WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA171 trade name]*

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

[MA171 trade name], manufactured at Macleods Pharmaceuticals Limited, Kachigam, Daman, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 04 November 2022.

[MA171 trade name] is indicated for malaria prevention during the malaria season (seasonal malaria chemoprevention, SMC) in children.

The active pharmaceutical ingredients of [MA171 trade name] are amodiaquine (as hydrochloride), pyrimethamine and sulfadoxine. These APIs, in combination with each other, are well-established and documented for the preventive treatment of malaria.

The efficacy and safety of amodiaquine (as hydrochloride), pyrimethamine/sulfadoxine combination in adults and children have been demonstrated based on extensive clinical experience in malaria chemoprevention.

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/sulfadoxine in malaria, the team of assessors advised that [MA171 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA171 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA171 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	04 November 2022	listed
Pharmaceutical quality	21 October 2022	MR
Bioequivalence	27 October 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	24 + 28 June 2022	MR
APIs	31 August 2020	MR*
FPP	28 June 2021	MR*
GCP/GLP (re-)inspection	09 September 2020	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.