WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

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

International Nonproprietary Names (INN):
Lamivudine / Zidovudine

Abstract

Lamivudine Zidovudine 150 mg/300 mg Tablets, manufactured at Strides Pharma Science Limited (formerly Strides Shasun Limited), Bangalore, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 30 June 2006.

Lamivudine/Zidovudine 150 mg/300 mg Tablets is 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 ingredients (APIs) of Lamivudine/Zidovudine 150 mg/300 mg Tablets are the nucleoside reverse transcriptase inhibitors (NRTIs) lamivudine and zidovudine. Each of these APIs, marketed as the therapeutic component of single products, 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 decreases in HIV-1 viral load and increases in CD4-cell count.

The most frequent adverse events observed during treatment were nausea and vomiting, abdominal pain, diarrhoea, elevation of liver enzymes and total bilirubin, myalgia, rash, headache, hairloss 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 advised that Lamivudine/Zidovudine 150 mg/300 mg Tablets is of acceptable quality, efficacy and safety to allow inclusion of Lamivudine/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.

*Formerly Strides Arcolab Limited and then Strides Shasun Limited

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

Initial acceptance	**Date**	**Outcome**
Status on PQ list	30 June 2006	listed
Quality	31 May 2006	MR
Bioequivalence	02 March 2006	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	26 May 2005	MR
API	18 May 2004	MR
FPP	27 May 2006	MR
GCP/GLP (re-)inspection	NA	NA

MR: meets requirements
NA: not applicable, not available

Requalification

Status on PQ list	06 July 2018	MR

MR: Meets requirements

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