WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA194 trade name]*

Artesunate 120 mg powder for injection + Sodium bicarbonate 50 mg/mL solution + Sodium chloride 9 mg/mL solution

[MA194 trade name], manufactured at Macleods Pharmaceuticals Limited, Kachigam, Daman, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 29 May 2024.

[MA194 trade name] is indicated for 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 [MA194 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 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 [MA194 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA194 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA194 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	29 May 2024	listed
Pharmaceutical quality	23 May 2024	MR
Bioequivalence	15 May 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	24 June 2022	MR
FPP	22 June 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

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