

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA160 trade name]*

Artemether/Lumefantrine 80mg/480mg tablets

[MA160 trade name], manufactured at Ipca Laboratories Limited, Mumbai, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 01 February 2022.

[MA160 trade name] is indicated for treatment 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 [MA160 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 treatment, the team of assessors advised that [MA160 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA160 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA160 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	01 February 2022	listed
Quality	14 January 2022	MR
Bioequivalence	27 January 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	31 May 2018	MR
FPP	25 January 2021	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.