WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB396 trade name]*

Bedaquiline (as fumarate) 100 mg tablets

[TB396 trade name], manufactured at Lupin Limited,Chikalthana, Aurangabad, Maharashtra State, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis (TB) on 16 November 2023.

[TB396 trade name] is indicated for 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 ingredient of [TB396 trade name] is bedaqualine (as fumarate).

The efficacy and safety of bedaquiline are well established based on extensive clinical experience in the treatment of TB.

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 bedaqualine in TB, the team of assessors advised that [TB396 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB396 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB396 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	16 November 2023	listed
Pharmaceutical quality	10 November 2023	MR
Bioequivalence	10 November 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	12 June 2020	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.