WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA426 trade name]*

International Nonproprietary Name (INN):
Lamivudine/Nevirapine/Zidovudine

Abstract

[HA426 trade name], manufactured at Mylan Laboratories Limited, Maharashtra, India, was accepted for the WHO list of prequalified products for the treatment of HIV/AIDS and listed on 24 February 2009.

[HA426 trade name] is indicated for the treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infected 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 (APIs) of [HA426 trade name] are the nucleoside analogue (NRTIs, lamivudine and zidovudine) and non- nucleoside reverse transcriptase inhibitor (NNRTI) nevirapine.

Each of these APIs, marketed as the therapeutic component of single as well as fixed dose combination products, is well-established and documented for the treatment of HIV/AIDS in combination with other products.

The combination of lamivudine, nevirapine and zidovudine has been investigated in several clinical trials in both, treatment-naïve and treatment-experienced patients. These studies have demonstrated significant decreases in HIV-1 viral load and increases in CD4-cell count.

The efficacy and safety profile of lamivudine, nevirapine and zidovudine is 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 accepted [HA426 trade name] for the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.
[1] Formerly Matrix Laboratories Ltd

Summary of Prequalification Status for [HA426 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	24 February 2009	Listed
Quality	23 January 2009	MR
Bioequivalence	21 May 2008	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	26 May 2005	MR
API	17 October 2006	MR
API	26 June 2008	MR
FPP	18 July 2008	MR
GCP/GLP (re-)inspection	NA	NA
Batch Analysis	NA	

MR: meets requirements
NA: not applicable, not available