WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA633 trade name]*

Efavirenz 600 mg tablets

[HA633 trade name], manufactured at Micro Labs Limited, Verna Industrial Estate, Goa–403722, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 24 October 2017.
[HA633 trade name] is indicated for the treatment of human immunodeficiency virus (HIV) 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 [HA633 trade name] is efavirenz.

The efficacy and safety of efavirenz 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 efavirenz in HIV/AIDS, the team of assessors advised that [HA633 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA633 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA633 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	24 October 2017	listed
Quality	26 September 2017	MR
Bioequivalence	02 October 2017	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 September 2014	MR*
FPP	18 June 2016	MR
GCP/GLP (re-)inspection	NA	NA

API: active pharmaceutical ingredient
FPP: finished pharmaceutical product
GCP: good clinical practice [quality standard]
GLP: good laboratory practice [quality standard]
GMP: good manufacturing practice [quality standard]
MR: meets requirements
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available
PQ: prequalification

The table represents the status of relevant completed activities only.

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