

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA088 trade name]*

Artemether/Lumefantrine 20mg/120mg Tablets

[MA088 trade name], manufactured at Strides Pharma Science Limited, Bengaluru, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 24 June 2013.

[MA088 trade name] is indicated for the treatment of uncomplicated cases of malaria due to *Plasmodium falciparum* strains which are susceptible to artemether and lumefantrine in adults, children and infants weighing 5 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 of [MA088 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 [MA088 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA088 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [MA088 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	24 June 2013	Listed
Quality	19 April 2013	MR
Bioequivalence	22 April 2013	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API1	23 October 2009	MR
API2	08 December 2011	MR
FPP	25 August 2011	MR
GCP/GLP (re-)inspection	NA	NA
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 NA: not applicable, not available PQ: prequalification	

MR: meets requirements

NA: not applicable, not available

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.