WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA122 trade name]*

Artemether/lumefantrine 80 mg/480 mg tablets

[MA122 trade name], manufactured at Cipla limited, Tehsil Nalagarh, District Solan, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 17 July 2017.

[MA122 trade name] is indicated for the treatment of uncomplicated malaria due to *Plasmodium falciparum* in adults and children of 35 kg and above. 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 [MA122 trade name] are the artemisinin derivative 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/lumefantrine in malaria, the team of assessors advised that [MA122 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA122 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA122 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	17 July 2017	listed
Quality	19 Nov 2016	MR
Bioequivalence	27 Nov 2016	MR
Safety, Efficacy	NA	NA
GMP (re-)inspection		
API	14 Feb 2014	MR
API	16 April 2014	MR
FPP	22 June 2016	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.