WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA410 trade name]*

Tenofovir disoproxil fumarate 300 mg tablets

[HA410 trade name], manufactured at Matrix Laboratories Limited (subsequently Mylan Laboratories Limited), Nashik, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS and hepatitis B on 27 October 2009.

[HA410 trade name] is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infection in patients weighing 30 kg or more. It is also indicated for the treatment of chronic hepatitis B. 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 of [HA410 trade name] is tenofovir disoproxil fumarate.

The efficacy and safety of tenofovir disoproxil fumarate is well established based on extensive clinical experience in the treatment of HIV/AIDS and hepatitis B.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of tenofovir disoproxil fumarate in HIV/AIDS and hepatitis B, the team of assessors advised that [HA410 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA410 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA410 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	27 October 2009	listed
Quality	22 July 2009	MR
Bioequivalence	22 September 2007	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	23 June 2008	MR
FPP	11 August 2009	MR
GCP/GLP (re-)inspection	23 January 2008	MR

API: active pharmaceutical ingredient
FPP: finished pharmaceutical product
GCP: good clinical practice [quality standard]
GLP: good laboratory practice [quality standard]
GMP: good manufacturing practice [quality standard]
MR: meets requirements
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available
PQ: prequalification

The table represents the status of relevant completed activities only.

Requalification	5 November 2018

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