

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA680 trade name]*

Dolutegravir (as sodium) 50 mg Tablets

[HA680 trade name] manufactured at Cipla Limited, Pithampur, Madhya Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of human immunodeficiency virus (HIV) infection on 24 October 2017.

[HA680 trade name] is indicated, in combination with other antiretroviral medicines, for the treatment of human immunodeficiency virus (HIV) infection in patients weighing at least 20 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 [HA680 trade name] is the antiviral agent dolutegravir.

The efficacy and safety profile of dolutegravir is well established based on extensive clinical experience in the treatment of human immunodeficiency virus (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 dolutegravir therapy in human immunodeficiency virus (HIV) infection the team of assessors advised that [HA680 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA680 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [HA680 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	24 October 2017	Listed
Quality	03 October 2017	MR
Bioequivalence	04 October 2017	MR
Safety, Efficacy	NA	NA
GMP (re-)inspection		
API	15 March 2016	MR
FPP	06 October 2017	MR
GCP (re-)inspection	23 June 2008	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 NA: not applicable, not available PQ: prequalification		

MR: meets requirements

NA: not applicable, not available

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