WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA726 trade name]*

Emtricitabine/Tenofovir disoproxil fumarate 200 mg/300 mg Tablets

[HA726 trade name], manufactured at Emcure Pharmaceuticals Limited, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 21 April 2020.

[HA726 trade name] is indicated in combination with other antiretroviral medicines for the treatment of HIV-1 infection in adults and adolescents over 10 years of age and 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 ingredients (APIs) of [HA726 trade name] are the nucleoside reverse transcriptase inhibitor emtricitabine and the nucleotide reverse transcriptase inhibitor tenofovir disoproxil fumarate.

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

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 emtricitabine and tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that [HA726 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA726 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.

Summary of Prequalification Status for [HA726 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	21 April 2020	Listed
Quality	08 April 2020	MR
Bioequivalence	09 April 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	07 September 2019	MR
API	01 October 2019	MR*
FPP	15 February 2019	MR
GCP/GLP (re-)inspection		
GLP (re-)inspection	29 September 2017	MR
GCP (re-)inspection	23 February 2018	MR

MR: meets requirements
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available

The table represents the status of relevant completed activities only.