WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets*

International Nonproprietary Names (INN)
Lamivudine/tenofovir disoproxil fumarate

Abstract

Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets , manufactured at Cipla Limited, Maharashtra, India was included in the WHO list of prequalified products for the treatment of HIV/AIDS on 21 December 2016.

Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets is indicated in combination with other antiretroviral products for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults and patients from 10 years of age and weighing at least 30 kg.

Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets may be used for pre-exposure exposure prophylaxis (PrEP) in adults and patients weighing at least 35 kg at substantial risk of HIV infection.

Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 Tablets may be used for post exposure prophylaxis (PEP) in adults and patients weighing at least 30 kg with an exposure that has potential for HIV transmission.

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/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets are the nucleoside reverse transcriptase inhibitor lamivudine and the nucleotide reverse transcriptase inhibitor tenofovir disoproxil fumarate.

The APIs, as separate formulations, have been investigated in antiretroviral combination therapy in several clinical trials, in both treatment-naïve and treatment-experienced patients.

The most frequent adverse events observed during treatment with lamivudine and tenofovir disoproxil fumarate were hypophosphataemia, dizziness, diarrhoea, nausea and vomiting.

The most serious safety concerns with lamivudine and tenofovir disoproxil fumarate are renal failure and proximal renal tubulopathy.
Discontinuation of therapy with lamivudine and tenofovir disoproxil fumarate in patients co-infected with HIV and HBV may be associated with severe acute exacerbations of hepatitis.

The efficacy and safety profile of lamivudine and tenofovir disoproxil fumarate is well established based on extensive clinical experience in the treatment of HIV/AIDS.

On the basis of data submitted and public information on the use of lamivudine and tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets of acceptable quality, efficacy and safety to allow inclusion of Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets in 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/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	21 Dec 2016	listed				
Dossier Evaluation (Quality assurance)						
Quality	08 Dec 2016	MR				
Bioequivalence	23 July 2016	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	07 March 2014	MR				
API	18 Sept 2014	MR				
API	22 Aug 2016	MR				
API	22 Aug 2016	MR				
FPP	14 Feb 2014	MR				
GCP/GLP (re-)inspection	NA	NA				

MR: meets requirements
NA: not applicable, not available