WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA518 trade name][*]
Abacavir (as sulfate)/lamivudine 60 mg/30 mg dispersible tablets

Abstract

[HA518 trade name] manufactured at Cipla Limited, Patalganga, Maharashtra State, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 8 January 2014.

[HA518 trade name] is indicated for the treatment of HIV infection in children**.** 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 (APIs) of [HA518 trade name] are the nucleoside reverse transcriptase inhibitors (NRTI) lamivudine and abacavir. Each of these APIs, marketed as the therapeutic component of single products, is well-established and documented for the treatment of HIV/AIDS in combination with other products.

There is also an **Alert Card** included in each [HA518 trade name], pack to remind the patients´ caregivers and medical staff about abacavir hypersensitivity. The patient should keep this card with him/her at all times.
Within this WHOPAR this alert card is appended as an attachment to the Patient Information Leaflet (PIL, WHOPAR part 3).

The efficacy and safety profile of abacavir and lamivudine is well established based on extensive clinical experience in the treatment of HIV/AIDS.

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 combination therapy in HIV/AIDS, the team of assessors advised that [HA518 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA518 trade name] in the list of prequalified medicinal products.

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

Summary of Prequalification Status for [HA518 trade name]:

Initial Acceptance	**Date**	**Outcome**
Status on PQ list,	**08 January 2014**	**listed**
Quality	03 December 2013	MR
Bioequivalence	15 November 2013	MR
Safety, Efficacy	NA	NA
GMP (re-)inspection		
API	12 February 2011	MR
API	19 August 2011	MR
FPP	30 October 2007	MR
GCP/GLP (re)inspection	06 July 2012	MR

MR: meets requirements
NA: not applicable, not available

Requalification	19 November 2020	MR

MR: meets requirements