WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA433 trade name][*]

Lamivudine/Nevirapine/Zidovudine 30mg/50mg/60 mg dispersible tablets

Abstract

[HA433 trade name], manufactured at Matrix Laboratories Ltd, Secunderabad, India was accepted for the WHO list of prequalified medicinal products for the treatment of HIV/AIDS and listed on 26 October 2009.

[HA433 trade name] is indicated for the treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infected children weighing less than 25 kg.

The active pharmaceutical ingredients (APIs) of [HA433 trade name] are the nucleoside analogue reverse transcriptase inhibitors (NRTIs) lamivudine and zidovudine, and the 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.

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 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 advised that [HA433 trade name] of acceptable quality, efficacy and safety to allow inclusion of [HA433 trade name] in 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 [HA433 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	26 October 2009	Listed
Quality	04 June 2009	MR
Bioequivalence	28 May 2009	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	17 October 2006	MR
API	26 May 2005	MR
API	23 June 2008	MR
FPP	11 August 2009	MR
GCP/GLP (re-)inspection	21 July 2009	MR
Batch Analysis	NA	

Requalification	01 April 2019	MR

MR: meets requirements
NA: not applicable, not available