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

## [HA352 trade name]*

Efavirenz 600 mg film-coated tablets

[HA352 trade name], manufactured at Cipla Ltd., Goa, India, Goa, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 16 December 2008.

[HA352 trade name] is indicated for the treatment of HIV-1 infection in combination with other antiretroviral agents in adults and adolescents. 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 of [HA352 trade name] is the non-nucleoside reverse transcriptase inhibitor efavirenz.

The efficacy and safety of efavirenz is well established based on extensive clinical experience in the treatment of HIV-1 infection in combination with other antiretroviral agents.

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 efavirenz in the treatment of HIV-1 infection , the team of assessors advised that [HA352 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA352 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [HA352 trade name]:**

| **Initial acceptance** | **Date** | **Outcome** |
|---|---|---|
| **Status on PQ list** | 16 December 2008 | Listed |
| Quality | 20 November 2008 | MR |
| Bioequivalence | 04 December2008 | MR |
| Safety, efficacy | NA | NA |
| **GMP (re-)inspection** | | |
| API | 28 May 2005 | MR |
| FPP | 01 August 2007 | MR |
| **GCP/GLP (re-)inspection** | 24 May 2006 | MR |
| API: active pharmaceutical ingredient<br>FPP: finished pharmaceutical product<br>GCP: good clinical practice [quality standard]<br>GLP: good laboratory practice [quality standard] | GMP: good manufacturing practice [quality standard]<br>MR: meets requirements<br>MR*: desk review (based on recent inspection reports)<br>NA: not applicable, not available<br>PQ: prequalification | |

The table represents the status of relevant completed activities only.

| | |
|---|---|
| **Requalification** | 27 January 2021 |

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