WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA138 trade name]*

Artemether/Lumefantrine 80mg/480mg tablets

[MA138 trade name], manufactured at Strides Pharma Science Limited, Bangalore, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 6 February 2019.

[MA138 trade name] is indicated for the treatment of uncomplicated cases of malaria. 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 [MA138 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/lumefantrine in malaria, the team of assessors advised that [MA138 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA138 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [MA138 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	06 February 2019	Listed
Quality	21 January 2019	MR
Bioequivalence	25 January 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	15 February 2018	MR
API	28 February 2018	MR*
FPP	16 June 2016	MR
GCP/GLP (re-)inspection	06 October 2017	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	

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