WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA718 trade name]*

Dolutegravir (as sodium) 50 mg tablets

Abstract

[HA718 trade name], manufactured at Laurus Labs Limited (Unit-II), Atchutapuram Mandal, Andhra Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of human immunodeficiency virus (HIV) infection on 14 October 2019.

[HA718 trade name] is indicated, in combination with other antiretroviral medicines, for the treatment of human immunodeficiency virus (HIV) infection. 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 [HA718 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 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 HIV infection, the team of assessors advised that [HA718 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA718 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 [HA718 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	14 October 2019	listed
Quality	03 October 2019	MR
Bioequivalence	07 October 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	07 September 2017	MR
FPP	17 March 2017	MR
GCP/GLP (re-)inspection	06 October 2017	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