WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

STOCRIN® 30 mg/ml oral solution[1]

International Nonproprietary Name (INN):
Efavirenz

Abstract

STOCRIN® 30 mg/ml oral solution, manufactured at Patheon Inc, Ontario, Canada and Merck Sharp & Dohme B.V., Haarlem, The Netherlands, was submitted to be considered for prequalification in 2005 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 23 May 2006.

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.
The shelf-life at this storage condition is 36 months.
After first opening: 1 month"

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/000250/human_med_001066.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/000250/WC500058947.pdf
Part 3	Package Leaflets	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000250/WC500058946.pdf
Part 4	Summaries Product Characteristics	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000250/WC500058946.pdf
Part 5	Labelling	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000250/WC500058946.pdf
Part 6	Discussion	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Scientific_Discussion/human/000250/WC500058943.pdf
Part 8	Steps taken following Authorization	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Procedural_steps_taken_and_scientific_information_after_authorisation/human/000250/WC500058949.pdf

Parts 2a, 2b and 7 of the WHOPAR for STOCRIN® 30 mg/ml oral solution are included here.

STOCRIN® 30 mg/ml oral solution contains the non-nucleoside reverse transcriptase inhibitor efavirenz Its WHO recommended use is for the treatment of HIV/AIDS (in combination with other antiretroviral products).

The most frequent adverse reactions observed during treatment with efavirenz are nervous system disorders, headache, dizziness, coordination and balance disturbances, psychiatric disorders such as abnormal dreaming, insomnia, anxiety and depression, skin rash, nausea, fatigue, increases in blood lipids and elevations of liver enzymes.
The most serious adverse reactions of efavirenz were skin reactions (rash, Stevens-Johnson syndrome), psychiatric disorders, (such as psychosis, suicide ideation/attempt and suicide) and pancreatitis and hepatic failure.

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

[4] http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000250/human_med_001066.jsp&mid=WC0b01ac058001d124

Summary of Prequalification Status for STOCRIN® 30 mg/ml oral solution

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	23 May 2006	listed	28 Sept 2017	listed
Dossier Evaluation	April 2006	MR	14 Aug 2017	requalified

MR: meets requirements

The table represents the status of relevant completed activities only.