

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA709 trade name]*

Darunavir 400mg film-coated tablets

[HA709 trade name], manufactured at Laurus Labs Limited (Unit II), Atchutapuram Mandal, Andhra Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of human immunodeficiency virus (HIV) infection on 12 June 2020.

[HA709 trade name] is indicated in combination with other antiretroviral medicines for the treatment of human immunodeficiency virus (HIV) infection in adults and adolescents weighing at least 35kg or protease inhibitor-experienced children and adolescents with a body weight of at least 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 ingredient of [HA709 trade name] is darunavir.

The efficacy and safety of darunavir is 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 darunavir in HIV infection, the team of assessors advised that [HA709 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA709 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA709 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	12 June 2020	listed
Quality	29 May 2020	MR
Bioequivalence	03 June 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	04 September 2017	MR
FPP	17 March 2017	MR
GCP/GLP (re-)inspection	NA	NA
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.