WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA205 trade name]*

Artemether / Lumefantrine 20 mg/120 mg uncoated tablets

[MA205 trade name], manufactured at Macleods Pharmaceuticals Limited, Daman, India and Oxalis Labs, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 05 July 2025.

[MA205 trade name] is indicated for the treatment of uncomplicated cases of malaria due to *Plasmodium falciparum.* 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 [MA205 trade name] are artemether and lumefantrine.

The efficacy and safety of artemether and lumefantrine 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 artemether and lumefantrine in the treatment of malaria, the team of assessors advised that [MA205 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA205 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA205 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	05 July 2025	listed
Pharmaceutical quality	16 June 2025	MR
Bioequivalence	19 June 2025	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	24 June 2022	MR
APIs	24 March 2023	MR
APIs	26 June 2023	MR
APIs	23 June 2025	MR*
FPP	27 April 2023	MR
FPP	30 May 2024	MR*
GCP/GLP (re-)inspection	10 February 2023	MR

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