WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA200 trade name]*

nevirapine 50 mg/5 ml oral suspension

[HA200 trade name], manufactured at Cipla Limited, Dist Dhar (M.P.) 454 775, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 25 May 2009.

[HA200 trade name] is indicated, in combination with other antiretroviral medicines, for the treatment of HIV-1 infected children with a body weight of less than 25 kg and for primary prophylaxis of HIV infection in newborn infants born to HIV-positivepregnant women. 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 [HA200 trade name] the non-nucleoside reverse transcriptase inhibitor (NNRTI) nevirapine. The use of nevirapine in combination with other antiretroviral medicines is well-established and documented for the treatment of HIV/AIDS. There is also experience of the use of nevirapine for the prevention of mother-to-child transmission of HIV-1.

Nevirapine, in combination with other antiretroviral drugs has been investigated in several clinical trials in both, treatment-naïve and treatment-experienced patients. These studies have demonstrated significant decreases in HIV-1 viral load and increases in CD4-cell count. Studies to evaluate the efficacy of nevirapine to prevent vertical transmission of HIV-1 have demonstrated a reduction in the infection rate in babies born to HIV-positive mothers.

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 nevirapine in HIV/AIDS, the team of assessors advised that [HA200 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA200 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 [HA200 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	25 May 2009	Listed
Quality	17 March 2009	MR
Bioequivalence	22 January 2007	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	28 June 2005 14 October 2006	MR
FPP	1 August 2007	MR
GCP/GLP (re-)inspection	20 January 2007	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.

Requalification	31 March 2020