WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB413 trade name]*

Pyridoxine hydrochloride 10 mg tablets

[TB413 trade name], manufactured at S Kant Healthcare Ltd. Vapi-396 195, Gujarat, India, was included in the WHO list of prequalified medicinal products for the treatment of peripheral neuropathy induced by tuberculosis medicines, including isoniazid, cycloserine and terizidone, on 13 March 2025.
[TB413 trade name] is indicated for treatment of peripheral neuropathy induced by tuberculosis medicines. 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 [TB413 trade name] is pyridoxine hydrochloride.

The efficacy and safety of pyridoxine hydrochloride are well established based on extensive clinical experience in the treatment of peripheral neuropathy.

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 the treatment of peripheral neuropathy induced by tuberculosis medicines, the team of assessors advised that [TB413 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB413 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB413 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

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

Initial acceptance	**Date**	**Outcome**
Status on PQ list	13 March 2025	listed
Pharmaceutical quality	25 February 2025	MR
Bioequivalence	27 February 2025	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	21 September 2020	MR*
FPP	27 February 2025	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