WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA557 trade name] *

International Non-proprietary Names (INNs):
Lamivudine/Nevirapine/Zidovudine
30mg/50mg/60mg dispersible tablets

Abstract

[HA557 trade name], manufactured at Strides Pharma Science Limited[ǂ], Bangalore, India was accepted for the WHO list of prequalified medicinal products for the treatment of HIV/AIDS and listed on 24 October 2014.

[HA557 trade name] is indicated for the treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infected children weighing less than 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 dispersible tablets 30mg/50mg/60mg are the nucleoside analogue reverse transcriptase inhibitors (NRTIs) lamivudine and zidovudine, and the non-nucleoside reverse transcriptase inhibitor (NNRTI) nevirapine.

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 [HA557 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA557 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.

[ǂ] Formerly Strides Shasun Ltd

Summary of Prequalification Status for [HA557 trade name]:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	24 Oct 2014	listed				
Dossier Evaluation (Quality assurance)						
Quality	26 Sept 2014	MR				
Bioequivalence	13 Oct 2014	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
APIs	16 April 2014	MR				
FPP	22 Oct 2013	MR				
GCP/GLP (re-)inspection	18 Feb 2013	MR				

MR: meets requirements
NA: not applicable, not available