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

[HA552 trade name][*]

**Abstract**

[HA552 trade name], manufactured at Strides Pharma Science Ltd 36/7, Suragajakknahalli, Indlavadi Cross, Anekal Taluk, Bangalore-562 106, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 18 February 2015.

[HA552 trade name] is indicated in antiretroviral combination therapy for the treatment of HIV-1 infected adults and adolescents from 10 years of age and weighing at least 30 kg. [HA552 trade name] may be used for pre-exposure prophylaxis in certain high-risk populations.

The active pharmaceutical ingredients (APIs) of [HA552 trade name] are the nucleoside reverse transcriptase inhibitor emtricitabine and the nucleotide reverse transcriptase inhibitor tenofovir disoproxil fumarate. The APIs have been investigated in combination therapy in several clinical trials, 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 [HA552 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA552 trade name] in the list of prequalified medicinal products.

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

**Summary of Prequalification Status for [HA552 trade name]**

| | **Initial Acceptance** | |
|---|---|---|
| | **Date** | **Outcome** |
| Status on PQ list, i.e. date of listing | 18 Feb 2015 | listed |
| Quality | 04 Feb 2015 | MR |
| Bioequivalence | 12 Feb 2015 | MR |
| Safety, Efficacy | NA | NA |
| GMP(re-)inspection | | |
| API | 05 Jan 2013 | MR |
| API | 19 June 2014 | MR |
| APIs | 28 Aug 2014 | MR |
| API | 12 Sept 2014 | MR |
| API | 24 Jan 2015 | MR |
| FPP | 22 Oct 2013 | MR |
| GCP/GLP (re-)inspection | 18 Feb 2013 | MR |

MR: meets requirements
NA: not applicable, not available