

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[NT014 trade name]*

Albendazole 400 mg chewable tablets

[NT014 trade name], manufactured at Mepro Pharmaceuticals Pvt. Ltd., Gujarat, India, was included in the WHO list of prequalified medicinal products for the treatment of neglected tropical diseases on 16 August 2024.

[NT014 trade name] is indicated for treatment of certain helminthic 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.

{NT014 trade name} contains excipients which restrict its use in infants and pregnant women; see WHOPAR part 3 (section 2) and part 4 (section 4.4) for more information'

The active pharmaceutical ingredient of [NT014 trade name] is albendazole.

The efficacy and safety of albendazole is well established based on extensive clinical experience in the treatment of helminthic 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, the team of assessors advised that [NT014 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [NT014 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [NT014 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	16 August 2024	listed
Pharmaceutical quality	23 July 2024	MR
Bioequivalence	24 July 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	02 September 2022	MR
API	20 January 2023	MR
FPP	17 March 2023	MR
GCP/GLP (re-)inspection	09 June 2023	MR
<div> <div> API: active pharmaceutical ingredient FPP: finished pharmaceutical product GCP: good clinical practice [quality standard] GLP: good laboratory practice [quality standard] </div> <div> GMP: good manufacturing practice [quality standard] MR: meets requirements NA: not applicable, not available PQ: prequalification </div> </div>		