WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA136 trade name]*

Artemether/lumefantrine 20 mg / 120 mg dispersible tablets

[MA136 trade name], manufactured at Ipca Laboratories Limited, U.T. of Dadra and Nagar Haveli and Daman and Diu, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 19 June 2018.

[MA136 trade name] is indicated for the treatment of uncomplicated cases of malaria due to *Plasmodium falciparum* strains which are susceptible to artemether as well as to 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 (APIs) of [MA136 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 artemisinin-based combination therapy in malaria, the team of assessors advised that [MA136 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA136 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA136 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	19 June 2018	**listed**
Quality	08 February 2018	MR
Bioequivalence	09 February 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	26 February 2016	MR
FPP	30 April 2015	MR
GCP/GLP (re-)inspection	23 February 2018	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.

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