

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA767 trade name]*

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

[HA767 trade name], manufactured at Micro Labs Ltd, Verna, Goa, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 28 June 2022.

[HA767 trade name] is indicated for HIV-1. 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 [HA767 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 efficacy and safety of efavirenz/lamivudine/tenofovir disoproxil fumarate combination 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 [HA767 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA767 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA767 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	28 June 2022	listed
Quality	14 June 2022	MR
Bioequivalence	20 June 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	01 October 2019	MR
FPP	12 April 2019	MR*
GCP/GLP (re-)inspection	08 April 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.