WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Rifabutin Capsules USP 150mg[1]

International Nonproprietary Name (INN):
Rifabutin

Abstract

Rifabutin Capsules USP 150mg, manufactured at Lupin Limited was submitted to be considered for prequalification in 2014 when the product was licensed / registered in at least one of the ICH regions and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS related conditions (specifically for tuberculosis treatment in HIV/AIDS infected patients who require an antiretroviral therapy containing a boosted protease inhibitor) on 17 Nov 2014.

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), the United States of America "US Food and Drug Administration" (http://www.fda.gov), 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.

Based on the above, 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 (www.fda.gov/drugsatfda, FDA Application No. 090033, last accessed October 2015).
The prescribing information as certified to be FDA approved texts are included in this WHOPAR.

Parts 2a, 2b, 4, 5 and 7 of the WHOPAR for Rifabutin Capsules USP 150mg are included here. Since a separate Patient Information Leaflet is not available, part 3 is not included in this WHOPAR.

Rifabutin Capsules USP 150mg contains rifabutin. Its WHO recommended use is for TB treatment in HIV/AIDS infected patients who require an antiretroviral therapy containing a boosted protease inhibitor.

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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://apps.who.int/prequal/info_general/documents/TRS961/TRS961_Annex10.pdf

[3] http://apps.who.int/prequal/info_general/documents/TRS986/TRS986_ANNEX-5_SRA-Guide.pdf

The most frequent adverse events observed during treatment with rifabutin were gastrointestinal reactions (nausea, diarrhoea), elevated liver enzymes, haematological abnormalities (neutropenia, anaemia), hypersensitivity reactions, rash, myalgia and discoloured urine.
The most serious adverse effects of rifabutin are hepatitis, haemolysis, myositis and uveitis.

The efficacy and safety profile of rifabutin is well established based on the clinical experience in the treatment of mycobacterial infections in HIV/AIDS patients.

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 25°C. Avoid excursions above 30.

Store in the original and keep the bottle tightly closed to protect from moisture. Protect from light.

The shelf-life at this storage condition is 24 months.

Summary of Prequalification Status for Rifabutin Capsules USP 150mg

	Initial Acceptance			
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	17 Nov 2014	listed		
Dossier Evaluation	12 Nov 2014	MR		

MR: meets requirements

The table represents the status of relevant completed activities only.