

## WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

**[NT005 trade name]\***

Albendazole 400 mg tablets

[NT005 trade name], manufactured at Cipla Limited Indore (Unit-IV), Mumbai, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of neglected tropical diseases on 31 March 2021.

[NT005 trade name] is currently indicated for the treatment of cestode infections, lymphatic filariasis and other nematode 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 of [NT005 trade name] is albendazole.

The efficacy and safety of albendazole are well established based on extensive clinical experience in the treatment of cestode infections, lymphatic filariasis and other nematode 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, the team of assessors advised that [NT005 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [NT005 trade name] in the list of prequalified medicinal products.

### Summary of prequalification status for [NT005 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	31 March 2021	listed
Pharmaceutical quality	12 March 2021	MR
Bioequivalence	23 March 2021	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
API	12 April 2019	MR
FPP	16 June 2020	MR
<b>GCP/GLP (re-)inspection</b>	15 December 2017	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 MR*: desk review (based on recent inspection reports) NA: not applicable, not available PQ: prequalification		

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