

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

**[TB353 trade name]\***

Protionamide 250mg tablets

[TB353 trade name], manufactured at Technolog Private Joint Stock Company 8, Stara prorizna street, Uman City, Cherkassy Region, 20300, 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 in combination with other antituberculosis agents for the treatment of all forms of tuberculosis caused by *Mycobacterium tuberculosis* in adults and children. [TB353 trade name] is only indicated as a second-line antimycobacterial drug when resistance to or toxicity from first-line drugs has developed. 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(s) of [TB353 trade name] is protionamide.

The efficacy and safety of protionamide is well established based on extensive clinical experience in the treatment of all forms of tuberculosis caused by *Mycobacterium 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 all forms of tuberculosis caused by *Mycobacterium 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      |
| <b>GMP (re-)inspection</b>                                                                                                                                                                                                                                                                                                        |                   |         |
| API                                                                                                                                                                                                                                                                                                                               | 25 February 2021  | MR      |
| FPP                                                                                                                                                                                                                                                                                                                               | 07 December 2018  | MR      |
| <b>GCP (re-)inspection</b>                                                                                                                                                                                                                                                                                                        | 18 January 2019   | MR      |
| <b>GLP (re-)inspection</b>                                                                                                                                                                                                                                                                                                        | 23 February 2018  | 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 |                   |         |

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.