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

## [HA536 trade name][*]

Lamivudine 30 mg Tablets

[HA536 trade name], manufactured at Micro Labs Ltd, Verna Industrial Estate, Goa, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 18 February 2013.

[HA536 trade name] is indicated in combination with other antiretroviral medicinal for the treatment of HIV-1 infection in infants and children aged 4 weeks and weighing 3 to 24.9 kg.

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 [HA536 trade name] is the nucleoside reverse transcriptase inhibitor (NRTI) lamivudine. This API is well established and documented for the treatment of HIV/AIDS in combination with other products.

The efficacy and safety of lamivudine 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 lamivudine in HIV/AIDS, the team of assessors advised that [HA536 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA536 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 [HA536 trade name]:**

| **Initial acceptance** | **Date** | **Outcome** |
|---|---|---|
| **Status on PQ list** | 18 Feb 2013 | listed |
| Quality | 13 Feb 2013 | MR |
| Bioequivalence | 06 Feb 2013 | MR |
| Safety, efficacy | NA | NA |
| **GMP (re-)inspection** | | |
| API 1 | 27 Jan 2011 | MR |
| API 1 | 23 June 2011 | |
| FPP | 18 Jan 2013 | MR |
| **GCP/GLP (re-)inspection** | MR | 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.

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|---|---|
| **Requalification** | 17 June 2019 |