WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA523trade name]*

Lamivudine10 mg/mL Oral Solution

[HA523 trade name], manufactured at Macleods Pharmaceuticals Limited, Tehsil Baddi, Solan, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 5 February 2013.

[HA523 trade name] is indicated for the treatment of HIV-1 infection in infants and children weighing 2 kg to less than 14 kg in combination with other antiretroviral agents. 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 [HA523 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 lamivudine in HIV/AIDS, the team of assessors advised that [HA523 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA523 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA523 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	05 Feb 2013	Listed
Quality	01 Feb 2013	MR
Bioequivalence	10 Dec 2012	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	3 Oct 2017	MR
API	21 April 2016	MR
API	19 May 2017	MR
API	7 Sep 2017	MR
FPP	27 Aug 2018	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.

The table represents the status of relevant completed activities only.

Requalification	30 July 2019