WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA631 trade name][1]

International Nonproprietary Names (INN)/strength/pharmaceutical form
emtricitabine/tenofovir disoproxil fumarate 200 mg/300 mg tablets

Abstract

[HA631 trade name], manufactured at Micro Labs Limited, Verna, Goa, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 27 May 2016.

[HA631 trade name] is indicated in combination with at least one other antiretroviral product for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults and adolescents over 10 years of age and weighing at least 30 kg. [HA631 trade name] may be used for pre-exposure prophylaxis in adults and adolescents (weighing at least 35 kg) at substantial risk of HIV infection.

The active pharmaceutical ingredients (APIs) of [HA631 trade name] are the nucleoside reverse transcriptase inhibitor emtricitabine and the nucleotide reverse transcriptase inhibitor tenofovir disoproxil fumarate. The APIs have been investigated in several clinical trials for pre-exposure prophylaxis and in combination therapy with other antiretrovirals for the treatment of HIV, in both treatment-naïve and treatment-experienced patients.

The efficacy and safety profile of emtricitabine 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 emtricitabine and tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that [HA631 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA631 trade name] in the list of prequalified medicinal products.

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

Summary of Prequalification Status for [HA631 trade name]:

Initial Acceptance	**Date**	**Outcome**
Status on PQ list,	27 May 2016	listed
Dossier Evaluation (Quality assurance)		
Quality	18 March 2016	MR
Bioequivalence	04 April 2016	MR
Safety, Efficacy	NA	NA
Inspection Status		
GMP(re-)inspection		
API	07 March 2014	MR
API	18 Sept 2014	MR
API	17 April 2015	MR
API	04 Dec 2015	MR
FPP	17 Oct 2014	MR
GCP (re-)inspection	18 March 2016	MR

MR: meets requirements
NA: not applicable, not available