyrazinamide 500 mg tablets

[TB243 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 09 January 2013.

[TB243 trade name] is indicated in combination with other tuberculosis medicines for the treatment of tuberculosis due to *Mycobacterium tuberculosis* including in regimens for drug-resistant 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 [TB243 trade name] is the antimycobacterial agent pyrazinamide.

The efficacy and safety of pyrazinamide 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 pyrazinamide in tuberculosis, the team of assessors advised that [TB243 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB243 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB243 trade name]

Initial acceptance	**Date**	**Outcome**
Status on PQ list	09 January 2013	Listed
Quality	09 January 2013	MR
Bioequivalence	09 February 2012	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	16 June 2011	MR
FPP	June 2012	MR
GCP/GLP (re-)inspection	NA	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	30 July 2019

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