WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA703 trade name][*]

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

Abstract

[HA703 trade name], manufactured at Lupin Limited, Nagpur, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 18 December 2019.

[HA703 trade name] is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in patients weighing at least 30 kg or more. It may also be used for pre-exposure prophylaxis (PrEP) as an additional prevention choice for adults and adolescents (weighing at least 35 kg) at substantial risk of HIV infection as part of combination prevention approaches.

The active pharmaceutical ingredients (APIs) of [HA703 trade name] are the nucleoside reverse transcriptase inhibitor lamivudine and the nucleotide reverse transcriptase inhibitor tenofovir disoproxil fumarate. The APIs, as separate formulations, have been investigated in antiretroviral combination therapy in several clinical trials, in both treatment-naïve and treatment-experienced patients.

The efficacy and safety profile of lamivudine and tenofovir disoproxil fumarate is well established based on extensive clinical experience in the prevention and 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 lamivudine and tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that [HA703 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA703 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 [HA703 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	18 Dec 2019	listed
Quality	16 Dec 2029	MR
Bioequivalence	17 Dec 2019	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	07 Sept 2017	MR
API	26 Aug 2019	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