

## WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

### [MA154 trade name]\*

#### Artemether/lumefantrine 40 mg/240 mg dispersible tablets

[MA154 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.

[MA154 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 [MA154 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 [MA154 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA154trade name] in the list of prequalified medicinal products.

#### Summary of prequalification status for [MA154 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
<b>GMP (re-)inspection</b>		
API	04 May 2018	MR
FPP	19 October 2018	MR
<b>GCP/GLP (re-)inspection</b>	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.