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

## [HA759 trade name]*

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

[HA759 trade name], manufactured at Hetero Labs Limited, Telangana State, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 28 June 2022.

[HA759 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 [HA759 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 [HA759 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA759 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [HA759 trade name]:**

| **Initial acceptance** | **Date** | **Outcome** |
|---|---|---|
| **Status on PQ list** | 28 June 2022 | listed |
| Quality | 31 May 2022 | MR |
| Bioequivalence | 20 June 2022 | MR |
| Safety, efficacy | NA | NA |
| **GMP (re-)inspection** | | |
| API | 01 October 2019 | MR* |
| FPP | 05 September 2020 | MR* |
| **GCP/GLP (re-)inspection** | 23 September 2020 | 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.