WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA510 trade name]*

nevirapine 50 mg dispersible tablets

[HA510 trade name], manufactured at Cipla Limited, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of human immunodeficiency virus (HIV) infection on 19 February 2014.

[HA510 trade name] is indicated in combination with other antiretroviral medicines for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in children weighing 3–24.9 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 (API) of [HA510 trade name] is the non-nucleoside reverse transcriptase inhibitor (NNRTI) nevirapine. The use of nevirapine in combination with other antiretroviral drugs is well-established and documented for the treatment of HIV/AIDS.

Nevirapine has been investigated in combination therapy in several clinical trials, in both treatment-naïve and treatment-experienced patients. These studies have demonstrated significant decrease in viral load, increase in CD4 cell counts and clinical benefits in terms of HIV progression events.

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 [HA510 trade name] in HIV/AIDS, the team of assessors advised that [HA510 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA510 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [HA510 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	19 February 2014	listed
Quality	30 January 2014	MR
Bioequivalence	10 February 2014	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	12 February 2011	MR
FPP	24 February 2011	MR
GCP/GLP (re-)inspection	17 February 2012	MR

MR: meets requirements
NA: not applicable, not available

The table represents the status of relevant completed activities only.

Requalification	6 May 2020

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