WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB398 trade name]*

Rifapentine 300 mg Film coated tablets

[TB398 trade name], manufactured at Macleods Pharmaceuticals Limited, at Oxalis Labs Lodhimajra, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 02 September 2023.

[TB398 trade name] is indicated, in combination with other tuberculosis medicines, for the initial treatment and prevention of tuberculosis due to *Mycobacterium 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 [TB398 trade name] is the antimycobacterial agent rifapentine.

The efficacy and safety of rifapentine 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 rifapentine in tuberculosis, the team of assessors advised that [TB398 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB398 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB398 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

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

Initial acceptance	**Date**	**Outcome**
Status on PQ list	02 September 2023	listed
Pharmaceutical quality	28 August 2023	MR
Bioequivalence	29 August 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	26 June 2023	MR
FPP	27 April 2023	MR
GCP/GLP (re-)inspection	15 February 2023	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