WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA108 trade name]*

Artemether/lumefantrine 80 mg/480 mg tablets

[MA108 trade name], manufactured at Novartis Saglik, Istanbul, Turkey, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 15 July 2015.

[MA108 trade name] is indicated for the treatment of uncomplicated 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 [MA108 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 malaria, the team of assessors advised that [MA108 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA108 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA108 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	15 July 2015	Listed
Quality	10 July 2015	MR
Bioequivalence	29 June 2015	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	22 June 2012	MR
API	28 June 2012	MR
FPP	NA	NA
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

The table represents the status of relevant completed activities only.

Requalification	22 March 2022

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