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 currently indicated in combination with other antiretroviral medicinal products for treatment of HIV-1 infection, for pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis. 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 , 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]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	23 May 2013	Listed
Pharmaceutical 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	NA	NA

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

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

Requalification	18 December 2019