

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA516 trade name]*

Tenofovir disoproxil fumarate 300 mg tablets

[HA516 trade name], manufactured at Macleods Pharmaceuticals Ltd., Kachigam Daman, India, Himachal Pradesh, India, and Madhya Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS and hepatitis B on 23 May 2013.

[HA516 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 [HA516 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 [HA516 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA516 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA516 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	23 May 2013	Listed
Quality	13 May 2013	MR
Bioequivalence	15 May 2013	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	NA	NA
GCP/GLP (re-)inspection		
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	18 December 2019
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* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.