WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA521 trade name]*

International Nonproprietary Name (INN)/strength/pharmaceutical form
lamivudine/zidovudine 150mg/300mg tablets

Abstract

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

[HA521 trade name] are indicated for the treatment of HIV-1 infection in combination with at least one other antiretroviral agent. 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 [HA521 trade name] are the nucleoside reverse transcriptase inhibitors (NRTIs), lamivudine and zidovudine. Each API, marketed as the therapeutic component of single products and in fixed-dose combination, 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 clinically relevant reduction in disease progression and mortality as well as significant decrease in HIV-1 viral load and increase in CD4-cell count.

The efficacy and safety profile of lamivudine and 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 accepted [HA521 trade name] for the list of prequalified medicinal products.

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

Summary of Prequalification Status for [HA521 trade name]:

	Initial Acceptance	
	Date	**Outcome**
Status on PQ list, i.e. date of listing	14 June 2013	listed
Dossier Evaluation (Quality assurance)		
Quality	06 June 2013	MR
Bioequivalence	01 Feb 2013	MR
Safety, Efficacy	NA	NA
Inspection Status		
GMP(re-)inspection		
API 1+ 2	27 Jan 2011	MR
FPP	13 Feb 2012	MR
GCP (re-)inspection	NA	MR
Batch Analysis	NA	NA

MR: meets requirements
NA: not applicable, not available