WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA117 trade name]*

Amodiaquine (as hydrochloride) 153 mg dispersible tablets + pyrimethamine/sulfadoxine 25 mg/500 mg dispersible tablets

[MA117 trade name], manufactured at Guilin Pharmaceutical Co Ltd, Guilin, China, was included in the WHO list of prequalified medicinal products for malaria prevention on 21 August 2018.

[MA117 trade name] is indicated for malaria prevention during the malaria season (seasonal malaria chemoprevention, SMC) in children. 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 [MA117 trade name] are amodiaquine (as hydrochloride), pyrimethamine and sulfadoxine.

The efficacy and safety of amodiaquine (as hydrochloride), pyrimethamine and sulfadoxine are well established based on extensive clinical experience in the malaria prevention.

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 amodiaquine (as hydrochloride), pyrimethamine and sulfadoxine in malaria prevention, the team of assessors advised that [MA117 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA117 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA117 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

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

Initial acceptance	**Date**	**Outcome**
Status on PQ list	21 August 2018	Listed
Pharmaceutical quality	07 August 2018	MR
Bioequivalence	14 August 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	13 March 2016	MR
API	22 March 2016	MR
API	04 May 2018	MR
FPP	25 March 2016	MR
GCP/GLP (re-)inspection	23 February 2018	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

Requalification	21 August 2023