# WHO Prequalification Programme
# WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

## [TB411 trade name]*

Ethambutol (as hydrochloride) 100 mg dispersible tablets

[TB411 trade name], manufactured at Lupin Limited, Chhatrapati Sambhajinagar, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 14 March 2025.

[TB411 trade name] is indicated in combination with other tuberculosis medicines for the treatment of tuberculosis due to *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 [TB411 trade name] is ethambutol hydrochloride.

The efficacy and safety of ethambutol 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 ethambutol hydrochloride, the team of assessors advised that [TB411 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB411 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [TB411 trade name]:**

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

| **Initial acceptance** | **Date** | **Outcome** |
|---|---|---|
| **Status on PQ list** | 14 March 2025 | listed |
| Pharmaceutical quality | 07 March 2025 | MR |
| Bioequivalence | 12 March 2025 | MR |
| Safety, efficacy | NA | NA |
| **GMP (re-)inspection** | | |
| API | 17 January 2023 | MR* |
| FPP | 28 January 2022 | MR |
| **GCP/GLP (re-)inspection** | 14 April 2022 | 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

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