WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA719 trade name]*

Darunavir (as ethanolate)/ritonavir 400mg/50mg film-coated tablets

[HA719 trade name], manufactured at Hetero Labs Limited, Hyderabad, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 01 July 2021.

[HA719 trade name] is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents weighing at least 40 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 [HA719 trade name] are darunavir and ritonavir.

The efficacy and safety of darunavir and ritonavir are well established based on extensive clinical experience in the treatment of human immunodeficiency virus 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 darunavir and ritonavir in HIV/AIDS, the team of assessors advised that [HA719 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA719 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA719 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	01 July 2021	listed
Pharmaceutical quality	15 June 2021	MR
Bioequivalence	24 June 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	01 October 2019	MR*
API	26 August 2019	MR*
FPP	05 October 2020	MR*
GCP/GLP (re-)inspection	15 December 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
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available
PQ: prequalification