WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA490 trade name] *

International Nonproprietary Name (INN):
lamivudine/zidovudine 150 mg/300 mg tablets

Abstract

[HA490 trade name], manufactured at Universal Corporation Ltd, Kikuyu, Kenya was accepted, in principle, for the WHO list of prequalified products for the treatment of HIV/AIDS on 21 October 2011.

[HA490 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 [HA490 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 [HA490 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 [HA490 trade name]:

	Initial Acceptance	
	Date	**Outcome**
Status on PQ list, i.e. date of listing	21 Oct 2011	listed
Dossier Evaluation		
Quality	24 Jun 2011	MR
Bioequivalence	12 Oct 2011	MR
Safety, Efficacy	NA	NA
Inspection Status		
GMP(re-)inspection		
APIs	18 Mar 2011	MR
FPP	16 Jun 2011	MR
GCP (re-)inspection	16 June 2011 (additional data provided 13 Oct 2011)	MR
Batch Analysis	NA	NA

MR: Meets Requirements
NA: not applicable, not available