WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB192 trade name]*

Ethambutol hydrochloride /Isoniazid/ Rifampicin 275mg/75mg/150mg tablets

[TB192 trade name] manufactured at Svizera Labs Private Ltd, Navi Mumbai, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 19 December 2012.

[TB192 trade name]is indicated for the initial treatment phase 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 ingredients (APIs) of [TB192 trade name] are the antimycobacterial agents ethambutol, isoniazid and rifampicin. The APIs are well-established and documented for the treatment of tuberculosis.

The efficacy and safety profile of [TB192 trade name]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 combination therapy in tuberculosis, the team of assessors advised that [TB192 trade name]is of acceptable quality, efficacy and safety to allow inclusion of [TB192 trade name]in the list of prequalified medicinal products.

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

Summary of Prequalification Status for [TB192 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	19 December 2012	listed
Quality	10 December 2012	MR
Bioequivalence	29 November 2012	MR
Safety, Efficacy	NA	NA
GMP (re-)inspection		
API	18 February 2011	MR
API	16 June 2011	MR
API	04 February 2012	MR
FPP	29 September 2012	MR
GCP/GLP inspection	24 May 2012	MR

MR: meets requirements

NA: not applicable, not available

Requalification	15 March 2021