

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

**[TB390 trade name]\***

Bedaquiline (as fumarate) 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 (TB) 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) is 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 bedaquiline in TB, 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      |
| <b>GMP (re-)inspection</b>  |                  |         |
| API   | 26 June 2023     | MR      |
| FPP   | 11 November 2022 | MR      |
| <b>GCP/GLP (re-)inspection</b>  | 15 February 2023 | MR      |
| API: active pharmaceutical ingredient<br>FPP: finished pharmaceutical product<br>GCP: good clinical practice [quality standard]<br>GLP: good laboratory practice [quality standard]<br>GMP: good manufacturing practice [quality standard]<br>MR: meets requirements<br>NA: not applicable, not available<br>PQ: prequalification |                  |         |

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