WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA526 trade name]*

Zidovudine 10 mg/mL oral solution

[HA526 trade name], manufactured at Macleods Pharmaceuticals Limited, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment and prophylaxis of HIV/AIDS on 14 June 2013.

[HA526 trade name] is indicated for HIV treatment and prophylaxis. 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 [HA526 trade name] is the nucleoside reverse transcriptase inhibitor (NRTI), zidovudine.

The efficacy and safety of zidovudine are well established based on extensive clinical experience in the treatment of HIV infection.

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 zidovudine in HIV/AIDS, the team of assessors advised that [HA526 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA526 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA526 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	**14 June 2013**	**listed**
Pharmaceutical quality	31 May 2013	MR
Bioequivalence	16 May 2013	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	16 February 2011	MR
API	18 March 2011	MR
API	19 August 2011	MR
API	14 December 2011	MR
FPP	24 February 2012	MR
GCP/GLP (re-)inspection	NA	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

Requalification	16 June 2020	MR