

**WHO Prequalification Programme**  
**WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**  
**[HA666 trade name]\***

Lamivudine/tenofovir disoproxil fumarate 300 mg/300 mg tablets

[HA666 trade name], manufactured at Cipla Limited, Maharashtra, India, was included in the WHO prequalified medicinal products for the treatment of human immunodeficiency virus (HIV) infection on 21 December 2016.

[HA666 trade name] is indicated in combination with other antiretroviral medicines, for the treatment of human immunodeficiency virus (HIV) infection in patients weighing at least 30 kg. [HA666 trade name] may also be used in these patients as part of regimens for pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) for HIV. 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 of [HA666 trade name] are lamivudine and tenofovir disoproxil fumarate.

The efficacy and safety of lamivudine and tenofovir disoproxil fumarate is well established based on extensive clinical experience in the treatment of human immunodeficiency virus (HIV) infection.

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 therapy in human immunodeficiency virus (HIV), the team of assessors advised that [HA666 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA666 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [HA666 trade name]:**

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	Date	Outcome
Status on PQ list	21 December 2016	Listed
Pharmaceutical quality	08 December 2016	MR
Bioequivalence	23 July 2016	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
API	07 March 2014	MR
API	18 September 2014	MR
API	22 August 2016	MR
API	22 August 2016	MR
FPP	14 February 2014	MR
<b>GCP/GLP (re-)inspection</b>	NA	NA
API: active pharmaceutical ingredient FPP: finished pharmaceutical product GCP: good clinical practice [quality standard] GLP: good laboratory practice [quality standard]	GMP: good manufacturing practice [quality standard] MR: meets requirements MR*: desk review (based on recent inspection reports) NA: not applicable, not available PQ: prequalification	
<b>Requalification</b>	15 August 2023	MR

MR: meets requirements

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