WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA620 trade name][1]

Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets

[HA620 trade name], manufactured at Micro Labs Limited, Verna, Goa, India was included in the WHO list of prequalified products for the treatment of HIV/AIDS on 9 July 2015.

[HA620 trade name] is indicated in combination with at least one other antiretroviral medicinal product for the treatment of human immunodeficiency virus (HIV-1) infection in patients 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 [HA620 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 is 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 [HA620 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA620 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [HA620 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	09 July 2015	listed
Quality	29 May 2015	MR
Bioequivalence	29 June 2015	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	07 March 2014	MR
API	18 September 2014	MR
FPP	17 October 2014	MR
GCP/GLP (re-)inspection	NA	NA

MR: meets requirements
NA: not applicable, not available

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