WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA353 trade name]*

Lamivudine 150 mg film-coated tablets

[HA353 trade name], manufactured at Cipla Ltd., Verna Salcete, Goa and Meditab Specialities Ltd., Kundaim, Goa, India, was accepted for the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 29 September 2010.

[HA353 trade name] is indicated for the treatment of HIV infection. 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 [HA353 trade name] is the nucleoside reverse transcriptase inhibitor (NRTI) lamivudine.

The efficacy and safety of 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 lamivudine in HIV infection, the team of assessors advised that [HA353 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA353 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA353 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	29 September 2010	Listed
Quality	19 July 2010	MR
Bioequivalence	NA	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	01 July 2005	MR
	14 October 2006	MR
FPP	10 September 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	

The table represents the status of relevant completed activities only.

Requalification	04 September 2020

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