WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Lamivudine/Nevirapine/Zidovudine Tablets 150mg/200mg/300mg *

International Nonproprietary Name (INN):
Lamivudine/Nevirapine/Zidovudine film-coated Tablets **150mg/200mg/300mg**

Abstract

Lamivudine/Nevirapine/Zidovudine Tablets 150mg/200mg/300mg, manufactured at Matrix Laboratories Limited, Maharashtra, India, was accepted for the WHO list of pre-qualified products for the treatment of HIV/AIDS and listed on 24 February 2009.

Lamivudine/Nevirapine/Zidovudine Tablets 150mg/200mg/300mg is indicated for the treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infected adults and children that weigh at least 25 kg.
Detailed information on the use of this product is described in the Summary of Product Characteristics (SPC), which can be found in this WHOPAR.

The active pharmaceutical ingredients (APIs) of Lamivudine/Nevirapine/Zidovudine Tablets 150mg/200mg/300mg 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 most frequent adverse events observed during treatment were nausea and vomiting, abdominal pain, diarrhoea, elevation of liver enzymes and total bilirubin, myalgia, rash, headache, hairloss and fatigue. The most important safety problems with these APIs are related to zidovudine and nevirapine: They can cause severe anaemia, neutropenia, leucopenia, hypersensitivity reactions, and hepatic toxicity. In patients with chronic hepatitis B infection discontinuation of lamivudine therapy can lead to deterioration of hepatic function and hepatitis flare.
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 Lamivudine/Nevirapine/Zidovudine Tablets 150mg/200mg/300mg for the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is under local DRA responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Summary of Prequalification Status for Lamivudine/Nevirapine/Zidovudine Tablets 150mg/200mg/300mg:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	24 Feb 2009	listed				
Dossier Evaluation						
Quality	23 Jan 2009	MR				
Bioequivalence	21 May 2008	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP (re-)inspection						
APIs	26 May 2005	MR				
	17 Oct 2006	MR				
	26 June 2008	MR				
FPP	18 July 2008	MR				
GCP (re-)inspection	NA	NA				
Batch Analysis	NA					

MR: meets requirements
NA: not applicable, not available