WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA696 trade name]*

International Nonproprietary Name (INN)/strength/pharmaceutical form:
Dolutegravir sodium, Lamivudine and Tenofovir Disoproxil Fumarate
50mg/300mg/300mg Tablets

Abstract

[HA696 trade name], manufactured at Hetero Labs Ltd, 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-1 (HIV-1) 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 ingredient (API) of [HA696 trade name] are the integrase inhibitor dolutegravir sodium and the nucleoside reverse transcriptase inhibitors lamivudine and tenofovir disoproxil fumarate.

The efficacy and safety profile of dolutegravir/lamivudine/tenofovir disoproxil fumarate combination are well established based on extensive clinical experience in the treatment of HIV/AIDS. This information is taken from the SmPC (WHOPAR part 4).

On the basis of data submitted and public information on the use of [HA696 trade name] 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]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	19 Dec 2019	listed
Quality	18 Dec 2019	MR
Bioequivalence	04 Dec 2019	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
APIs	26 Aug 2019	MR*
APIs	01 Oct 2019	MR*
FPP	30 Aug 2018	MR
GCP/GLP (re-)inspection	27 Oct 2017	MR

MR: meets requirements
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available

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