

**WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

Ethionamide 250 mg Tablets*

International Nonproprietary Name (INN):
Ethionamide

Abstract

Ethionamide 250 mg Tablets, manufactured at Macleods Pharmaceuticals Limited, Mumbai, India was accepted for the WHO list of prequalified products for the treatment of tuberculosis on 21 December 2007.

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 (SPC), 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 important adverse effects of 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 antituberculosis therapy the team of assessors accepted Ethionamide 250 mg Tablets for 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	21 Dec 2007	listed				
Dossier Evaluation						
Quality	27 Sept 2007	MR				
Bioequivalence	21 May 2007	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
APIs	NA	NA				
FPP	20 June 2007	MR				
GCP (re-)inspection	20 Sept 2007	MR				
Batch Analysis	NA	NA				

MR: Meets Requirements

NA: Not applicable, not available