WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Priftin [1]

International Nonproprietary Name (INN):
Rifapentine 150 mg film-coated tablets

Abstract

Priftin, manufactured at Sanofi S.p.A was submitted to be considered for prequalification in 2017 when the product was licensed / registered in the USA and subsequently accepted for the WHO list of prequalified products for the treatment of tuberculosis on 14 February 2017.

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 American U.S.Food and Drug Administration" (http://www.fda.gov/default.htm) 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.
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 package. Protect from excessive heat and humidity.
The shelf-life at this storage condition is 36 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.accessdata.fda.gov/scripts/cder/daf/).

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[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

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

Priftin contains rifapentine. Its recommended use is for the treatment of tuberculosis.
The most frequent adverse reactions observed during treatment with rifapentine are anaemia, lymphopenia, neutropenia, gastrointestinal symptoms, skin reactions, increased ALT, arthralgia, conjunctivitis, headache, anorexia and lymphadenopathy.
The most serious adverse reactions of rifapentine are pericarditis, myositis, pulmonary fibrosis and hypersensitivity.

The efficacy and safety profile of rifapentine is well established based on the extensive clinical experience in the treatment of tuberculosis.

Summary of Prequalification Status for Priftin

	Initial Acceptance			
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	14 Feb 2017	listed		
Dossier Evaluation	16 Jan 2017	MR		

MR: meets requirements

The table represents the status of relevant completed activities only.