

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA139 trade name]*

Dihydroartemisinin /piperaquine phosphate 40 mg/320 mg dispersible tablets

[MA139 trade name], manufactured at Guilin Pharmaceutical Co Ltd, Guangxi, China, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 19 November 2019.

[MA139 trade name] is currently indicated for uncomplicated malaria in adults, children and infants. 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 [MA139 trade name] are dihydroartemisinin and piperaquine phosphate.

The efficacy and safety of dihydroartemisinin and piperaquine phosphate are well established based on extensive clinical experience in the treatment of uncomplicated malaria in adults, children and infants. 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 dihydroartemisinin and piperaquine phosphate, the team of assessors advised that [MA139 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA139 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA139 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	Date	Outcome
Status on PQ list	19 November 2019	listed
Pharmaceutical quality	25 October 2019	MR
Bioequivalence	29 October 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	04 May 2018	MR
FPP	17 October 2018	MR
GCP/GLP (re-)inspection	18 January 2019	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 MR*: desk review (based on recent inspection reports) NA: not applicable, not available PQ: prequalification	

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

Dihydroartemisinin /piperaquine phosphate
40 mg/320 mg dispersible tablets (Guilin
Pharmaceutical Co Ltd), MA139

WHOPAR Part 1

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Requalification	01 September 2025
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