

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA658 trade name] *

Efavirenz 600 mg film-coated tablets

[HA658 trade name], manufactured at Shanghai Desano Bio-Pharmaceutical Co., Ltd., 1479 Zhangheng Road, Shanghai 201203, P.R. China was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 12 December 2017.

[HA658 trade name] is indicated for the treatment of HIV-1 infection. 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 (API) of [HA658 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 [HA658 trade name] is of acceptable quality, efficacy and safety to allow the inclusion of [HA658 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 [HA658 trade name] :

Initial acceptance	Date	Outcome
Status on PQ list	12 Dec 2017	listed
Quality	04 Dec 2017	MR
Bioequivalence	05 Dec 2017	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	09 Jan 2015	MR
GCP/GLP (re-)inspection	29 Sept 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.