# WHO Prequalification Programme
# WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

## [MA115 trade name]*

Artemether/lumefantrine 20 mg/120 mg dispersible tablets

[MA115 trade name], manufactured at Cipla limited, Indore special economic zone, Pithampur (MP), India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 17 July 2017.

[MA115 trade name] is indicated for the treatment of uncomplicated 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 (APIs) of [MA115 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 [MA115 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA115 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [MA115 trade name]:**

| **Initial acceptance** | **Date** | **Outcome** |
|---|---|---|
| **Status on PQ list** | 17 July 2017 | |
| Quality | 15 Aug 2016 | MR |
| Bioequivalence | 07 Sept 2016 | MR |
| **GMP (re-)inspection** | | |
| API | 17 Feb 2014 | MR |
| FPP | 16 Oct 2014 | MR |
| **GCP/GLP (re-)inspection** | 18 March 2016 | 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.