WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

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

International Nonproprietary Names (INN)/strength/pharmaceutical form
lamivudine/tenofovir disoproxil fumarate 300mg/300mg film-coated tablets

Abstract

Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets, manufactured at Matrix Laboratories Limited, Nashik, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 30 June 2010.

Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets is indicated in combination with at least one other antiretroviral medicinal product for the treatment of HIV-1 infected adults over 18 years of age.
Detailed information on the use of this product is described in the Summary of Product Characteristics (SPC), which can be found in this WHOPAR.

The active pharmaceutical ingredient (API) of Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets are the nucleoside reverse transcriptase inhibitors lamivudine and the nucleotide reverse transcriptase inhibitor tenofovir disoproxil fumarate. The APIs have been investigated in combination therapy in several clinical trials, in both treatment-naïve and treatment-experienced patients.

The most frequent adverse reactions observed during treatment of HIV/AIDS were hypophosphataemia, dizziness, headache, insomnia, cough, nasal symptoms, diarrhoea, vomiting, nausea, flatulence, abdominal pain/cramps, rash, hair loss, arthralgia, muscle disorder, fatigue, malaise and fever.

The most important safety problems with Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets are acute renal failure, renal failure and proximal renal tubulopathy. Discontinuation of therapy with Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets in patients co-infected with HIV and HBV may be associated with severe acute exacerbations of hepatitis.

The efficacy and safety profile of Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets 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 300mg/300mg Tablets is of acceptable quality, efficacy and safety to allow inclusion of Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets in the list of prequalified medicinal products.

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

Summary of Prequalification Status for Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300 mg Tablets:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	30 June 2010	listed				
Dossier Evaluation						
Quality	19 May 2010	MR				
Bioequivalence	24 Sept 2009	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP (re-)inspection						
APIs	28 May 2009	MR				
FPP	11 Aug 2009	MR				
GCP (re-)inspection	21 July 2009	MR				

MR: meets requirements
NA: not applicable, not available