WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB172 trade name]*

Pyrazinamide 500 mg Tablets

[TB172 trade name] manufactured at Micro Labs Limited, Tamil-Nadu, India, was accepted for the WHO list of prequalified medicinal products for the treatment of tuberculosis on 29 June 2009.

[TB172 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 [TB172 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 [TB172 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB172 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [TB172 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	29 June 2009	listed
Quality	23 March 2009	MR
Bioequivalence	18 November 2008	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	6 December 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
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	17 June 2019

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