

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA155 trade name]*

Artemether/lumefantrine 60 mg/360 mg dispersible tablets

[MA155 trade name], manufactured at Guilin Pharmaceutical Co., Ltd, Guilin, Guangxi, China, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 13 April 2021.

[MA155 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 [MA155 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 [MA155 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA155 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA155 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	13 April 2021	Listed
Quality	07 April 2021	MR
Bioequivalence	12 April 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	04 May 2018	MR
FPP	19 October 2018	MR
GCP/GLP (re-)inspection	23 February 2018	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 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.