WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA100 trade name]*

Artemether/lumefantrine 40mg/240mg Tablets

[MA100 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.

[MA100 trade name] is indicated for the treatment of uncomplicated malaria due to *Plasmodium falciparum*. 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 [MA100 trade name] are artemether and lumefantrine.

The efficacy and safety of artemether and lumefantrine 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/lumefantrine in uncomplicated malaria, the team of assessors advised that [MA100 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA100 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 [MA100 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