WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA551 trade name]*

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

Abstract

[HA551 trade name], manufactured at Sun Pharmaceutical Industries Limited, Himachal Pradesh, India was included in the WHO list of prequalified medicinal products for the prophylaxis and treatment of HIV/AIDS on 12 February 2015.

[HA551 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. [HA551 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.

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 ingredients (APIs) of [HA551 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 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 [HA551 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA551 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.
† Formerly Ranbaxy Laboratories Limited.

Summary of Prequalification Status for [HA551 trade name]

Initial acceptance	Date	Outcome
Status on PQ list	12 Feb 2015	listed
Dossier Evaluation (Quality assurance)		
Quality	27 Jan 2015	MR
Bioequivalence	04 Feb 2015	MR
Safety, Efficacy	NA	NA
Inspection Status		
GMP(re-)inspection		
APIs	07 March 2014	MR
APIs	18 Sept 2014	
FPP	16 March 2012	MR
GCP/GLP (re-)inspection	NA	NA

MR: meets requirements
NA: not applicable, not available