WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA683 trade name][*]

Darunavir (as ethanolate) 800 mg Tablets

Abstract

[HA683 trade name], manufactured at Mylan Laboratories Limited, Aurangabad-431136, Maharashtra, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 11 June 2019.

[HA683 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 in adults and adolescent patients 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 ingredient (API) of [HA683 trade name] is darunavir, a protease inhibitor.

The efficacy and safety profile of [HA683 trade name] is well-established, based on extensive clinical experience in the treatment of HIV infection.

On the basis of data submitted and public information on the use of combination therapy in HIV/AIDS, the team of assessors advised that [HA683 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA683 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [HA683 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	11 June 2019	listed
Quality	18 May 2019	MR
Bioequivalence	21 July 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

The table represents the status of relevant completed activities only.

MR: meets requirements
NA: not applicable, not available

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