WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB206 trade name]*

Protionamide 250 mg tablets

[TB206 trade name], manufactured at Lupin Limited, Chikalthana, Aurangabad, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 13 June 2014.

[TB206 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 [TB206 trade name] is protionamide.

The efficacy and safety of protionamide is 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 protionamide in tuberculosis, the team of assessors advised that [TB206 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB206 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB206 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	13 June 2014	listed
Quality	30 May 2014	MR
Bioequivalence	03 June 2014	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	29 November 2012	MR
FPP	23 February 2012	MR
GCP/GLP (re-)inspection	06 July 2012	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.

Requalification	09 February 2022

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