WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA678 trade name]*

Dolutegravir (as sodium) 50 mg Tablets

[HA678 trade name] manufactured at Mylan Laboratories 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 31 October 2018.

[HA678 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 [HA678 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 [HA678 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA678 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA678trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	31 October 2018	Listed
Quality	20 September 2018	MR
Bioequivalence	03 October 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	21 April 2016	MR
FPP	25 May 2018	MR
GCP (re-)inspection	21 July 2017	MR
GLP (re-)inspection	15 July 2016	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.

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