

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

[HA569 trade name]*

Nevirapine 100 mg Tablets

Abstract

[HA569 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.

[HA569 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 [HA569 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 [HA569 trade name] in [HA569 trade name], the team of assessors advised that [HA569 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA569 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 [HA569 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.

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|------------------------|------------------|
| Requalification | 18 December 2019 |
|------------------------|------------------|