WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA715 trade name]*

Emtricitabine/Tenofovir Disoproxil Fumarate 200mg/300mg Tablets

Abstract

[HA715 trade name], manufactured at Lupin Limited, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 05 February 2020.

[HA715 trade name] is indicated in combination with other antiretroviral products for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults and adolescents from 10 years of age and weighing at least 30 kg. [HA715 trade name] may be used for pre-exposure prophylaxis 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 [HA715 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 is well established based on extensive clinical experience in the treatment of HIV/AIDS.

On the basis of data submitted and public information on the use of [HA715 trade name] in HIV/AIDS, the team of assessors advised that [HA715 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA715 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [HA715 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	05 Feb 2020	listed
Quality	23 Jan 2020	MR
Bioequivalence	24 Jan 2020	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	26 Aug 2019	MR*
API	07 Sept 2017	MR
FPP	21 Sept 2018	MR
GCP/GLP (re-)inspection	23 Feb 2018	MR

MR: meets requirements
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available

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