

**WHO Prequalification Programme  
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

Terizidone Capsules 250 mg <sup>1</sup>

International Nonproprietary Name (INN):  
terizidone

**Abstract**

Terizidone Capsules 250 mg, manufactured at Macleods Pharmaceuticals Limited, Unit II, Plot No. 25 – 27, Survey No. 366, Premier Industrial Estate, Kachigam, Daman, 396210, India was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 28 November 2017.

Terizidone Capsules 250 mg is indicated in combination with other antituberculosis agents for the treatment of all forms of tuberculosis caused by *Mycobacterium tuberculosis*, as a second -line antimycobacterial drug when use of first line drugs is not appropriate due to resistance or intolerance. 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 Terizidone Capsules 250 mg is the antibiotic agent terizidone. The API is well-established and documented for the treatment of tuberculosis.

The most serious safety concerns with Terizidone Capsules 250 mg 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 Terizidone Capsules 250 mg 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 Terizidone Capsules 250 mg in tuberculosis, the team of assessors advised that Terizidone Capsules 250 mg is of acceptable quality, efficacy and safety to allow inclusion of Terizidone Capsules 250 mg in the list of prequalified medicinal products.

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<sup>1</sup>Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

**Summary of Prequalification Status for Terizidone Capsules 250 mg**

	<b>Initial Acceptance</b>					
	<b>Date</b>	<b>Outcome</b>	<b>Date</b>	<b>Outcome</b>	<b>Date</b>	<b>Outcome</b>
Status on PQ list	28 Nov 2017	listed				
<b>Dossier Evaluation (Quality assurance)</b>						
Quality	09 Nov 2017	MR				
Bioequivalence	10 Nov 2017	MR				
<b>Inspection Status</b>						
GMP(re-)inspection						
API	12 Aug 2016	MR				
FPP	NA	NA				
GCP/GLP (re-)inspection	14 July 2017	MR				

MR: meets requirements

NA: not applicable, not available