WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Rifampicin/Isoniazid/Pyrazinamide 75 mg/50 mg/150 mg Dispersible Tablets[1]

International Nonproprietary Names (INN):
Rifampicin/Isoniazid/Pyrazinamide

Abstract

Rifampicin/Isoniazid/Pyrazinamide 75mg/50mg/150mg Dispersible Tablets, manufactured at Macleods Pharmaceuticals Limited, Daman, India was accepted for the WHO list of prequalified products for the treatment of tuberculosis on 12 December 2017.

Rifampicin/Isoniazid/Pyrazinamide 75mg/50mg/150mg Dispersible Tablets is indicated for the initial treatment of tuberculosis in children 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 ingredients (APIs) of Rifampicin/Isoniazid/Pyrazinamide 75mg/50mg/150mg Dispersible Tablets are the antimycobacterial agents rifampicin, isoniazid and pyrazinamide. The APIs are well-established and documented for the treatment of tuberculosis.

The most frequent adverse events observed during treatment with rifampicin, isoniazid and pyrazinamide were peripheral neuropathy, transient increases of serum transaminases, hyperuricaemia, flushing and arthralgia.

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 most important adverse effects of isoniazid are peripheral and central neurotoxic effects, as well as severe and sometimes fatal hepatitis.

The most important adverse effect of pyrazinamide is liver damage, ranging from asymptomatic increase of serum transaminases to symptomatic liver dysfunction, and in rare cases also fatal liver failure.

The efficacy and safety profile of Rifampicin/Isoniazid/Pyrazinamide 75mg/50mg/150mg Dispersible Tablets is well-established based on extensive clinical experience in the treatment of tuberculosis.

On the basis of data submitted and public information on the use combination therapy in antituberculosis, the team of assessors advised that Rifampicin/Isoniazid/Pyrazinamide 75mg/50mg/150mg Dispersible Tablets is of acceptable quality, efficacy and safety to allow inclusion in the list of prequalified medicinal products.

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.

Summary of Prequalification Status for Rifampicin/Isoniazid/Pyrazinamide 75mg/50mg/150mg Dispersible Tablets:

Initial acceptance	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	12 December 2017	Listed
Quality	29 November 2017	MR
Bioequivalence	05 December 2017	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	22 July 2015	MR
API	13 November 2015	MR
API	16 September 2016	MR
API	24 August 2017	MR
API	26 August 2017	MR
API	28 August 2017	MR
FPP	NA	NA
GCP/GLP (re-)inspection	14 July 2017	MR

MR: Meets Requirements
NA: Not applicable, not available