WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA064 trade name]*

Artemether/Lumefantrine 20mg/120mg tablets

[MA064 trade name], manufactured at Cipla Ltd, Patalganga, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 22 May 2009.

[MA064 trade name] is indicated for 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 [MA064 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 malaria.

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 malaria, the team of assessors advised that [MA064 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA064 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA064 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	22 May 2009	listed
Quality	15 May 2009	MR
Bioequivalence	10 June 2008	MR
Bioequivalence	21 May 2010	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	20 October 2007	MR
FPP	24 July 2008	MR
GCP/GLP (re-)inspection	3 July 2009	NoC

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
NoC: Notice of concern
PQ: prequalification

The table represents the status of relevant completed activities only.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Requalification	17 May 2021