WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA809 trade name][*]

Abacavir (as sulfate)/ dolutegravir (as sodium)/ lamivudine 60mg/5mg/30mg film-coated dispersible tablets

[HA809 trade name], manufactured at Micro Labs Limited (ML06), Verna, Goa, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 31 March 2026.

[HA809 trade name] is currently indicated for HIV infection in infants and children over 4 weeks of age who weigh between 3 kg and 25 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 ingredients of [HA809 trade name] are abacavir (as sulfate), dolutegravir (as sodium) and lamivudine.

The efficacy and safety of abacavir (as sulfate), dolutegravir (as sodium) and lamivudine are well established based on extensive clinical experience in the treatment of HIV infection in infants and children over 4 weeks of age who weigh between 3 kg and 25 kg.

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 the use of abacavir (as sulfate), dolutegravir (as sodium) and lamivudine in HIV, the team of assessors advised that [HA809 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA809 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA809 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

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

Initial acceptance	**Date**	**Outcome**
Status on PQ list	31 March 2026	listed
Pharmaceutical quality	25 March 2026	MR
Bioequivalence	16 March 2026	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	24 June 2025	MR*
API	19 January 2024	MR
FPP	09 August 2024	MR
GCP/GLP (re-)inspection	18 February 2026	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