WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA720 trade name]*

Atazanavir (as sulfate)/ ritonavir 300mg/100mg film-coated tablets

[HA720 trade name], manufactured at Lupin Limited (Unit 1), Nagpur, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 04 May 2022.

[HA720 trade name] is indicated for the treatment of HIV-1 infected adults and children weighing at least 25 kg, in combination with other antiretroviral medicinal products. 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 [HA720 trade name] are atazanavir sulfate and ritonavir.

The efficacy and safety of atazanavir sulfate 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 [HA720 trade name] in HIV/AIDS, the team of assessors advised that [HA720 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA720 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA720 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	04 May 2022	listed
Quality	26 April 2022	MR
Bioequivalence	03 May 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	26 August 2019	MR*
API	04 May 2022	MR*
FPP	21 January 2022	MR
GCP/GLP (re-)inspection		
GLP (re-)inspection	23 February 2018	MR
GCP (re-)inspection	18 January 2019	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

The table represents the status of relevant completed activities only.

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