WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA167 trade name] *

Artemether/lumefantrine 20 mg/120 mg tablets

[MA167 trade name] *, manufactured at Ipca Laboratories Limited, Silvassa, Dadra and Nagar Haveli (U. T.), India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 9 February 2022.

[MA167 trade name]* is indicated for the treatment of uncomplicated malaria due to *Plasmodium falciparum* in adults, children and infants. 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 [MA167 trade name] are lumefantrine and the artemisinin derivative, artemether. The efficacy and safety of lumefantrine and artemether 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/lumefantrine in malaria, the team of assessors advised that [MA167 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA167 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA167 trade name] *

Initial acceptance	**Date**	**Outcome**
Status on PQ list	9 February 2022	listed
Quality	5 February 2022	MR
Bioequivalence	3 February 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	31 May 2018	MR
API	4 May 2018	MR
API	1 February 2019	MR
FPP	25 January 2021	MR
GCP/GLP (re-)inspection	23 February 2018	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	

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.