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 products for the treatment of HIV/AIDS on 14 June 2013.

[HA526 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 (API) of [HA526 trade name] is the nucleoside reverse transcriptase inhibitor (NRTI), zidovudine. The API is well established and documented for the treatment of HIV/AIDS in combination with other products.

The efficacy and safety profile of zidovudine is 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 combination therapy 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]:

Initial Acceptance	**Date**	**Outcome**
Status on PQ list	14 June 2013	listed
Quality	31 May 2013	MR
Bioequivalence	16 May 2013	MR
Safety, Efficacy	NA	NA
Inspection Status		
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

MR: meets requirements
NA: not applicable, not available

Requalification	16 June 2020	MR

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