WHO Pre-Qualification Project
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA060 trade name]*

International Nonproprietary Names (INN)/strength/pharmaceutical form
Lamivudine / Zidovudine 150mg/300mg film-coated tablets

Abstract

[HA060 trade name], manufactured at Cipla Ltd, Vikhroli, Mumbai, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 5 May 2003. Due to the outcome of a WHO inspection the product was removed from the list of Prequalified medicines on 27 May 2004. Following submission of new bioequivalence data and re-inspection, [HA060 trade name] was re-listed on 30 November 2004.

[HA060 trade name] is indicated for the treatment of HIV infection in combination with at least one other antiretroviral drug. 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 (APIs) of [HA060 trade name] are the nucleoside reverse transcriptase inhibitors (NRTI) lamivudine and zidovudine. Both APIs are marketed either alone or as components of fixed-dose combinations. Each 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 significant decrease in HIV-1 viral load and increase in CD4-cell count. Clinical end-point data indicate that therapy with lamivudine and zidovudine (in combination with one or more other antiretroviral agents) results in significant reduction in disease progression and mortality rate. With extensive clinical experience in the treatment of HIV infection, the efficacy and adverse-effect profile of lamivudine and zidovudine are well established.

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 infection, the team of assessors advised that [HA060 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA060 trade name] in the list of prequalified medicinal products.

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

Summary of the Prequalification Status for [HA060 trade name]:

	Initial Acceptance		**De-listed**		**Re-listed**	
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	5 May 03	listed	27 May 04	de-listed	30 Nov 04	re-listed
Dossier Evaluation						
Quality	31 Jan 03	MR				
Bioequivalence	24 Jan 02	MR			23 Nov 04	MR
Safety, Efficacy						
GMP (re-)inspection						
API						
FPP	8 Oct 01	MR				
GCP (re-)inspection			19 May 04	Critical	29 Nov 04	MR
Batch Analysis						

MR: meets requirements

The table represents the status of relevant completed activities only.

Requalification	18 April 2019	MR

MR: meets requirements