WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA172 trade name]*

Amodiaquine (as hydrochloride) 75 mg dispersible tablets +
Pyrimethamine/Sulfadoxine 12.5 mg/250 mg dispersible tablets

[MA172 trade name], manufactured at Universal Corporation Limited, Kikuyu, Kenya, was included in the WHO list of prequalified medicinal products for malaria prevention on 30 July 2023.

[MA172 trade name] is indicated for malaria prevention during the malaria season (seasonal malaria chemoprevention, SMC) in patients aged 3 months to less than 1 year. 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 [MA172 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 [MA172 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA172 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA172 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	30 July 2023	listed
Pharmaceutical quality	20 January 2023	MR
Bioequivalence	24 January 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	22 June 2021	MR*
APIs	24 June 2022	MR
API	28 June 2022	MR
FPP	17 March 2023	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
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.