WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA143 trade name]*

Artemether/Lumefantrine 40 mg/240 mg tablets

[MA143 trade name], manufactured by Macleods Pharmaceuticals Limited, At, Oxalis labs, Baddi, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 22 August 2019.

[MA143 trade name] is indicated for the treatment of uncomplicated cases of malaria due to *Plasmodium falciparum* strains which are susceptible to artemether and lumefantrine. 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(s) of [MA143 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 [MA143 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA143 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA143 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	22 August 2019	Listed
Quality	08 August 2019	MR
Bioequivalence	09 August 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	16 February 2017	MR
APIs	04 May 2018	MR
APIs	01 February 2019	MR
FPP	16 March 2018	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
NA: not applicable, not available
PQ: prequalification

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.