WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA746 trade name]*

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

[HA746 trade name], manufactured at Shanghai Desano Bio-Pharmaceutical Co., Ltd., Shanghai, P.R. China, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 02 September 2022.

[HA746 trade name] is indicated for the treatment of human immunodeficiency virus (HIV) infection in adults and adolescents weighing 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 [HA746 trade name] are dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate.

The efficacy and safety of dolutegravir (as sodium), lamivudine 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 dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that [HA746 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA746 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA746 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	02 September 2022	Listed
Quality	30 August 2022	MR
Bioequivalence	30 August 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	18 January 2019	MR
FPP	08 September 2020	MR*
GCP/GLP (re-)inspection	11 March 2022	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.

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