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

# [HA561 trade name][*]

International Nonproprietary Names (INN)/strength/pharmaceutical form
emtricitabine/tenofovir disoproxil fumarate 200 mg/300 mg tablets

## Abstract

[HA561 trade name], manufactured at Macleods Pharmaceuticals Limited, Kachigam, Daman, India, and Tehsil Baddi, Himachal Pradesh, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 8 April 2014.

[HA561 trade name] is indicated in combination with at least one other antiretroviral product for the treatment of HIV-1 infection in adults and adolescents over 10 years of age and weighing at least 30 kg. [HA561 trade name] may be used in combination with other measures for pre-exposure prophylaxis in adults and adolescents (weighing at least 35 kg) at substantial risk of HIV infection.

The active pharmaceutical ingredients (APIs) of [HA561 trade name] are the nucleoside reverse transcriptase inhibitor emtricitabine and the nucleotide reverse transcriptase inhibitor tenofovir disoproxil fumarate. The APIs have been investigated in several clinical trials for pre-exposure prophylaxis and in combination with other antiretrovirals for the treatment of HIV, in both treatment-naïve and treatment-experienced patients.

The efficacy and safety profile of emtricitabine and tenofovir disoproxil fumarate is 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 emtricitabine and tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that [HA561 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA561 trade name] in the list of prequalified medicinal products.

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

**Summary of Prequalification Status for [HA561 trade name]:**

| **Initial Acceptance** | **Date** | **Outcome** |
|---|---|---|
| Status on PQ list | 08 April 2014 | listed |
| **Dossier Evaluation (Quality assurance)** | | |
| Quality | 05 March 2014 | MR |
| Bioequivalence | 12 March 2014 | MR |
| Safety, Efficacy | NA | NA |
| **Inspection Status** | | |
| GMP(re-)inspection | | |
| API | 14 June 2012 | MR |
| API | 12 April 2013 | MR |
| FPP | 07 June 2012 | MR |
| GCP/GLP (re-)inspection | 12 Feb 2013 | MR |

MR: meets requirements
NA: not applicable, not available