WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA732 trade name][*]

International Nonproprietary Name (INN)/strength/pharmaceutical form:
Efavirenz/ Lamivudine/ Tenofovir disoproxil fumarate 400 mg/300 mg/300 mg Tablets

Abstract

[HA732 trade name], manufactured at Laurus Labs Ltd, Andhra Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 16 March 2020.

[HA732 trade name] is indicated for HIV-1 infection in patients weighing at least 30 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 ingredient (API) of [HA732 trade name] are the non-nucleoside reverse transcriptase inhibitor efavirenz, the nucleoside reverse transcriptase inhibitor lamivudine and the nucleotide reverse transcriptase inhibitor tenofovir disoproxil fumarate.

The efficacy and safety profile of Efavirenz/Lamivudine/Tenofovir disoproxil fumarate combination are well established based on extensive clinical experience in the treatment of HIV/AIDS. This information is taken from the SmPC (WHOPAR part 4).

On the basis of data submitted and public information on the use of [HA732 trade name] in HIV/AIDS, the team of assessors advised that [HA732 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA732 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [HA732 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	16 March 2020	listed
Quality	26 Feb 2020	MR
Bioequivalence	28 Feb 2020	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
APIs	07 Sept 2017	MR
FPP	17 March 2017	MR
GCP (re-)inspection	05 March 2019	
GCP/GLP (re-)inspection	07 March 2019	MR

MR: meets requirements
NA: not applicable, not available

[*] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.