WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA168 trade name]*

Artesunate 60mg powder for injection (with sodium bicarbonate 8.4mg/mL and arginine 20mg/mL injection)

[MA168 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 27 June 2023.

[MA168 trade name] is indicated for malaria treatment. 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 ingredient of [MA168 trade name] artesunate.
The efficacy and safety of artesunate 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 artesunate in malaria, the team of assessors advised that [MA168 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA168 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA168 trade name]:
The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

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

Initial acceptance	**Date**	**Outcome**
Status on PQ list	27 June 2023	listed
Pharmaceutical quality	12 June 2023	MR
Bioequivalence	15 June 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	26 September 2021	MR
FPP	19 September 2021	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
NA: not applicable, not available
PQ: prequalification

The table represents the status of relevant completed activities only.