WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB171 trade name]*

Pyrazinamide 400 mg tablets

[TB171 trade name], manufactured at Micro Labs Limited, Tamil-Nadu, India was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 29 June 2009.

[TB171 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 ingredient of [TB171 trade name] 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 [TB171 trade name] in tuberculosis, the team of assessors advised that [TB171 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB171 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB171 trade name]:

The table represents the status of relevant completed activities only.

Summary of prequalification status for [TB171 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	29 June 2009	listed
Quality	23 March 2009	MR
Bioequivalence	18 Nov 2008	NA
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	6 Dec 2005	MR
FPP	21 May 2009	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 NA: not applicable, not available PQ: prequalification	

The table represents the status of relevant completed activities only.

Requalification	4 November 2021

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