WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA371 trade name][*]
Abacavir (as sulfate) 300 mg tablets

Abstract

[HA371 trade name], manufactured at Cipla Ltd., Maharashtra, India, was accepted for the WHO list of prequalified products for the treatment of HIV/AIDS and was listed on 23 April 2008.

[HA371 trade name] is indicated for the treatment of HIV-1 infection in combination with other antiretroviral agents. Detailed conditions for the use of this product are described in the Summary of Product Characteristics (SPC), which is part of this WHOPAR.

The active pharmaceutical ingredient (API) of [HA371 trade name] is the nucleoside analogue reverse transcriptase inhibitor (NRTI) abacavir, a well-established and documented active substance for the treatment of HIV/AIDS in combination with other products.

There is an **Alert Card** included in each [HA371 trade name], to remind the patient 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 is well established based on extensive clinical experience in the treatment of Human Immunodeficiency Virus (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 combination therapy in HIV/AIDS, the team of assessors advised that [HA371 trade name], is of acceptable quality, efficacy and safety to allow the inclusion of [HA371 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 [HA371 trade name]:

Initial Acceptance	**Date**	**Outcome**
Status on PQ list	**23 April 2008**	**listed**
Quality	10 March 2008	MR
Bioequivalence	17 July 2006	MR
Safety, Efficacy	NA	NA
GMP (re-)inspection		
API	28 May 2005	MR
FPP	30 October 2007	MR
GCP (re-)inspection	20 January 2007	MR

MR: meets requirements
NA: not applicable, not available