WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA668 trade name]*

Lamivudine 300 mg Tablets

[HA668 trade name], manufactured at Beximco Pharmaceuticals Limited, Tongi, Gazipur, Bangladesh, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 21 January 2019.

[HA668 trade name] is indicated in combination with other antiretroviral agents for the treatment of of HIV-1 infection in adults, adolescents and children weighing at least 25 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 ingredient of [HA668 trade name] is lamivudine.

The efficacy and safety of lamivudine 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 in HIV/AIDS, the team of assessors advised that [HA668 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA668 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA668 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	21 January 2019	Listed
Quality	23 December 2018	MR
Bioequivalence	04 January 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	01 October 2019	MR*
FPP	12 March 2020	MR
GCP/GLP (re-)inspection	27 October 2017	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.