WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB382 trade name]*

Pyridoxine hydrochloride 10 mg Tablets

[TB382 trade name], manufactured at Macleods Pharmaceuticals Ltd, Daman, India, was included in the WHO list of prequalified medicinal products for tuberculosis (TB) on 13 May 2022.

[TB382 trade name] is currently indicated for treatment and prevention of peripheral neuropathy induced by TB medicines, including isoniazid, cycloserine and terizidone. 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 [TB382 trade name] is pyridoxine.

The efficacy and safety of pyridoxine hydrochloride are well established based on extensive clinical experience in 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 pyridoxine in tuberculosis, the team of assessors advised that [TB382 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB382 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB382 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	13 May 2022	listed
Quality	29 April 2022	MR
Bioequivalence	9 May 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	17 September 2020	MR
FPP	25 June 2021	MR*
GCP/GLP (re-)inspection	NA	NA

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.