WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA111 trade name]*

Artemether/lumefantrine 20 mg/120 mg tablets

[MA111 trade name], manufactured at Ajanta Pharma Limited, Maharashtra, India and Ajanta Pharma Limited, Gujarat, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 6 October 2014.

[MA111 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 [MA111 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 and lumefantrine in malaria, the team of assessors advised that [MA111 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA111 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 [MA111 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	6 Oct 2014	Listed
Quality	12 Aug 2014	MR
Bioequivalence	19 Aug 2014	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	1 February 2019	MR
API	4 May 2018	MR
API	10 June 2020	MR*
FPP	10 June 2020	MR*
FPP	18 November 2020	MR*
GCP/GLP (re-)inspection	NA	NA

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	27 January 2021