WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA737 trade name][*]

Dolutegravir (as sodium) /lamivudine/tenofovir disoproxil fumarate 50mg/300mg/300mg tablets

[HA737 trade name], manufactured at Lupin Limited, Nagpur, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of human immunodeficiency virus (HIV) on 09 December 2022.

[HA737 trade name] is indicated for treatment of HIV. 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 [HA737 trade name] are dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate.

The efficacy and safety of dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate are well established based on extensive clinical experience in the treatment of HIV.

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 dolutegravir/lamivudine/tenofovir disoproxil fumarate in HIV, the team of assessors advised that [HA737 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA737 trade name] in the list of prequalified medicinal products.

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

Summary of prequalification status for [HA737 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	09 December 2022	listed
Quality	07 November 2022	MR
Bioequivalence	17 November 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	26 September 2019	MR*
API	03 June 2020	MR*
API	13 August 2020	MR*
API	12 June 2022	MR*
FPP	21 January 2022	MR
GCP/GLP (re-)inspection	03 June 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.