WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA524 trade name] *

International Nonproprietary Name (INN)
Lamivudine/Nevirapine/Zidovudine

Abstract

[HA524 trade name], manufactured at Strides Arcolab Limited, Bangalore, India was included in the WHO list of prequalified products for the treatment of HIV/AIDS on 13 June 2014.

[HA524 trade name] is indicated for the treatment of HIV-1 infection in adults and children that weigh at least 25 kg. For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

The active pharmaceutical ingredients (API) of [HA524 trade name] are the nucleoside reverse transcriptase inhibitors (NRTIs) lamivudine and zidovudine, and the non-nucleoside reverse transcriptase inhibitor (NNRTI) nevirapine.

The APIs, as separate formulations, have been investigated in combination therapy in several clinical trials, in both treatment-naïve and treatment-experienced patients. The efficacy and safety profile of lamivudine, nevirapine and zidovudine are well established based on extensive clinical experience in the treatment of HIV infection.

On the basis of data submitted and public information on the use of combination therapy in HIV/AIDS, the team of assessors advised that [HA524 trade name] of acceptable quality, efficacy and safety to allow inclusion of [HA524 trade name] in the list of prequalified medicinal products.

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

Summary of Prequalification Status for [HA524 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	13 June 2014	Listed
Quality	13 May 2014	MR
Bioequivalence	16 May 2014	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	19 August 2011	MR
API	14 December 2011	MR
API	26 April 2012	MR
API	05 January 2013	MR
API	16 April 2014	MR
FPP	25 August 2011	MR
GCP/GLP (re-)inspection	18 February 2013	MR

MR: meets requirements
NA: not applicable, not available