WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB223 trade name]*

Ethambutol hydrochloride/ isoniazid/pyrazinamide/rifampicin 275mg/75mg/400mg/150mg tablets

[TB223 trade name], manufactured at Micro Labs Limited, Bangalore, Karnataka, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis (TB) on 7 December 2016.

[TB223 trade name] is indicated for TB treatment. 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 [TB223 trade name] are ethambutol hydrochloride, isoniazid, pyrazinamde and rifampicin.

The efficacy and safety of ethambutol hydrochloride, isoniazid, pyrazinamide and rifampicin are well established based on extensive clinical experience in the treatment of TB.
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 ethambutol hydrochloride, isoniazid and rifampicin ethambutol hydrochloride, isoniazid, pyrazinamide and rifampicin in TB, the team of assessors advised that [TB223 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB223 trade name] in the list of prequalified medicinal products.

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

Summary of prequalification status for [TB223 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	07 December 2016	listed
Quality	28 October 2016	MR
Bioequivalence	04 November 2016	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	25 June 2015	MR
API	25 June 2015	MR
API	10 December 2015	MR
FPP	10 December 2015	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.