

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB373 trade name]*

Levofloxacin (as hemihydrate) 500 mg Tablets

[TB373 trade name], manufactured at PT. Caprifarmino Laboratories, Bandung Barat, Indonesia, was included in the WHO list of prequalified medicinal products for tuberculosis on 02 November 2021.

[TB373 trade name] is indicated for treatment or prevention 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 [TB373 trade name] is levofloxacin (as hemihydrate). The efficacy and safety of levofloxacin are well established based on extensive clinical experience in the treatment and prevention 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 levofloxacin in tuberculosis, the team of assessors advised that [TB373 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB373 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 [TB373 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	02 November 2021	listed
Quality	13 May 2021	MR
Bioequivalence	27 May 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	10 October 2019	MR*
FPP	24 January 2020	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.