WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[**MA083 trade name**][*]

Artesunate/Amodiaquine (as hydrochloride) 25 mg/ 67.5 mg tablets

[MA083 trade name] manufactured at Guilin Pharmaceutical Co. Ltd, Guilin, China was included in the WHO list of prequalified medicinal products for the treatment of malaria on 16 November 2012.

[MA083 trade name] is indicated for the treatment 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 of [MA083 trade name] are the 4-aminoquinoline amodiaquine and the artemisinin derivative artesunate.

The efficacy and safety profile of artesunate and amodiaquine are well established based on 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 artemisinin-based combination therapy in malaria, the team of assessors advised that [MA083 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA083 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA083 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	16 Nov 2012	listed
Quality	17 Sept 2012	MR
Bioequivalence	17 Sept 2012	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	Aug 2012	MR
FPP	26 Feb 2010	MR
GCP/GLP (re-)inspection	25 Oct 2012	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.

Requalification	17 May 2021

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