WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets*

International Nonproprietary Names (INN): *Artesunate/Mefloquine*

Abstract

Artesunate/Mefloquine 25/50mg FDC(Fixed Dose Combination) Cipla Tablets manufactured at Cipla Ltd, Patalganga, Maharashtra, India, was accepted for the WHO list of prequalified medicinal products for the treatment of Malaria on 12 September 2012.

Artesunate/Mefloquine 25/50mg FDC(Fixed Dose Combination) Cipla Tablets is a so called artemisinin-based combination therapy (ACT) for the treatment of uncomplicated cases of malaria due to *Plasmodium falciparum.*

It was developed in collaboration with DNDi, Switzerland, a not-for-profit drug research and development organization.

Detailed information on the use of this product is described in the Summary of Product Characteristics (SmPC), which can be found in this WHOPAR.

Efficacy and safety of artesunate/mefloquine in adults and children with uncomplicated *P. falciparum* malaria in the setting of mono- and mixed infections have been demonstrated in several comparative clinical trials conducted in different endemic regions.

The most frequent adverse events are headache, dizziness, vomiting, nausea, fatigue, pyrexia, arthralgias, myalgias, anorexia, sleep disorders, and palpitations.
The most important safety problems with these APIs are neuropsychiatric side effects and vomiting, alterations to the electrocardiogram (ECG), tingling in hands and feet, and rash.

On the basis of data submitted and public information on the use of artemisinin-based combination therapy in malaria, the team of assessors advised that Artesunate/Mefloquine 25/50mg FDC(Fixed Dose Combination) Cipla Tablets is of acceptable quality, efficacy and safety to allow inclusion of the product in the list of prequalified medicinal products.

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

Summary of Prequalification Status for Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	12 Sept 2012	listed				
Dossier Evaluation (Quality assurance)						
Quality	24 Aug 2012	MR				
Bioequivalence	04 Sept 2012	MR				
Safety, Efficacy	16 Aug 2012	MR				
Inspection Status						
GMP(re-)inspection						
API 1	17 Feb 2011	MR				
API 2	NA	NA				
FPP	24 Feb 2011	MR				
GCP (re-)inspection	NA	NA				
Batch Analysis	NA	NA				

MR: meets requirements
NA: not applicable, not available