WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA715 trade name]*

Emtricitabine/tenofovir disoproxil fumarate 200 mg/300 mg tablets

[HA715 trade name], manufactured at Lupin Limited, Nagpur, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 05 February 2020.

[HA715 trade name] is indicated in combination with another antiretroviral medicine for the treatment of HIV infection in adults and adolescents weighing at least 30 kg. It is also indicated, preferably in combination with another antiretroviral medicine, for post-exposure prophylaxis (PEP) in adults and adolescents weighing at least 30 kg who have been exposed to HIV. 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 [HA715 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 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 [HA715 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA715 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA715 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	05 February 2020	listed
Pharmaceutical quality	23 January 2020	MR
Bioequivalence	24 January 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	26 August 2019	MR*
API	07 September 2017	MR
FPP	21 September 2018	MR
GCP/GLP (re-)inspection	23 February 2018	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

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