WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Ethionamide 250 mg Tablets*

International Nonproprietary Name (INN):
Ethionamide 250mg Tablets

Abstract

Ethionamide 250 mg Tablets, manufactured at Micro Labs Ltd, 92, Sipcot Industrial Complex, Hosur – 635126, Tamilnadu, India was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 19 December 2012.

Ethionamide 250 mg Tablets is indicated for the treatment of 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 Ethionamide 250 mg Tablets is the antimycobacterial agent ethionamide. The API is well-established and documented for the treatment of tuberculosis.

The most frequent adverse events observed during treatment with ethionamide were epigastric discomfort, abdominal pain, anorexia, nausea, vomiting, diarrhoea, elevated serum transaminases.

The most serious safety concerns with ethionamide are hepatitis, psychotic disturbances, encephalopathy, peripheral and optic neuritis, and a pellagra-like syndrome.

The efficacy and safety profile of Ethionamide 250 mg 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 ethionamide therapy in tuberculosis, the team of assessors advised that Ethionamide 250 mg Tablets is of acceptable quality, efficacy and safety to allow inclusion of Ethionamide 250 mg Tablets in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is under local DRA responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Summary of Prequalification Status for Ethionamide 250 mg Tablets:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	19 Dec 2012	listed				
Dossier Evaluation (Quality assurance)						
Quality	05 Oct 2012	MR				
Bioequivalence	10 Aug 2012	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	17 Dec 2012	MR				
FPP	20 April 2012	MR				
GCP (re-)inspection	18 May 2012	MR				
Batch Analysis	NA	NA				

MR: meets requirements
NA: not applicable, not available