WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA210 trade name]*

Artemether/lumefantrine 80 mg/480 mg tablets

[MA210 trade name], manufactured at Oxalis Labs, Solan, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of uncomplicated malaria on 09 September 2025.

[MA210 trade name] is indicated for the treatment of uncomplicated malaria due *to Plasmodium falciparum* in adults and children weighing 35 kg and above. 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 [MA210 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 uncomplicated malaria due *to Plasmodium falciparum.*

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 [MA210 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA210 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA210 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	09 September 2025	listed
Pharmaceutical quality	21 August 2025	MR
Bioequivalence	29 August 2025	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	24 June 2022	MR
APIs	24 March 2023	MR
API	18 July 2025	MR*
API	04 July 2025	MR*
FPP	27 April 2023	MR
GCP/GLP (re-)inspection	15 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

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