WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB400 trade name][*]

Isoniazid/pyrazinamide/rifampicin 50 mg/150 mg/75 mg dispersible tablets

[TB400 trade name], manufactured at Lupin Limited, Aurangabad, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 16 August 2024.

[TB400 trade name] is indicated in children weighing less than 25 kg, for the initial treatment of non-severe tuberculosis (TB) due to drug-susceptible *Mycobacterium tuberculosis*. It is also indicated in combination with other medicine(s), in infants and children weighing less than 25 kg, for the initial treatment of drug-susceptible *M. tuberculosis* tuberculosis that does not meet the criteria for non-severe TB. 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 [TB400 trade name] are isoniazid, pyrazinamide and rifampicin.

The efficacy and safety of isoniazid, pyrazinamide and rifampicin 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, pyrazinamide and rifampicin in tuberculosis, the team of assessors advised that [TB400 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB400 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB400 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	16 August 2024	listed
Pharmaceutical quality	29 July 2024	MR
Bioequivalence	01 August 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	16 June 2020	MR*
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