WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA685 trade name][*]

International Nonproprietary Name (INN)/strength/pharmaceutical form:
Darunavir (as ethanolate) 600 mg Tablets

Abstract

[HA685 trade name], manufactured at Mylan Laboratories Limited, Plot No. H-12 and H-13, MIDC, Waluj Industrial Area, Aurangabad-431136, Maharashtra, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 11 June 2019.

[HA685 trade name] co-administered with low dose ritonavir is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus type 1 (HIV-1) infection.

The active pharmaceutical ingredient (API) of [HA685 trade name] is darunavir, a protease inhibitor.

The efficacy and safety profile of [HA685 trade name] is well-established, based on extensive clinical experience with darunavir 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 combination therapy in HIV/AIDS, the team of assessors advised that [HA685 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA685 trade name] in the list of prequalified medicinal products.

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

Summary of Prequalification Status for [HA685 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	11 June 2019	listed
Quality	18 May 2019	MR
Bioequivalence	26 Sept 2017	MR
Safety, Efficacy	NA	NA
GMP (re-)inspection		
API	21 Apr 2016	MR
FPP	15 July 2016	MR
GCP (re-)inspection	21 Dec 2017	
GLP (re-)inspection	07 Nov 2018	MR

MR: meets requirements
NA: not applicable, not available