WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA717 trade name]*

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

Abstract

[HA717 trade name], manufactured at Laurus Labs Ltd, Atchutapuram Mandal, Andhra Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 22 August 2019.

[HA717 trade name] is indicated for HIV-1 infection in adults and adolescents over 10 years of age and weighing at least 30 kg. 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 ingredient(s) (APIs) of [HA717 trade name] are the nucleoside reverse transcriptase inhibitor emtricitabine, and the nucleotide reverse transcriptase inhibitor tenofovir disoproxil fumarate.

The efficacy and safety profile of emtricitabine and tenofovir disoproxil fumarate combination 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 [HA717 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA717 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [HA717 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	22 Aug 2019	listed
Quality	01 Aug 2019	MR
Bioequivalence	09 Aug 2019	MR
Safety, Efficacy	NA	NA
GMP (re-)inspection		
APIs	07 Sept 2017	MR
FPP	13 March 2017	MR
GCP/GLP (re-) inspection		
GLP (re-)inspection	19 Oct 2018	MR

MR: meets requirements
NA: not applicable, not available

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