WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[NT017 trade name]*

Miltefosine 50mg capsules

[NT017 trade name], manufactured at Zydus Lifesciences Limited, Kundaim Industrial Estate, OSD Block – II, Kundaim, Goa-403 115, India, was included in the WHO list of prequalified medicinal products for the treatment of leishmaniasis on 22 February 2024.

[NT017 trade name] is indicated either alone or in combination with other drugs for the treatment of visceral leishmaniasis and cutaneous leishmaniasis. 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 [NT017 trade name] is miltefosine.

The efficacy and safety of miltefosine are well established based on extensive clinical experience in the treatment of visceral leishmaniasis and cutaneous leishmaniasis.

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 miltefosine in leishmaniasis, the team of assessors advised that [NT017 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [NT017 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [NT017 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	22 February 2024	listed
Pharmaceutical quality	25 January 2024	MR
Bioequivalence	08 February 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	22 September 2023	MR
FPP	21 April 2023	MR
GCP/GLP (re-)inspection	04 January 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