WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA712 trade name][1]
Lamivudine/Tenofovir disoproxil fumarate 300 mg/300 mg Tablets

Abstract

[HA712 trade name] manufactured at Celltrion Pharm Inc, Cheongju-si, Republic of Korea was included in the WHO list of prequalified medicinal products for the treatment of human immunodeficiency virus (HIV-1) on 17 December 2019.

[HA712 trade name] is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in patients weighing at least 30 kg or more.

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 (APIs) of [HA712 trade name] are the antiretroviral agents' lamivudine and tenofovir disoproxil fumarate. The APIs are well-established and documented for the treatment Human Immunodeficiency Virus (HIV).

The efficacy and safety profile of lamivudine and tenofovir disoproxil fumarate is well established based on extensive clinical experience in the treatment and prevention of infections in HIV patients.

On the basis of data submitted and public information on the use of lamivudine and tenofovir disoproxil fumarate in treatment of human immunodeficiency virus (HIV-1) infection in patients weighing at least 30 kg or more, the team of assessors advised that [HA712 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA712 trade name] in the list of prequalified medicinal products.

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

Summary of Prequalification Status for [HA712 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	17 Dec 2019	listed
Quality	11 Dec 2019	MR
Bioequivalence	12 Dec 2019	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	19 May 2017	MR
API	07 Sept 2017	MR
FPP	04 Feb 2018	MR*
GCP/GLP (re-)inspection	30 May 2019	MR

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