WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA424trade name]*

Lamivudine 150 mg Tablets

[HA424 trade name], manufactured at Macleods Pharmaceuticals Limited, Kachigam, Daman, India, and Macleods Pharmaceuticals Limited Tehsil Baddi, Solan, Himachal Pradesh India, and was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 14 December 2010.

[HA424 trade name] is indicated in combination with other antiretroviral agents for the treatment of Human Immunodeficiency Virus (HIV) infected 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 [HA424 trade name] is lamivudine.

The efficacy and safety of lamivudine is well established based on extensive clinical experience in the treatment of HIV infection.

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 [HA424 trade name] in HIV/AIDS, the team of assessors advised that [HA424 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA424 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA424 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	14 Dec 2010	listed
Quality	15 Sep 2010	MR
Bioequivalence	NA	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	Oct 2006	MR
API	6 June 2009	MR
API	27 March 2009	MR
FPP	Feb 2010	MR
GCP/GLP (re-)inspection	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.

The table represents the status of relevant completed activities only.

Requalification	13 May 2019