

**WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

[HA629 trade name] *

International Nonproprietary Name (INN)
Lamivudine/Nevirapine/Zidovudine

Abstract

[HA629 trade name], manufactured at Micro Labs Limited, Goa, India was included in the WHO list of prequalified products for the treatment of HIV/AIDS on 04 May 2019.

[HA629 trade name] is indicated for the treatment of HIV-1 infection in 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 (API) of [HA629 trade name] 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 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 [HA629 trade name] of acceptable quality, efficacy and safety to allow inclusion of [HA629 trade name] in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility.

Summary of Prequalification Status for [HA629 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	04 May 2019	listed
Quality	04 April 2019	MR
Bioequivalence	23 April 2019	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	24 January 2015	MR
API	21 April 2016	MR
APIs	24 January 2017	MR
API	24 February 2017	MR
APIs	01 August 2018	MR*
FPP	23 November 2018	MR
GCP/GLP (re-)inspection	21 March 2018	MR

MR: meets requirements

MR*: desk review (based on recent inspection reports)

NA: not applicable, not available