WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[NT020 trade name][*]

Azithromycin (as dihydrate) 500 mg film-coated tablets

[NT020 trade name], manufactured at Rusan Pharma Ltd., Dehradun, Uttarakhand, India, was included in the WHO list of prequalified medicinal products for the management of neglected tropical diseases on 19 December 2025.

[NT020 trade name] is indicated for the treatment of yaws (≥6 months) and, in adults and adolescents, for susceptible bacterial infections including cholera, enteric fever, gonorrhoea, Chlamydia trachomatis infections, and acute dysentery. 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 [NT020 trade name] is azithromycin.

The efficacy and safety of azithromycin is well established based on extensive clinical experience in the treatment of neglected tropical diseases.

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 azithromycin in the management of neglected tropical diseases, the team of assessors advised that [NT020 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [NT020 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [NT020 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	19 December 2025	listed
Pharmaceutical quality	27 November 2025	MR
Bioequivalence	17 December 2025	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	25 July 2025	MR
FPP	10 February 2025	MR*
GCP/GLP (re-)inspection	20 September 2024	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