WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA764 trade name]*

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

[HA764 trade name], manufactured at Aizant Drug Research Solutions Pvt. Ltd., Dundigal-Gandimaisamma Mandal, Hyderabad-500 100, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 15 July 2022.

[HA764 trade name] is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in patients weighing at least 35 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 [HA764 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 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 efavirenz, lamivudine and tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that [HA764 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA764 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA764 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	15 July 2022	listed
Quality	09 July 2022	MR
Bioequivalence	15 July 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	18 January 2019	MR
FPP	11 March 2022	MR
GCP/GLP (re-)inspection	11 March 2022	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.