WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB353 trade name][*]

Protionamide 250 mg tablets

[TB353 trade name], manufactured at Technolog Private Joint Stock Company, Uman City, Cherkassy Region, Ukraine, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 08 September 2021.

[TB353 trade name] is indicated for treatment of 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 [TB353 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 [TB353 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB353 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB353 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	08 September 2021	listed
Quality	12 February 2020	MR
Bioequivalence	13 February 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	25 February 2021	MR
FPP	07 December 2018	MR
GLP (re-)inspection	18 January 2019	MR
GLP (re-)inspection	23 February 2018	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.

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