WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA448 trade name]*

Lamivudine/tenofovir disoproxil fumarate 300 mg/300 mg tablets

[HA448 trade name], manufactured at Hetero Labs Limited, Hyderabad, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on September 2011.

[HA448 trade name] is indicated for is indicated in combination with another antiretroviral medicine for the treatment of human immunodeficiency virus (HIV) infection in adults and adolescents weighing at least 30 kg. 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 [HA448 trade name] are lamivudine and tenofovir disoproxil fumarate.

The efficacy and safety of 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 lamivudine and tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that [HA448 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA448 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA448 trade name]:

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

Initial acceptance	**Date**	**Outcome**
Status on PQ list	01 September 2011	listed
Pharmaceutical quality	25 July 2011	MR
Bioequivalence	14 June 2011	MR
Safety, efficacy	NA	MR
GMP (re-)inspection		
API	27 January 2011	MR
FPP	28 August 2009	MR
GCP/GLP (re-)inspection	NA	NA

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

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

Requalification	06 May 2020