WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA186 trade name]*

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

[MA186 trade name], manufactured at Ipca Laboratories Limited, Sejavta, Ratlam, Madhya Pradesh, India was included in the WHO list of prequalified medicinal products for the treatment of malaria on 05 September 2023.

[MA186 trade name] is indicated for treatment of 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 [MA186 trade name] is the artemisinin derivative 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 [MA186 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA186 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA186 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	05 September 2023	listed
Pharmaceutical quality	03 July 2023	MR
Bioequivalence	05 July 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	30 November 2022	MR*
FPP	24 June 2022	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
NA*: Not inspected for GCP/GLP since a biowaiver applies

The table represents the status of relevant completed activities only.

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