WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA790 trade name]*

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

[HA790 trade name], manufactured at Lupin Limited, Nagpur, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 05 July 2025.

[HA790 trade name] is currently indicated for the treatment of HIV-1 infection in infants and children aged from 4 weeks and weighing 6 to 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 [HA790 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-1.

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 abacavir (as sulfate), dolutegravir (as sodium) and lamivudine, the team of assessors advised that [HA790 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA790 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA790 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	05 July 2025	listed
Pharmaceutical quality	16 June 2025	MR
Bioequivalence	20 June 2025	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	24 June 2025	MR*
API	04 April 2025	MR
API	07 July 2023	MR
FPP	20 October 2024	MR
GCP/GLP (re-)inspection	23 January 2025	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.