WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Rifampicin 300 mg Capsules*

International Nonproprietary Name (INN):
Rifampicin

Abstract

Rifampicin 300 mg Capsules, manufactured at Macleods Pharmaceuticals Ltd, Daman, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 13 July 2018.

Rifampicin 300 mg Capsules is indicated, in combination with other antituberculosis agents, for the treatment of tuberculosis caused by drug-susceptible *Mycobacterium tuberculosis*. Detailed information on the use of this product is described in the Summary of Product Characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredient (API) of Rifampicin 300 mg Capsules is the antimycobacterial agent rifampicin. The API is well documented for the treatment of tuberculosis.

The most important adverse reactions of rifampicin are hepatotoxicity, particularly cholestatic reactions, and skin reactions. It can also potentiate the hepatotoxicity of the other anti-tuberculosis medications.

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

On the basis of data submitted and public information on the use of rifampicin in antituberculosis therapy, the team of assessors advised that Rifampicin 300 mg Capsules is of acceptable quality, efficacy and safety to allow inclusion of Rifampicin 300 mg Capsules in the list of prequalified medicinal products.

* 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.

Summary of Prequalification Status for Rifampicin 300 mg Capsules:

Initial acceptance	**Date**	**Outcome**
Status on PQ list,	17 July 2018	listed
Quality	11 June 2018	MR
Bioequivalence	19 June 2018	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	22 July 2015	MR
API	24 August 2017	MR
FPP	05 January 2018	MR
GCP/GLP (re-)inspection	14 July 2017	MR

MR: meets requirements
NA: not applicable, not available