WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB356 trade name][*]

Levofloxacin (as hemihydrate) 100 mg dispersible tablets

[TB356 trade name], manufactured at Micro Labs Ltd, Tamil Nadu, India, was included in the WHO list of prequalified medicinal products for the prevention and treatment of tuberculosis on 22 October 2019.

[TB356 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 (API) of [TB356 trade name] is the antibacterial agent levofloxacin.

The efficacy and safety profile of [TB356 trade name] is 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 [TB356 trade name] therapy in tuberculosis, the team of assessors advised that [TB356 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB356 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [TB356 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	22 October 2019	listed
Quality	10 October 2019	MR
Bioequivalence	17 October 2019	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	30 January 2015	MR
FPP	10 April 2019	MR
GCP/GLP (re-)inspection	16 February 2018	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.

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