WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA793 trade name]*

Dolutegravir (as sodium) 10 mg dispersible tablets

[HA793 trade name], manufactured at Micro Labs Limited, Verna, Goa, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 17 July 2025.

[HA793 trade name] is currently indicated in combination with other antiretroviral medicines, for the treatment of human immunodeficiency virus (HIV) infection in children from birth weighing at least 2 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 [HA793 trade name] is dolutegravir (as sodium).

The efficacy and safety of dolutegravir (as sodium) are 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 (as sodium) in HIV/AIDS, the team of assessors advised that [HA793 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA793 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA793 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 2025	listed
Pharmaceutical quality	09 May 2025	MR
Bioequivalence	14 May 2025	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	15 January 2025	MR
FPP	09 August 2024	MR
GCP/GLP (re-)inspection	09 December 2022	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.