WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA729 trade name][*]

Dolutegravir (as sodium)/lamivudine/tenofovir disoproxil fumarate 50 mg/300 mg/300 mg film-coated tablets

[HA729 trade name], manufactured at Strides Pharma Science Limited, Karnataka, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 12 June 2020.

[HA729 trade name] is indicated for human immunodeficiency virus infection in adults and adolescents who weigh at least 30 kg. 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 [HA729 trade name] are dolutegravir, lamivudine and tenofovir disoproxil fumarate.

The efficacy and safety of dolutegravir, lamivudine and tenofovir disoproxil fumarate are well established based on extensive clinical experience in the treatment of human immunodeficiency virus infection.

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 [HA729 trade name] in HIV/AIDS, the team of assessors advised that [HA729 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA729 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA729 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	12 June 2020	listed
Pharmaceutical quality	30 May 2020	MR
Bioequivalence	03 June 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	07 September 2017	MR
APIs	19 January 2019	MR
FPP	28 October 2019	MR*
GCP/GLP (re-)inspection	27 October 2017	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