WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA128 trade name]*

Artemether/lumefantrine 40 mg/240 mg tablets

[MA128 trade name], manufactured at Ajanta Pharma Limited, Paithan, Aurangabad, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 21 April 2017.

[MA128 trade name] is indicated for 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 [MA128 trade name] are lumefantrine and the artemisinin derivative artemether.

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 [MA128 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA128 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA128 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	21 April 2017	listed
Quality	14 March 2017	MR
Bioequivalence	04 April 2017	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	20 April 2014	MR
FPP	29 April 2016	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.

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