WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB394 trade name]*

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

[TB394 trade name], manufactured at Lupin Limited, Aurangabad, Maharashtra State, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 17 October 2024.

[TB394 trade name] is currently 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 [TB394 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 [TB394 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB394 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB394 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	17 October 2024	listed
Pharmaceutical quality	07 October 2024	MR
Bioequivalence	09 October 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	31 March 2023	MR
API	20 April 2023	MR*
FPP	28 January 2022	MR*
GCP/GLP (re-)inspection	26 January 2024	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