WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA535 trade name]*

Tenofovir disoproxil fumarate 300 mg tablets

[HA535 trade name], manufactured at Strides Pharma Science Limited, Bangalore, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 21 October 2013.

[HA535 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 and for pre-exposure prophylaxis (PrEP) as an additional prevention choice for adults and adolescents (weighing at least 35 kg). It is also indicated for the treatment of chronic hepatitis B in adults with compensated liver disease and evidence immune active disease, adults with evidence of lamivudine-resistant hepatitis B virus, and adults with decompensated liver disease. 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 (API) of [HA535 trade name] is the nucleotide reverse transcriptase inhibitor 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 infections.

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 [HA535 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA535 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.
† Formerly Strides Shasun Limited.

Summary of prequalification status for [HA535 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	21 Oct 2013	Listed
Quality	09 Oct 2013	MR
Bioequivalence	10 Oct 2013	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API 1+ 2	12 Apr 2013	MR
FPP	14 Dec 2013	MR
GCP/GLP (re-)inspection	18 Feb 2013	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

The table represents the status of relevant completed activities only.

Requalification	04 September 2020