WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA770 trade name][*]

Efavirenz/Lamivudine/Tenofovir disoproxil fumarate 400 mg/300 mg/300 mg Tablets

[HA770 trade name], manufactured at Cipla Ltd, Patalganga, Maharashtra, India and Cipla Quality Chemical Industries Limited (Cipla QCIL), Kampala, Uganda, and was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 02 May 2023.

[HA770 trade name] is indicated for treatment of human immunodeficiency virus type 1 (HIV-1) infection in patients 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 ingredients of [HA770 trade name] are efavirenz, lamivudine and tenofovir disoproxil fumarate.

The efficacy and safety of efavirenz, lamivudine and tenofovir disoproxil fumarate are 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 efavirenz/lamivudine/tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that [HA770 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA770 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 [HA770 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	02 May 2023	listed
Quality	20 January 2023	MR
Bioequivalence	22 January 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	18 January 2019	MR
API	26 August 2019	MR*
FPP	30 October 2020	MR*
FPP	22 September 2022	MR
GCP/GLP (re-)inspection	23 March 2023	MR

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

The table represents the status of relevant completed activities only.