WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Rifampicin/Isoniazid 75 mg/50 mg Dispersible Tablets*

Abstract

Rifampicin/Isoniazid 75 mg/50 mg Dispersible Tablets, manufactured at Macleods Pharmaceuticals Limited, Unit II, Kachigam, Daman, India was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 31 August 2017.

Rifampicin/Isoniazid 75 mg/50 mg Dispersible Tablets is indicated for the continuation phase of treatment of tuberculosis, caused by *Mycobacterium tuberculosis* in children weighing less that 25 kg 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 75 mg/50 mg Dispersible Tablets are the antimycobacterial agents rifampicin and isoniazid. The APIs are well-established and documented for the treatment of tuberculosis.

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

The most serious safety concerns with rifampicin are hepatotoxicity, particularly cholestatic reactions, and skin reactions. It can also potentiate the hepatotoxicity of other anti-tuberculosis medications.

The most serious safety concerns with isoniazid are peripheral and central neurotoxic effects, as well as severe and sometimes fatal hepatitis.

The efficacy and safety profile of Rifampicin/Isoniazid 75 mg/50 mg 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 of rifampicin and isoniazid in antituberculosis, the team of assessors advised that Rifampicin/Isoniazid 75 mg/50 mg Dispersible Tablets is of acceptable quality, efficacy and safety to allow inclusion of Rifampicin/Isoniazid 75 mg/50 mg Dispersible Tablets in the list of prequalified medicinal products.

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* 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 75 mg/50 mg Dispersible Tablets:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	31 Aug 2017	listed				
Dossier Evaluation (Quality assurance)						
Quality	18 July 2017	MR				
Bioequivalence	14 Nov 2016	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	19 March 2014	MR				
API	22 July 2015	MR				
API	13 Nov 2015	MR				
API	25 June 2016	MR				
API	23 Aug 2016	MR				
FPP	23 May 2014	MR				
GCP / GLP (re-)inspection	14 July 2017	MR				

MR: meets requirements
NA: not applicable, not available