WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB008 trade name]*

Ethambutol hydrochloride 400mg tablets

Abstract

[TB008 trade name], manufactured at Cadila Pharmaceuticals Ltd, Dholka, Ahmedabad, India was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 13 November 2003.

[TB008 trade name] 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 [TB008 trade name] is the antimycobacterial agent ethambutol.
The efficacy and safety of ethambutol are well established based on extensive clinical experience in the treatment of tuberculosis.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of ethambutol hydrochloride in tuberculosis, the team of assessors advised that [TB008 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB008 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [TB008 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	13 Nov 2003	listed
Quality	NA	NA
Bioequivalence	NA	NA
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	02 Nov 2002	MR
GCP/GLP (re-)inspection	NA	NA

MR: meets requirements
NA: not applicable, not available

The table represents the status of relevant completed activities only.

Requalification	11 December 2018

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.