WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA439 trade name][*]

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

Abstract

[HA439 trade name], manufactured at Cipla Ltd, Verna Industrial Estate, Goa, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 5 October 2011.

[HA439 trade name] is indicated in combination with at least one other antiretroviral product for the treatment of HIV-1 infection in adults and adolescents over 10 years of age and weighing at least 30 kg. [HA439 trade name] may be used in combination with other measures for pre-exposure prophylaxis (PrEP) in adults and adolescents (weighing at least 35 kg) at substantial risk of HIV infection.

The active pharmaceutical ingredients (APIs) of [HA439 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 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 [HA439 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA439 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 [HA439 trade name]:

Initial Acceptance	**Date**	**Outcome**
Status on PQ list	5 Oct 2011	listed
Dossier Evaluation		
Quality	30 Aug 2011	MR
Bioequivalence	6 July 2011	MR
Safety, Efficacy	NA	NA
Inspection Status		
GMP (re-)inspection		
APIs	10-12 Feb 2011	MR
FPP	6-9 Sept 2010	MR
GCP (re-)inspection	25-26 Sept 2011	MR

MR: meets requirements
NA: not applicable, not available

Requalification	19 December 2019	MR

MR: meets requirements