

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[NT021 trade name]*

Albendazole 400mg tablets

[NT021 trade name], manufactured at Ipca Laboratories Limited, Silvassa 396 230, U.T. of Dadra and Nagar Haveli and Daman and Diu, India, was included in the WHO list of prequalified medicinal products for the treatment of broad-spectrum anthelmintic infections, on 19 December 2025.

[NT021 trade name] is indicated for anthelmintic infections. 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 [NT021 trade name] is albendazole

The efficacy and safety of albendazole is well established based on extensive clinical experience in the treatment of anthelmintic infections

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 albendazole in neglected tropical diseases, the team of assessors advised that [NT021 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [NT021 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [NT021 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	19 December 2025	listed
Pharmaceutical quality	27 November 2025	MR
Bioequivalence	05 December 2025	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	02 September 2022	MR
FPP	29 June 2023	MR
GCP/GLP (re-)inspection	17 January 2025	MR
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 NA: not applicable, not available PQ: prequalification	

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