WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA514 trade name]*

International Non-proprietary Names (INNs):
Lamivudine/Tenofovir disoproxil fumarate 300 mg/300 mg Tablets

Abstract

[HA514 trade name], manufactured at Macleods Pharmaceutical Limited, Daman, India was accepted for the WHO list of prequalified products for the treatment of tuberculosis on 10 April 2014.

[HA514 trade name] is indicated in combination with at least one other antiretroviral medicinal product for the treatment of HIV-1 infection in adults and children weighing at least 30 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 ingredients (APIs) of [HA514 trade name] are the nucleoside reverse transcriptase inhibitor lamivudine and the nucleotide reverse transcriptase inhibitor tenofovir disoproxil fumarate

The efficacy and safety profile of Lamivudine and tenofovir disoproxil fumarate are well established based on extensive clinical experience in the treatment of HIV/AIDS.
For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

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 [HA514 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA514 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [HA514 trade name]:

	Initial Acceptance	
	Date	**Outcome**
Status on PQ list, i.e. date of listing	10 April 2014	Listed
Quality	21 March 2014	MR
Bioequivalence	02 April 2014	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	14 June 2012	MR
API	24 May 2013	MR
FPP	24 Feb 2012	MR
GCP/GLP (re-)inspection	12 Feb 2013	MR

MR: Meets Requirements
NA: Not applicable, not available

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.