WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA631 trade name][*]

Emtricitabine/tenofovir disoproxil fumarate 200 mg/300 mg tablets

[HA631 trade name], manufactured at Micro Labs Limited, Verna, Goa, India, was included in the WHO list of prequalified medicinal products for HIV on 27 May 2016.

[HA631 trade name] is currently indicated for treatment and prevention of HIV infection and 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 ingredients of [HA631 trade name] are emtricitabine and tenofovir disoproxil fumarate.

The efficacy and safety of emtricitabine and tenofovir disoproxil fumarate are well established based on extensive clinical experience in the prevention and treatment of HIV infection and treatment of 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 emtricitabine and tenofovir disoproxil fumarate, the team of assessors advised that [HA631 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA631 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA631 trade name]:

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

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

Initial acceptance	**Date**	**Outcome**
Status on PQ list	27 May 2016	listed
Pharmaceutical quality	18 March 2016	MR
Bioequivalence	04 April 2016	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	07 March 2014	MR
API	18 September 2014	MR
API	17 April 2015	MR
API	04 December 2015	MR
FPP	17 October 2014	MR
GCP/GLP (re-)inspection	18 March 2016	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

Requalification	15 August 2023