

## WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

### [HA766 trade name]\*

Efavirenz/lamivudine/tenofovir disoproxil fumarate 400mg/300mg/300mg tablets

[HA766 trade name], manufactured at Aizant Drug Research Solutions Pvt. Ltd., Hyderabad, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 24 November 2022.

[HA766 trade name] is indicated for the treatment of Human Immunodeficiency Virus Type1 (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 [HA766 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 and tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that [HA766 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA766 trade name] in the list of prequalified medicinal products.

#### Summary of prequalification status for [HA766 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	24 November 2022	listed
Quality	04 November 2022	MR
Bioequivalence	15 November 2022	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
APIs	18 January 2019	MR
FPP	29 June 2022	MR*
<b>GCP/GLP (re-)inspection</b>	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 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.

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