WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA137 trade name]*

Artemether/lumefantrine 20 mg / 120 mg dispersible tablets

[MA137 trade name], manufactured at Macleods Pharmaceuticals Limited, At, Oxalis Labs,Tehsil Baddi, Dist. Solan, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 22 August 2019.

[MA137 trade name] is indicated for the treatment of *Plasmodium falciparum* 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 of [MA137 trade name] are artemether and lumefantrine

The efficacy and safety of artemether and lumefantrineare 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 lumefantrine and artemetherin malaria, the team of assessors advised that [MA137 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA137 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA137 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	22 August 2019	listed
Quality	19 July 2019	MR
Bioequivalence	02 August 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	16 February 2017	MR
API	04 May 2018	MR
FPP	16 March 2018	MR
GCP/GLP (re-)inspection	14 July 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.