WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA498 trade name][*]

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

Abstract

[HA498 trade name], manufactured at Hetero Labs Limited, Telangana, India, was included in the WHO list of prequalified medicinal products for the prophylaxis and treatment of HIV/AIDS on 24 June 2013.

[HA498 trade name] is indicated in combination with at least one other antiretroviral product for the treatment of HIV-1 infected adults and adolescents over 10 years of age and weighing at least 30 kg. [HA498 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 [HA498 trade name] are the nucleoside reverse transcriptase inhibitor emtricitabine and the nucleotide reverse transcriptase inhibitor tenofovir disoproxil (as fumarate). The APIs have been investigated in several clinical trials for pre-exposure prophylaxis and in combination with other antiretrovirals for treatment of HIV, in both treatment-naïve and treatment-experienced patients.

The efficacy and safety profile of emtricitabine and tenofovir disoproxil 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 in HIV/AIDS, the team of assessors advised that [HA498 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA498 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 [HA498 trade name]:

Initial Acceptance	**Date**	**Outcome**
Status on PQ list	24 June 2013	listed
Dossier Evaluation (Quality assurance)		
Quality	17 June 2013	MR
Bioequivalence	12 June 2013	MR
Safety, Efficacy	NA	NA
Inspection Status		
GMP(re-)inspection		
API	27 Jan 2011	MR
FPP	16 Feb 2012	MR
GCP/GLP (re-)inspection	18 Feb 2013	MR
Batch Analysis	NA	NA

MR: meets requirements
NA: not applicable, not available