WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA211 trade name]*

Artemether / Lumefantrine 20 mg/120 mg uncoated tablets

[MA211 trade name], manufactured at Quality Chemical Industries Limited, Luzira Industrial Park, Kampala, Uganda was included in the WHO list of prequalified medicinal products for the treatment of malaria on 27 August 2026.

[MA211 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 [MA211 trade name] are artemether and lumefantrine.

The efficacy and safety of are 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 malaria, the team of assessors advised that [MA211 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA211 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA211 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 August 2026**	listed
Pharmaceutical quality	31 July 2026	MR
Bioequivalence	19 June 2026	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	07 July 2023	MR
APIs	17 April 2025	MR*
APIs	10 October 2025	MR
FPP	16 May 2025	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