WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA092 trade name]*

Artemether/Lumefantrine 20mg/120mg Dispersible Tablets

[MA092 trade name], manufactured at Ajanta Pharma Limited, Paithan, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 19 December 2012.

[MA092 trade name] is indicated for the treatment of uncomplicated cases of malaria due to *Plasmodium falciparum* strains which are susceptible to artemether and lumefantrine in adults, children and infants weighing 5 kg and above. 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 [MA092 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 [MA092 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA092 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [MA092 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	19 December 2012	Listed
Quality	17 December 2012	MR
Bioequivalence	10 December 2012	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API1	NA	NA
API2	18 March 2011	MR
FPP	NA	NA
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
NA: not applicable, not available
PQ: prequalification

MR: meets requirements
NA: not applicable, not available
The table represents the status of relevant completed activities only.

Requalification	31 October 2019

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