WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA141 trade name]*

Dihydroartemisinin /piperaquine phosphate 20 mg/160 mg dispersible tablets

[MA141 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.

[MA141 trade name] is currently indicated for the treatment of uncomplicated malaria in children. 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 [MA141 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 children.

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 [MA141 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA141 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA141 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	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

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

Requalification	**01 September 2025**