

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA403 trade name]*

Efavirenz 600 mg tablet

[HA403 trade name], manufactured at Matrix Laboratories Limited, Secunderabad, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 25 July 2008.

[HA403 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 [HA403 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 [HA403 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA403 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA403 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	25 July 2008	listed
Quality	12 March 2008	MR
Bioequivalence	30 November 2007	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	28 May 2005	MR
FPP	26 July 2007	MR
GCP/GLP (re-)inspection	21 June 2008	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.

† Formerly Matrix Laboratories Limited.

Requalification	19 December 2018	MR
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