WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA682 trade name]*

Dolutegravir (as sodium) 50mg tablets

[HA682 trade name], manufactured at Hetero Labs Limited, Telangana, India, was included in the WHO prequalified medicinal products for the treatment of human immunodeficiency virus (HIV) infection on 17 July 2018.

[HA682 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. [HA682 trade name] may also be used in these patients as part of a regimen for post-exposure prophylaxis to HIV. 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 [HA682 trade name] is dolutegravir (as sodium).

The efficacy and safety 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), the team of assessors advised that [HA682 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA682 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA682 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	17 July 2018	Listed
Pharmaceutical quality	19 June 2018	MR
Bioequivalence	25 June 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	24 February 2017	NA
FPP	12 June 2015	MR
GCP/GLP (re-)inspection	17 November 2017	NA

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

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