WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Norvir[1]

International Nonproprietary Name (INN):
Ritonavir 100mg Tablets

Abstract

Norvir (Ritonavir 100mg tablets), manufactured at AbbVie Deutschland GmbH & Co. KG, Ludwigshafen, Germany was submitted to be considered for prequalification in 2010 when the product was licensed / registered in the European Union and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS on 01 June 2010.

The "Procedure for prequalification of pharmaceutical products[2]" defines specific evaluation mechanisms for products approved by regulatory authorities, which apply similar stringent standards for quality, safety and efficacy as those required by WHO.

The prequalification of this product by the WHO Prequalification of Medicines Programme (PQP) is based on the approval by a stringent regulatory authority (SRA), namely the "European Medicines Agency" (EMA http://www.ema.europa.eu/ema/) in line with the "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities"[3].

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Programme. However, according to the SRA guideline WHO may request additional data when considered necessary for the safe use of the product in regions relevant for prequalified products and such information may be included in the WHOPAR as a separate piece of information. In order to safeguard product quality throughout its entire intended shelf-life, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant.

Based on the submitted stability data WHO PQTm considers the following storage condition appropriate for the product when distributed in regions with zone III, IVa and IVb climatic conditions, based on available stability information:

"Do not store above 30°C. Store in the original bottle in order to protect from moisture.
The shelf-life at this storage condition is 24 months."

This WHOPAR refers to the information available at the approving stringent regulatory authority in terms of the assessment of the quality, efficacy and safety as well as steps taken after the prequalification (http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000127/human_med_000932.jsp&mid=WC0b01ac058001d124). (Web link assessed 19 May 2019)

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.
[2] http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS961_Annex10.pdf
[3] http://apps.who.int/prequal/info_general/documents/TRS986/TRS986_ANNEX-5_SRA-Guide.pdf
https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification_February2017_0.pdf

WHOPAR part		**Reference**[4]
Part 1	Summary for the Public	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/000127/WC500028729.pdf
Part 3	Package Leaflets	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000127/WC500028728.pdf
Part 4	Summaries Product Characteristics	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000127/WC500028728.pdf
Part 5	Labelling	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000127/WC500028728.pdf
Part 6	Discussion	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Scientific_Discussion/human/000127/WC500028725.pdf
Part 8	Steps taken following Authori-zation	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Procedural_steps_taken_and_scientific_information_after_authorisation/human/000127/WC500028730.pdf

Parts 2a, 2b and 7 of the WHOPAR for Norvir are included here.

Norvir contains the protease inhibitor ritonavir.
Its WHO recommended use is as a pharmacokinetic enhancer for the treatment of HIV/AIDS in combination with other antiretroviral products.
The most frequent adverse reactions observed during treatment with ritonavir are gastrointestinal (including diarrhoea, nausea, vomiting, abdominal pain), neurological disturbances (including paraesthesia and oral paraesthesia) and fatigue/asthenia.
The most serious adverse reactions of ritonavir are severe skin reactions, hepatitis, pancreatitis and myopathy.

The efficacy and safety profile of ritonavir is well established based on the extensive clinical experience in the treatment of HIV/AIDS.

Summary of Prequalification Status for Norvir

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	01 June 2010	listed	05 Dec 2016	listed
Dossier Evaluation	May 2010	MR	05 Dec 2016	requalified

MR: meets requirements
The table represents the status of relevant completed activities only.

[4] http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000127/human_med_000932.jsp&mid=WC0b01ac058001d124