

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA200 trade name]*

Artesunate 120 mg powder for injection co-packaged with solvent for reconstitution (arginine
20mg/mL /sodium bicarbonate 8.4mg/mL injection)

[MA200 trade name], manufactured at Guilin Pharmaceutical Co., Limited, Guangxi, China, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 12 December 2024.

[MA200 trade name] is indicated for the treatment of severe malaria. 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 [MA200 trade name] is the artemisinin derivative artesunate. The efficacy and safety of artesunate is well established based on extensive clinical experience in the treatment of severe 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 the treatment of severe malaria, the team of assessors advised that [MA200 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA200 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA200 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	12 December 2024	listed
Pharmaceutical quality	06 December 2024	MR
Bioequivalence	10 December 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	28 September 2023	MR
FPP	22 September 2023	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	