WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA521 trade name]*

Lamivudine/zidovudine 150 mg/300 mg tablets

[HA521 trade name], manufactured at Hetero Labs, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 14 June 2013.

[HA521 trade name] is indicated for treatment of HIV-1 infection as part of antiretroviral combination therapy. 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 ingredients of [HA521 trade name] are the nucleoside reverse transcriptase inhibitors (NRTIs), lamivudine and zidovudine. Each active pharmaceutical ingredient, marketed as the therapeutic component of single products and in fixed-dose combinations, is well-established and documented for the treatment of HIV/AIDS in combination with other products.

The combination of lamivudine and zidovudine has been investigated in several clinical trials in both treatment-naïve and treatment-experienced patients. These studies have demonstrated a clinically relevant reduction in disease progression and mortality as well as a significant decrease in HIV-1 viral load and an increase in CD4 cell counts.

The efficacy and safety of lamivudine and 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 lamivudine and zidovudine in the treatment of HIV/AIDS, the team of assessors advised that HA521 is of acceptable quality, efficacy and safety to allow inclusion of HA521 in the list of prequalified medicinal products.

Summary of prequalification status for [HA521 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	06 June 2013	MR
Bioequivalence	01 Feb 2013	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs (lamivudine and zidovudine)	27 Jan 2011	MR
FPP	13 Feb 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	04 September 2020