WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA740 trade name][1]

Abacavir (as sulfate)/Lamivudine 600 mg/300 mg tablets

[HA740 trade name], manufactured at Macleods Pharmaceuticals Limited, Tehsil Baddi, Dist. Solan, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 11 May 2021.

[HA740 trade name], is indicated in combination with other antiretroviral agents for the treatment of Human Immunodeficiency Virus (HIV) 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 ingredients of [HA740 trade name] are abacavir (as sulfate) and lamivudine.

The efficacy and safety of abacavir (as sulfate) and lamivudine 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 abacavir (as sulfate) and lamivudine in HIV/AIDS, the team of assessors advised that [HA740 trade name], is of acceptable quality, efficacy and safety to allow inclusion of [HA740 trade name], in the list of prequalified medicinal products.

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

Summary of Prequalification Status for [HA740 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	**11 May 2021**	listed
Quality	08 February 2021	MR
Bioequivalence	11 February 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	26 August 2019	MR*
APIs	01 October 2019	MR*
FPP	23 October 2019	MR
GCP/GLP (re-)inspection	01 September 2020	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.