

**WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

[HA644 trade name] *
Lamivudine

Abstract

[HA644 trade name] manufactured at Micro Labs Ltd, Verna Industrial Estate, Goa, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 26 October 2016.

[HA644 trade name] is indicated in combination with other antiretroviral agents for the treatment of Human Immunodeficiency Virus (HIV-1) infected adults, adolescents and children weighing at least 25 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 ingredient (API) of [HA644 trade name] is the nucleoside reverse transcriptase inhibitor (NRTI) lamivudine. This API is well-established and documented for the treatment of HIV/AIDS in combination with other products.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

The efficacy and safety profile of [HA644 trade name] is well established, based on extensive clinical experience in the treatment of HIV.

On the basis of data submitted and public information on the use of combination therapy in HIV infection, the team of assessors advised that [HA644 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA644 trade name] in the list of prequalified medicinal products.

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

Summary of Prequalification Status for [HA644 trade name]:

	Initial Acceptance					
	Date	Outcome	Date	Outcome	Date	Outcome
Status on PQ list, i.e. date of listing	26 Oct 2016					
Dossier Evaluation (Quality assurance)						
Quality	05 Oct 2016	MR				
Bioequivalence	18 Oct 2016	MR				
Safety, Efficacy		MR				
Inspection Status						
GMP(re-)inspection						
API	07 March 2014	MR				
API	18 Sept 2014	MR				
FPP	18 June 2016	MR				
GCP/GLP (re-)inspection	NA	NA				

MR: meets requirements

NA: not applicable, not available