WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA650 trade name][*]

International Nonproprietary Names (INN):
Lopinavir / Ritonavir 200 mg/ 50 mg tablets

Abstract

[HA650 trade name], manufactured at Hetero Labs Limited, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 19 June 2018.

[HA650 trade name] is indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) infection in adults and children weighing 10 kg or more. 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 (APIs) of [HA650 trade name] are the protease inhibitors (PI) lopinavir and ritonavir. The combination of these APIs is well-established and documented for the treatment of HIV/AIDS in combination with other products.

The efficacy and safety profile of Lopinavir and Ritonavir is well established based on extensive clinical experience in the treatment of HIV.

On the basis of data submitted and public information on the use of combination therapy in HIV/AIDS, the team of assessors considered by consensus that the benefit–risk profile of [HA492 trade name] was acceptable and has advised inclusion of [HA650 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 [HA650 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	19 June 2018	listed
Quality	08 May 2018	MR
Bioequivalence	11 May 2018	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	18 September 2014	MR
API	24 February 2017	MR
FPP	23 March 2018	MR
GCP/GLP (re-)inspection	NA	NA

MR: meets requirements
NA: not applicable, not available