WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Ethambutol hydrochloride/Isoniazid 400mg/150mg tablets*

International Nonproprietary Name (INN):
Ethambutol, isoniazid

Abstract

Ethambutol hydrochloride/Isoniazid 400mg/150mg tablets, manufactured at Cadila Pharmaceuticals Limited, Dholka, Ahmedabad, India was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 28 April 2010.

Ethambutol hydrochloride/Isoniazid 400mg/150mg 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 ingredients (APIs) of Ethambutol hydrochloride/Isoniazid 400mg/150mg tablets are the antimycobacterial agents ethambutol and isoniazid. The APIs are well-established and documented for the treatment of tuberculosis.

The most frequent adverse events observed during treatment with ethambutol and isoniazid were peripheral neuropathy (usually preceded by paraesthesias of the feet and hands), transient increases of serum transaminases (ALT, AST) and hyperuricaemia, especially in patients with gout.

The most important adverse effects of ethambutol and isoniazid are retrobulbar neuritis with a reduction in visual acuity, other peripheral and central neurotoxic effects, and severe and sometimes fatal hepatitis.

The efficacy and safety profile of Ethambutol hydrochloride/Isoniazid 400mg/150mg 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 ethambutol/isoniazid in tuberculosis, the team of assessors advised that Ethambutol hydrochloride/Isoniazid 400mg/150mg tablets is of acceptable quality, efficacy and safety to allow inclusion of Ethambutol hydrochloride/Isoniazid 400mg/150mg 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 Ethambutol hydrochloride/Isoniazid 400mg/150mg tablets:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	28 April 2010	listed				
Dossier Evaluation						
Quality	24 Sept 2009	MR				
Bioequivalence	28 Jan 2010	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
APIs	14 Oct 2006	MR				
	30 Nov 2005	MR				
FPP	22 Aug 2008	MR				
GCP (re-)inspection	26 Aug 2005	MR				
Batch Analysis	NA	NA				

MR: meets Requirements
NA: not applicable, not available