WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA765 trade name]*

Dolutegravir 10 mg dispersible tablets

[HA765 trade name], manufactured at Macleods Pharmaceuticals Limited, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 14 December 2021.

[HA765 trade name] is indicated for combination with other antiretroviral medicines, for the treatment of human immunodeficiency virus (HIV) infection in children at least 4 weeks of age or older and weighing at least 3 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 of [HA765 trade name] is the antiviral agent dolutegravir. The use of dolutegravir in combination with other antiretroviral medicines is well-established and documented for the treatment of HIV/AIDS.

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 in the treatment of HIV/AIDS, the team of assessors advised that [HA765 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA765 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA765 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	14 December 2021	listed
Quality	25 November 2021	MR
Bioequivalence	10 December 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	27 August 2021	MR*
FPP	23 October 2019	MR
GCP/GLP (re-)inspection	07 September 2020	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.