WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Cycloserine 250 mg Capsules *

International Nonproprietary Name(s) (INN):
Cycloserine 250 mg Capsules

Abstract

Cycloserine 250 mg Capsules manufactured at Biocom JSC, 54 Chapaevsky Cr, 355016 Stavropol, Russian Federation, was accepted for the WHO list of prequalified medicinal products for the treatment of tuberculosis on 20 August 2013.

Cycloserine 250 mg Capsules 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 Cycloserine 250 mg Capsules is the antibiotic agent cycloserine. The API is well-established and documented for the treatment of tuberculosis.

The most serious safety concerns with cycloserine are psychiatric and central nervous system (CNS) disorders. The most frequent adverse events observed during treatment were headache, tremor, dysarthria, vertigo, depression, confusion, anxiety, nervousness, drowsiness, dizziness and lethargy. CNS adverse reactions appear to be dose-related, and occur within the first 2 weeks of therapy in about 15 to 30% of patients. CNS symptoms generally disappear when the drug is discontinued.

The efficacy and safety profile of cycloserine 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 cycloserine in tuberculosis, the team of assessors advised that Cycloserine 250 mg Capsules is of acceptable quality, efficacy and safety to allow inclusion of Cycloserine 250 mg Capsules in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Summary of Prequalification Status for Cycloserine 250 mg Capsules:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	20 Aug 2013	listed				
Dossier Evaluation (Quality assurance)						
Quality	30 July 2013	MR				
Bioequivalence	31 Jan 2013	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	01 Dec 2012	MR				
FPP	18 July 2012	MR				
GCP (re-)inspection	NA	NA				
Batch Analysis	NA	NA				

MR: meets requirements
NA: not applicable, not available