WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

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

International Nonproprietary Names (INN)
lamivudine/nevirapine/zidovudine

Abstract

Lamivudine+Nevirapine+Zidovudine 150mg+200mg+300mg Tablets, manufactured at Macleods Pharmaceuticals Limited, Kachigam, Daman, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 24 May 2012.

Lamivudine+Nevirapine+Zidovudine 150mg+200mg+300mg Tablets 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 (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredients (APIs) of Lamivudine+Nevirapine+Zidovudine 150mg+200mg+300mg Tablets are the nucleoside analogue reverse transcriptase inhibitors (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 serious safety concerns 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 advised that Lamivudine+Nevirapine+Zidovudine 150mg+200mg+300mg Tablets is of acceptable quality, efficacy and safety to allow inclusion of Lamivudine+Nevirapine+Zidovudine 150mg+200mg+300mg Tablets in the list of prequalified medicinal products.

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

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

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	24 May 2012	listed				
Dossier Evaluation (Quality assurance)						
Quality	18 May 2012	MR				
Bioequivalence	22 March 2012	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	18 March 2011	MR				
FPP	19 Feb 2010	MR				
GCP (re-)inspection	NA	NA				
Batch Analysis	NA	NA				

MR: meets requirements
NA: not applicable, not available