WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA099 trade name]*

Artemether/lumefantrine 20mg/120mg tablets

[MA099 trade name], manufactured at Mylan Laboratories Limited, Sinnar, Nashik, India, was included in the WHO list of prequalified medicinal products for the treatment of uncomplicated malaria on 16 May 2014.

[MA099 trade name] is indicated for treatment of uncomplicated malaria. 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 of [MA099 trade name] are artemether and lumefantrine.

The efficacy and safety of artemether and lumenfantrine are well established based on extensive clinical experience in the treatment of uncomplicated malaria due to *Plasmodium falciparum.*

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 artemether/lumenfantrine in uncomplicated malaria, the team of assessors advised that [MA099 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA099 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 [MA099 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	16 May 2014	listed
Quality	11 April 2014	MR
Bioequivalence	28 April 2014	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	14 Dec 2011	MR
API	26 April 2012	MR
FPP	28 June 2012	MR
GCP/GLP (re-)inspection		
GCP (re-)inspection	28 March 2013	MR
GLP (re-)inspection	28 March 2013	MR

API: active pharmaceutical ingredient
FPP: finished pharmaceutical product
GCP: good clinical practice [quality standard]
GLP: good laboratory practice [quality standard]
GMP: good manufacturing practice [quality standard]
MR: meets requirements
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available
PQ: prequalification

The table represents the status of relevant completed activities only.

Requalification	17 May 2021