

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB369 trade name]*

Isoniazid/rifapentine 300 mg/300 mg film-coated tablets

[TB369 trade name], manufactured at Macleods Pharmaceuticals Limited, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 13 May 2022.

[TB369 trade name] is indicated for the prevention of tuberculosis caused by *Mycobacterium tuberculosis* in patients above 2 years of age and weighing more than 10 kg. 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 ingredients of [TB369 trade name] are the antimycobacterial agents isoniazid and rifapentine. The efficacy and safety of isoniazid and 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 isoniazid and rifapentine in tuberculosis, the team of assessors advised that [TB369 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB369 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB369 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	13 May 2022	listed
Quality	28 April 2022	MR
Bioequivalence	4 May 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	23 November 2018	MR
API	27 August 2020	MR*
FPP	23 October 2019	MR
GCP/GLP (re-)inspection	14 September 2020	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.