WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA727 trade name]*

Efavirenz/lamivudine/tenofovir disoproxil fumarate 600 mg/300 mg/300 mg tablets

[HA727 trade name], manufactured at Laurus Labs Limited, (Unit-II), Atchutapuram Mandal Andhra Pradesh, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 12 June 2020.

[HA727 trade name] is indicated for the treatment of human immunodeficiency virus type-1 (HIV-1) infection in adults and adolescents weighing at least 35 kg.

The active pharmaceutical ingredients (APIs) of [HA727 trade name] are the non-nucleoside reverse transcriptase inhibitor efavirenz, the nucleoside reverse transcriptase inhibitor lamivudine and the nucleotide reverse transcriptase inhibitor tenofovir disoproxil fumarate.

The APIs, as separate formulations, have been investigated in combination therapy in several clinical trials, in both treatment-naïve and treatment-experienced patients.

The efficacy and safety profile of efavirenz, lamivudine and tenofovir disoproxil fumarate is well established based on extensive clinical experience in the treatment of 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 combination therapy in HIV/AIDS, the team of assessors advised that [HA727 trade name], is of acceptable quality, efficacy and safety to allow the inclusion of [HA727 trade name], in the list of prequalified medicinal products.

Summary of Prequalification Status for [HA727 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	**12 June 2020**	**listed**
Quality	30 May 2020	MR
Bioequivalence	04 June 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	07 September 2017	MR
FPP	17 March 2017	MR
GCP/GLP (re-)inspection		
GCP (re-)inspection	05 March 2019	MR
GCP/GLP (re-)inspection	07 March 2019	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
NA: not applicable, not available
PQ: prequalification

The table represents the status of relevant completed activities only.

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