

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA635 trade name]*

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

[HA635 trade name], manufactured at Mylan Laboratories Limited, Sinnar, Maharashtra State, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 16 December 2015.

[HA635 trade name] is indicated for treatment of HIV. 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 [HA635 trade name] are abacavir (as sulfate) and lamivudine.

The efficacy and safety of abacavir 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 and lamivudine in HIV, the team of assessors advised that [HA635 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA635 trade name] in the list of prequalified medicinal products.

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

Summary of prequalification status for [HA635 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	16 December 2015	listed
Quality	11 December 2015	MR
Bioequivalence	08 December 2015	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	03 January 2013	MR
API	16 April 2014	MR
API	09 September 2014	MR
API	12 September 2014	MR
API	24 January 2015	MR
FPP	12 June 2015	MR
GCP/GLP (re-)inspection	NA	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 NA: not applicable, not available PQ: prequalification

The table represents the status of relevant completed activities only.