

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA732 trade name]*

Efavirenz/Lamivudine/Tenofovir disoproxil fumarate 400mg/300mg/300mg Tablets

[HA732 trade name], manufactured at Laurus Labs Limited, Andhra Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 16 March 2020.

[HA732 trade name] is indicated for HIV treatment. 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 [HA732 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 [HA732 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA732 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA732 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

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

Initial acceptance	Date	Outcome
Status on PQ list	16 March 2020	listed
Pharmaceutical quality	26 February 2020	MR
Bioequivalence	28 February 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	07 September 2017	MR
FPP	17 March 2017	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 MR*: desk review (based on recent inspection reports) NA: not applicable, not available PQ: prequalification		

Requalification	01 December 2025
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