WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Lamivudine and Zidovudine 150 mg/300 mg Tablets[1]

International Nonproprietary Name (INN):
Lamivudine/Zidovudine

Abstract

Lamivudine and Zidovudine 150 mg/300 mg Tablets, manufactured at Anhui Biochem Bio-Pharmaceutical Co. Ltd, Hefei city, China was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 18 December 2018.

Lamivudine/Zidovudine 150 mg/300 mg Tablets is indicated in combination with another antiretroviral agent for the treatment of human immunodeficiency virus (HIV) infection in adults, adolescents and children weighing over 25 kg. 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(s) of Lamivudine and Zidovudine 150 mg/300 mg Tablets are the nucleoside reverse transcriptase inhibitors (NRTIs) lamivudine and zidovudine.

The most frequent adverse events observed during treatment with lamivudine/zidovudine were nausea, vomiting, abdominal pain, diarrhoea, elevation of liver enzymes and total bilirubin, myalgia, rash, headache, hair loss and fatigue.

The most serious safety concerns with lamivudine/zidovudine are related to zidovudine which 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 the extensive clinical experience in the treatment of HIV/AIDS.

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

[1] 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 USP, 150 mg/300 mg: HA656

Initial acceptance	**Date**	**Outcome**
Status on PQ list	18 Dec 2018	listed
Quality	06 Nov 2018	MR
Bioequivalence	07 Nov 2018	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
APIs	23 Jan 2016	MR
FPP	18 Aug 2018	MR
GCP/GLP (re-)inspection	03 Aug 2018	MR

MR: meets requirements
NA: not applicable, not available