WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA710 trade name]*

Darunavir 600mg film-coated tablets

[HA710 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.

[HA710 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 who have previously been treated with a protease inhibitor or in children and adolescents from the age of 3 years with a body weight of at least 14 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 [HA710 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 [HA710 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA710 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [HA710 trade name]:

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

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.