# WHO Prequalification Programme
# WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

## [HA696 trade name][*]

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

[HA696 trade name], manufactured at Hetero Labs Limited, Jeedimetla, Hyderabad, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 19 December 2019.

[HA696 trade name] is indicated for the treatment of human immunodeficiency virus (HIV) infection in adults and adolescents weighing at least 30 kg. [HA696 trade name] may also be used in these patients for post-exposure prophylaxis 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 [HA696 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 [HA696 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA696 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [HA696 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** | 19 December 2019 | listed |
| Pharmaceutical quality | 18 December 2019 | MR |
| Bioequivalence | 04 December 2019 | MR |
| Safety, efficacy | NA | NA |
| **GMP (re-)inspection** | | |
| API | 26 August 2019 | MR* |
| API | 01 October 2019 | MR* |
| FPP | 30 August 2018 | 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

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