WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB360 trade name]*

Isoniazid/Rifampicin 50 mg /75 mg tablets

[TB360 trade name], manufactured at Lupin Limited, A-28/1, MIDC Area, Chikalthana, Aurangabad, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis caused by the bacterium *Mycobacterium tuberculosis* in children weighing less than 25 kg on 20 August 2021.
[TB360 trade name] is indicated for 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 ingredients of [TB360 trade name] are isoniazid and rifampicin.

The efficacy and safety of isoniazid 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 and rifampicin in tuberculosis, the team of assessors advised that [TB360 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB360 trade name] in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Summary of prequalification status for [TB360 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	20 August 2021	listed
Quality	16 August 2021	MR
Bioequivalence	17 August 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	21 July 2021	MR*
API	23 November 2018	MR
FPP	30 June 2020	MR*
GCP/GLP (re-)inspection	15 June 2018	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.