WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB159 trade name]*

Pyrazinamide 400 mg Tablets

[TB159 trade name] manufactured at Macleods Pharmaceuticals Ltd, Kachigam, Daman (U.T), India, was accepted for the WHO list of prequalified medicinal products for the treatment of tuberculosis on 23 March 2007.

[TB159 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 (API) of [TB159 trade name] is the antibiotic agent pyrazinamide.

The efficacy and safety of pyrazinamide 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 pyrazinamide in tuberculosis, the team of assessors advised that [TB159 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB159 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [TB159 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	23 March 2007	listed
Quality	11 December 2006	MR
Bioequivalence	26 January 2007	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	6 December 2005	MR
FPP	23 March 2005	MR
GCP/GLP (re-)inspection	22 January 2007	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	16 July 2018