WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Lamivudine and Zidovudine Tablets 150 mg + 300 mg*

International Nonproprietary Names (INNs):
Lamivudine
Zidovudine

Abstract

Lamivudine and Zidovudine Tablets 150 + 300 mg manufactured at Ranbaxy Laboratories Limited, Himachal Pradesh, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 11 August 2005.

Lamivudine and Zidovudine Tablets 150 + 300 mg 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 Lamivudine and Zidovudine Tablets 150 + 300 mg 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.

The most frequent adverse events observed during treatment were headache, nausea, vomiting, abdominal pain, diarrhoea, myalgia, rash, hair loss, and fatigue.

The most serious safety concerns with the combination relates to zidovudine: it can cause severe anaemia, neutropenia, and leucopenia. In patients with chronic hepatitis B infection, discontinuation of lamivudine can lead to hepatic deterioration and hepatitis flare.

With extensive clinical experience in the treatment of HIV infection, the efficacy and adverse-effect profile of lamivudine and zidovudine are well established.

On the basis of data submitted and public information on the use of combination therapy in HIV infection, the team of assessors advised that Lamivudine and Zidovudine Tablets 150 + 300 mg is of acceptable quality, efficacy and safety to allow inclusion of Lamivudine and Zidovudine Tablets 150 + 300 mg in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is under local drug regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Summary of Prequalification Status for Lamivudine and Zidovudine Tablets 150 + 300 mg:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	11 August 2005	listed				
Dossier Evaluation						
Quality	13 July 2005	MR				
Bioequivalence	27 July 2005	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	26 May 2005	MR				
FPP	15 June 2005	MR				
GCP (re-)inspection	6 July 2005	MR				
Batch Analysis	NA	NA				

MR: meets requirements
NA: not applicable, not available