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

[HA486 trade name] *

Zidovudine 50 mg/5 ml oral solution

[HA486 trade name], manufactured at Hetero Labs Limited, Hyderabad, India was accepted, in principle, for the WHO list of prequalified products for the treatment of HIV/AIDS on 3 November 2011.

[HA486 trade name is indicated for the treatment of children with HIV-1 infection in combination with other antiretroviral agents and for the primary prophylaxis of HIV-1 infection in neonates. 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 [HA486 trade name] is the nucleoside reverse transcriptase inhibitor (NRTI), zidovudine. The API is well established and documented for the treatment of HIV/AIDS in combination with other products.

The efficacy and safety profile of zidovudine is well established based on extensive clinical experience in the treatment of HIV infection.

On the basis of data submitted and public information on the use of combination therapy in HIV/AIDS, the team of assessors accepted [HA486 trade name] for inclusion in the list of prequalified medicinal products.

**Summary of prequalification status for [HA486 trade name]:**

| **Initial acceptance** | **Date** | **Outcome** |
|---|---|---|
| **Status on PQ list** | **3 Nov 2011** | **listed** |
| Quality | **21 Oct 2011** | MR |
| Bioequivalence | **20 Oct 2011** | MR |
| Safety, efficacy | NA | NA |
| **GMP (re-)inspection** | | |
| API | **27 Jan 2011** | MR |
| FPP | **28 Aug 2011** | MR |
| **GCP/GLP (re-)inspection** | NA | NA |
| API: active pharmaceutical ingredient<br>FPP: finished pharmaceutical product<br>GCP: good clinical practice [quality standard]<br>GLP: good laboratory practice [quality standard] | GMP: good manufacturing practice [quality standard]<br>MR: meets requirements<br>NA: not applicable, not available<br>PQ: prequalification | |

The table represents the status of relevant completed activities only.

| | | |
|---|---|---|
| **Requalification** | 04 September 2020 | MR |

MR: meets requirements

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.