

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB412 trade name]*

Rifapentine 150 mg dispersible tablets

[TB412 trade name], manufactured at Macleods Pharmaceuticals Limited, at Oxalis Labs Tehsil Baddi, Dist. Solan, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 05 July 2025.

[TB412 trade name] is indicated in combination with other tuberculosis medicines, for the treatment and prevention of tuberculosis caused by bacteria called *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 [TB412 trade name] is rifapentine.

The efficacy and safety of rifapentine are 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 [TB412 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB412 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB412 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	05 July 2025	listed
Pharmaceutical quality	10 June 2025	MR
Bioequivalence	18 June 2025	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
<div> <div> API: active pharmaceutical ingredient FPP: finished pharmaceutical product GCP: good clinical practice [quality standard] GLP: good laboratory practice [quality standard] </div> <div> GMP: good manufacturing practice [quality standard] MR: meets requirements NA: not applicable, not available PQ: prequalification </div> </div>		