

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA389 trade name]*

Efavirenz 200 mg Tablets

[HA389 trade name], manufactured at Strides Pharma Science Ltd., Bangalore, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 24 February 2009.

[HA389 trade name] is indicated for the treatment of HIV-1 infection in combination with other antiretroviral agents. Detailed conditions for the use of this product are described in the Summary of Product Characteristics (SmPC), which is part of this WHOPAR.

The active pharmaceutical ingredient (API) of [HA389 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 [HA389 trade name] is of acceptable quality, efficacy and safety to allow the inclusion of [HA389 trade name] in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's responsibility.

Summary of Prequalification Status for [HA389 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	24 Feb 2009	listed
Quality	22 Jan 2009	MR
Bioequivalence	01 Mar 2007	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	23 Apr 2008	MR
FPP	26 May 2005	MR
GCP/GLP (re-)inspection	26 Sept 2007	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		

Requalification	30 Sep 2019
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