WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Lamivudine and Zidovudine 150mg/300mg Tablets*

International Nonproprietary Name (INN):
Lamivudine/Zidovudine 150mg/300mg Tablets

Abstract

Lamivudine and Zidovudine Tablets 150 mg/300 mg, manufactured at Shanghai Desano Bio-pharmaceutical Co., Ltd., Shanghai, China was accepted, in principle, for the WHO list of prequalified products for the treatment of HIV/AIDS on 21 July 2017.

Lamivudine and Zidovudine Tablets 150 mg/300 mg 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 Lamivudine and Zidovudine Tablets 150 mg/300 mg 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 most frequent adverse events were nausea and vomiting, abdominal pain, diarrhoea, elevation of liver enzymes and total bilirubin, myalgia, rash, headache, hair-loss and fatigue. The most important safety problems are related to zidovudine: it can cause severe anaemia, neutropenia and leucopenia. In patients with chronic hepatitis B infection discontinuation of lamivudine therapy can lead to hepatic deterioration and hepatitis flare.

The efficacy and safety profile of lamivudine and zidovudine is well established based on extensive clinical experience in the treatment of HIV infection.

On the basis of data submitted and public information on the use of combination therapy in HIV/AIDS, the team of assessors accepted Lamivudine and Zidovudine Tablets 150 mg/300 mg for the list of prequalified medicinal products.

*Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

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

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	21 July 2017	listed				
Dossier Evaluation (Quality assurance)						
Quality	07 May 2016	MR				
Bioequivalence	12 July 2017	MR				
Inspection Status						
GMP(re-)inspection						
APIs	NA	NA				
FPP	09 Jan 2015	MR				
GCP (re-)inspection	16 March 2016	MR				
GCP/GLP inspection	18 March 2016	MR				

MR: meets requirements
NA: not applicable, not available