WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Ritonavir Tablets 100 mg*
International Nonproprietary Name (INN): ritonavir

Abstract

Ritonavir Tablets 100 mg manufactured at Mylan Laboratories Ltd., Malegaon, India was accepted for the WHO list of prequalified products for the treatment of HIV/AIDS on 14 December 2010.

Ritonavir Tablets 100 mg is indicated for the treatment of HIV infection in combination with other antiretroviral products. Detailed information on the use of this product is provided in the Summary of Product Characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredient (API) of Ritonavir Tablets 100 mg is the protease inhibitor ritonavir. It is well-established and documented for the treatment of HIV/AIDS in combination with other antiretroviral products, in both treatment-naïve and treatment-experienced patients. Studies have demonstrated significant decreases in HIV-1 load and increases in CD4-cell count.

The most frequent adverse events observed during treatment are nausea & vomiting, diarrhea, headache, tiredness, tingling around the lips and mouth, rash, changes in fat distribution.

The most important safety problems with ritonavir are diarrhea, pancreatitis, lipid elevations, interactions with other drug products. Rare increases in the PR interval have been reported.

On the basis of data submitted and public information on the use of combination therapy in HIV/AIDS, the team of assessors accepted Ritonavir Tablets 100 mg for the list of prequalified medicinal products.

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* Trade names are not prequalified by WHO. This is under local DRA responsibility. Throughout this WHOPAR, the proprietary name is given as an example only.

Summary of Prequalification Status for Ritonavir Tablets 100 mg:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	Dec 2010	listed				
Dossier Evaluation						
Quality	Nov 2010	MR				
Bioequivalence	Dec 2010	MR				
Safety, Efficacy	Dec 2010	MR				
Inspection Status						
GMP (re-)inspection						
APIs	June 2008	MR				
FPP	Aug 2009	MR				
GCP (re-)inspection	Apr 2009	MR				
Batch Analysis	NA					

MR: meets requirements
NA: not applicable, not available