

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB183 trade name]*

Ethambutol hydrochloride/ isoniazid/ rifampicin
275mg/75mg/150mg tablets

[TB183 trade name], manufactured at Macleods Pharmaceuticals Ltd, Daman India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 22 October 2008.

[TB183 trade name] is indicated for the initial treatment of tuberculosis due to *Mycobacterium 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(s) of [TB183 trade name] is ethambutol hydrochloride, isoniazid and rifampicin.

The efficacy and safety of ethambutol hydrochloride, isoniazid and rifampicin is 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, isoniazid and rifampicin in tuberculosis, the team of assessors advised that [TB183 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB183 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB183 trade name]:

	Initial Acceptance	
	Date	Outcome
Status on PQ list	22 October 2008	listed
Quality	26 Sept 2008	MR
Bioequivalence	27 Nov 2007	MR
Safety, Efficacy	NA	NA
GMP(re-) inspection		
APIs	17 March 2007	MR
	30 Nov 2005	MR
	14 Oct 2006	waived (only source)
FPP	20 June 2007	MR
GCP (re-)inspection	NA	NA
Batch Analysis	NA	NA

MR: meets requirements

NA: not applicable, not available

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