WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB390 trade name][*]

Bedaquiline (as fumararte) 100 mg tablets

[TB390 trade name], manufactured at Macleods Pharmaceuticals Limited, Tehsil Baddi, Dist. Solan, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 04 November 2024.

[TB390 trade name] is indicated in combination with other tuberculosis medicines for the treatment of drug-resistant 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 [TB390 trade name] is bedaquiline (as fumarate).

The efficacy and safety of bedaquiline (as fumarate) 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 bedaquiline (as fumarate) in tuberculosis, the team of assessors advised that [TB390 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB390 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB390 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	04 November 2024	listed
Pharmaceutical quality	24 October 2024	MR
Bioequivalence	28 October 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	26 June 2023	MR
FPP	11 November 2022	MR
GCP/GLP (re-)inspection	15 February 2023	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.