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 Shanghai Desano Bio-pharmaceutical Co. Ltd, Shanghai, China, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 20 September 2018.

Lamivudine/Nevirapine/Zidovudine 150mg/200mg/300mg Tablets is indicated for the treatment of HIV-1 infection in 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 (API) of Lamivudine/Nevirapine/Zidovudine 150mg/200mg/300mg Tablets 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 most frequent adverse events observed during treatment are 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, skin 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 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 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 the national medicines regulatory authority's (NMRA) 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**
Status on PQ list	20 September 2018	listed
Quality	17 August 2018	MR
Bioequivalence	04 September 2018	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
APIs	28 February 2018	MR
FPP	09 January 2015	MR
GCP/GLP (re-)inspection	24 November 2017	MR

MR: meets requirements
NA: not applicable, not available