

**WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

[HA568 trade name]*

Nevirapine 50 mg Tablets

Abstract

[HA568 trade name], manufactured at Micro Labs Limited, Verna, Goa, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 19 February 2014.

[HA568 trade name] is indicated for the treatment of HIV-1 infection in combination with other antiretrovirals. 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 [HA568 trade name] is the non-nucleoside reverse transcriptase inhibitor (NNRTI) nevirapine. The efficacy and safety of nevirapine are well established based on extensive clinical experience in the treatment of HIV.

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 [HA568 trade name] in [HA568 trade name], the team of assessors advised that [HA568 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA568 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 [HA568 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	19 February 2014	Listed
Quality	31 January 2014	MR
Bioequivalence	NA	NA
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	05 November 2013	MR
FPP	18 January 2013	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.

Requalification	18 December 2019
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