WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA765 trade name]*

Dolutegravir (as sodium) 10 mg dispersible tablets

[HA765 trade name], manufactured at Macleods Pharmaceuticals Limited, Village Theda, 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 in 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. It 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 [HA765 trade name] is dolutegravir.

The efficacy and safety of dolutegravir are well established based on extensive clinical experience in 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 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]:

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	14 December 2021	listed
Pharmaceutical 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

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