WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA062 trade name]*

Artemether/Lumefantrine 20 mg/120 mg Tablets

[MA062 trade name], manufactured at Ipca Laboratories Ltd, Silvassa, Dadra and Nagar Haveli, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 15 December 2009.

[MA062 trade name] is indicated for 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 ingredients of [MA062 trade name] are lumefantrine and 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 [MA062 trade name] in malaria, the team of assessors advised that [MA062 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA062 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA062 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	15 December 2009	listed
Quality	23 October 2009	MR
Bioequivalence	22 September 2008	MR
Safety, efficacy	NA	MR
GMP (re-)inspection		
API	14 February 2008	MR
FPP	30 January 2008	MR
GCP/GLP (re-)inspection	28 November 2008	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	06 March 2020	MR

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