

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

[MA110 trade name]\*

Artemether/lumefantrine 20 mg/120 mg dispersible tablets

[MA110 trade name], manufactured at Strides Pharma Science Limited, Suragajakkanahalli, Bangalore, India and Universal Corporation Limited, Kikuyu Town, Kikuyu, Kenya, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 12 December 2017.

[MA110 trade name] is indicated for 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 of [MA110 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 [MA110 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA110 trade name] in the list of prequalified medicinal products.

### Summary of prequalification status for [MA110 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	12 December 2017	listed
Quality	8 December 2017	MR
Bioequivalence	11 December 2017	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
API	14 November 2014	MR
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FPP	17 June 2016	MR
<b>GCP/GLP (re-)inspection</b>	6 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	

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.

# Formerly known as 'Strides Shasun Limited'.