

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB401 trade name]*

Pyridoxine hydrochloride 50mg film-coated tablets

[TB401 trade name], manufactured at S Kant Healthcare Ltd, Vapi, Gujarat, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 20 November 2023

[TB401 trade name] is indicated for the 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 of [TB401 trade name] pyridoxine hydrochloride.

The efficacy and safety of pyridoxine hydrochloride are well established based on extensive clinical experience in the treatment and prevention of isoniazid-induced peripheral neuropathy in patients at risk of the condition.

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 tuberculosis, the team of assessors advised that [TB401 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB401 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB401 trade name]:

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

Initial acceptance	Date	Outcome
Status on PQ list	20 November 2023	MR
Pharmaceutical quality	10 November 2023	MR
Bioequivalence	16 November 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	21 September 2020	MR*
FPP	16 June 2022	MR
GCP/GLP (re-)inspection		
API: active pharmaceutical ingredient	GMP: good manufacturing practice [quality standard]	
FPP: finished pharmaceutical product	MR: meets requirements	
GCP: good clinical practice [quality standard]	MR*: desk review (based on recent inspection reports)	
GLP: good laboratory practice [quality standard]	NA: not applicable, not available	
	PQ: prequalification	

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