WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA697 trade name]*

Lopinavir/ritonavir 40 mg/10 mg granules for oral suspension

[HA697 trade name], manufactured at Mylan Laboratories Limited, Sinnar, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 27 October 2020.

[HA697 trade name] is indicated for the treatment of human immunodeficiency virus (HIV-1) infection in infants and children patients14 days and older, weighing over 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 ingredients of [HA697 trade name] are lopinavir and ritonavir. The combination of these APIs are well-established and documented for the treatment of HIV/AIDS.

The efficacy and safety of lopinavir and ritonavir 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 the use of combination therapy in HIV/AIDS, the team of assessors advised that [HA697 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA697 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA697 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	27 October 2020	listed
Quality	10 January 2020	MR
Bioequivalence	13 January 2020	MR
Safety, efficacy		NA
GMP (re-)inspection		
API	07 October 2019	MR
API	22 November 2019	MR
FPP	10 November 2017	MR
GCP/GLP (re-)inspection	21 July 2017	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
NA: not applicable, not available
PQ: prequalification