

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA681 trade name]*

Efavirenz 600 mg tablets

[HA681 trade name], manufactured at The Government Pharmaceutical Organization, Bueng Sanan, Pathumthani, Thailand, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 15 August 2018.

[HA681 trade name] is indicated for the treatment of HIV-1 infection in combination with other antiretroviral agents. 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 [HA681 trade name] is the non-nucleoside reverse transcriptase inhibitor efavirenz.

The efficacy and safety profile of efavirenz is well established based on extensive clinical experience in the treatment of HIV infection.

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 combination therapy in HIV/AIDS, the team of assessors advised that [HA681 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA681 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [HA681 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	15 August 2018	listed
Quality	12 July 2018	MR
Bioequivalence	25 July 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	31 July 2015	MR
API	06 October 2017	MR
FPP	02 June 2017	MR
GCP/GLP (re-)inspection	15 December 2017	MR
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.