

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

**[TB383 trade name]\***

Pyridoxine hydrochloride 50 mg tablets

[TB383 trade name], manufactured at Macleods Pharmaceuticals Limited, Kachigam, Daman, India, was included in the WHO list of prequalified medicinal products for the treatment and prevention of isoniazid-induced peripheral neuropathy, on 13 May 2022.

[TB383 trade name] is indicated for treatment and prevention of isoniazid-induced peripheral neuropathy in patients at risk of the condition. 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 [TB383 trade name] is pyridoxine hydrochloride.

The efficacy and safety of pyridoxine hydrochloride are well established based on extensive clinical experience in the treatment and prevention of peripheral neuropathy. Pyridoxine is also indicated for preventing isoniazid toxicity in all children receiving high-dose isoniazid regimens for the treatment of drug-resistant 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 hydrochloride in patients with tuberculosis using isoniazid, the team of assessors advised that [TB383 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB383 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [TB383 trade name]:**

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