WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA091 trade name]*

Artemether/lumefantrine 20 mg/120 mg tablets

[MA091 trade name], manufactured at Macleods Pharmaceutical Limited, Daman, India and Oxalis Labs, Solan, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of the treatment of malaria on 21 October 2013.

[MA091 trade name] is indicated for the treatment of uncomplicated cases of 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 of [MA091 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 the treatment of malaria, the team of assessors advised that [MA091 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA091 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA091 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	21 Oct 2013	Listed
Quality	1 Oct 2013	MR
Bioequivalence	9 Oct 2013	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	16 June 2011	MR
FPP	19 Feb 2010	MR
GCP/GLP (re-)inspection	12 Feb 2013	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.