

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[NT016 trade name]*

Albendazole 400 mg chewable tablets

[NT016 trade name], manufactured at Indoco Remedies Limited, Nalagarh, Himachal Pradesh, India was included in the WHO list of prequalified medicinal products for helminthic infections on 30 August 2024.

[NT016 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.

[NT016 trade name] contains excipients which restrict its use in infants, pregnant and breast-feeding women. See WHOPAR parts 3 (section 2) and 4 (section 4.4) for further information.

The active pharmaceutical ingredients of [NT016 trade name] is albendazole.

The efficacy and safety of albendazole are 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 on the use of albendazole in helminthic infections, the team of assessors advised that [NT016 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [NT016 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [NT016 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	30 August 2024	listed
Pharmaceutical quality	19 August 2024	MR
Bioequivalence	27 August 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	02 September 2022	MR
FPP	20 August 2022	MR
GCP/GLP (re-)inspection	15 March 2024	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>		