WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA761 trade name]*

Lopinavir/ritonavir 200mg/50mg tablets

[HA761 trade name], manufactured at Micro Labs Limited, Verna Industrial Estate, Verna, Goa, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 02 September 2023.

[HA761 trade name] is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV) infection in adults and children weighing 35 kg or more. 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 [HA761 trade name] are lopinavir and ritonavir.

The efficacy and safety of lopinavir and ritonavir 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 lopinavir and ritonavir in HIV/AIDS, the team of assessors advised that [HA761 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA761 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA761 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	02 September 2023	listed
Pharmaceutical quality	28 July 2023	MR
Bioequivalence	31 July 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	19 October 2022	MR*
FPP	29 July 2022	MR
GCP/GLP (re-)inspection	09 June 2023	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.