WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA483 trade name][*]

Zidovudine 300 mg film-coated tablets

[HA483 trade name], manufactured at Micro Labs Ltd, Verna, Goa, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 20 August, 2010.

[HA483 trade name] is indicated for the treatment of children with HIV-1 infection in combination with other antiretroviral agents and for the primary prophylaxis of HIV-1 infection in neonates. 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 [HA483 trade name] is nucleoside reverse transcriptase inhibitor (NRTI) zidovudine.

The efficacy and safety of zidovudine is well established based on extensive clinical experience in the treatment of HIV/AIDS.

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 combination therapy in HIV/AIDS, the team of assessors advised that [HA483 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA483 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA483 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	20 Aug 2010	listed
Pharmaceutical quality	22 July 2010	MR
Bioequivalence	13 Aug 2010	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	28 May 2009	MR
FPP	18 March 2010	MR
GCP/GLP (re-)inspection	NA	NA

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

Requalification	01 April 2019