WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB402 trade name][*]

Rifapentine 150mg dispersible tablets

[TB402 trade name], manufactured at Lupin Limited, Chikalthana, Aurangabad 431 210, Maharashtra State, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 21 November 2024.

[TB402 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 [TB402 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 [TB402 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB402 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB402 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	21 November 2024	listed
Pharmaceutical quality	06 November 2024	MR
Bioequivalence	13 November 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	31 March 2023	MR
FPP	28 January 2022	MR*
GCP/GLP (re-)inspection	14 April 2022	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