WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA516 trade name][*]

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

Abstract

[HA516 trade name], manufactured at Macleods Pharmaceuticals Ltd, Kachigam, Daman, India, and Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS and hepatitis B on 23 May 2013.

[HA516 trade name] is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infection in patients weighing 30 kg or more and for pre-exposure prophylaxis (PrEP) as an additional prevention choice for adults and adolescents (weighing at least 35 kg). It is also indicated for the treatment of chronic hepatitis B in adults with compensated liver disease and evidence immune active disease, adults with evidence of lamivudine-resistant hepatitis B virus, and adults with decompensated liver disease.

The active pharmaceutical ingredient (API) of [HA516 trade name] is the nucleotide reverse transcriptase inhibitor tenofovir disoproxil fumarate. The API has been investigated in combination therapy in several clinical trials, in both treatment-naïve and treatment-experienced patients.

The efficacy and safety profile of [HA516 trade name] is well established based on extensive clinical experience in the treatment of HIV/AIDS and hepatitis B.

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 tenofovir disoproxil fumarate in HIV/AIDS and hepatitis B, the team of assessors advised that [HA516 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA516 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 [HA516 trade name]:

	Initial Acceptance	
	Date	**Outcome**
Status on PQ list	23 May 2013	listed
Dossier Evaluation		
Quality	13 May 2013	MR
Bioequivalence	15 May 2013	MR
Safety, Efficacy	NA	NA
Inspection Status		
GMP (re-)inspection		
API	NA	NA
FPP	NA	NA
GCP (re-)inspection	NA	NA

MR: meets requirements
NA: not applicable, not available

Requalification	18 December 2019	MR

MR: meets requirements