WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA752 trade name]*

Dolutegravir (as sodium), Lamivudine and Tenofovir Disoproxil Fumarate
50 mg/300 mg/300 mg Tablets

[HA752 trade name], manufactured at Celltrion Pharm Inc, Cheongju-si, Chungcheongbuk-do, Republic of Korea, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS infection on 27 June 2023.

[HA752 trade name] is indicated for 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 [HA752 trade name] are dolutegravir sodium, lamivudine and tenofovir disoproxil fumarate.

The efficacy and safety of dolutegravir sodium, lamivudine and tenofovir disoproxil fumarate are well established based on extensive clinical experience in the treatment of HIV/AIDS 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 dolutegravir sodium, lamivudine and tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that [HA752 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA752 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA752 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	27 June 2023	listed
Quality	08 June 2023	MR
Bioequivalence	15 June 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	18 January 2019	MR
FPP	12 August 2021	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.