WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA688 trade name]*

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

[HA688 trade name], manufactured at Mylan Laboratories Limited, Madhya Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 18 December 2018.

[HA688 trade name] is indicated for the treatment of human immunodeficiency virus (HIV) infection in adults and adolescents weighing at least 30 kg. [HA688 trade name] may also be used in these patients for post-exposure prophylaxis to 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 [HA688 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/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 dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that [HA688 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA688 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA688 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	18 December 2018	listed
Pharmaceutical quality	19 September 2018	MR
Bioequivalence	26 September 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	24 January 2015	MR
API	27 August 2015	MR
API	21 April 2016	MR
API	21 July 2017	MR
API	07 September 2017	MR
FPP	25 May 2018	MR
GCP/GLP (re-)inspection	07 November 2018	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	22 May 2024