WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA198 trade name][*]

Amodiaquine (as hydrochloride) 153 mg dispersible tablets +

Pyrimethamine/Sulfadoxine 25 mg/500 mg dispersible tablet

[MA198 trade name], manufactured at Ajanta Pharma Ltd, Chhatrapati Sambhajinagar, Maharashtra, India, was included in the WHO list of prequalified medicinal products for malaria on 17 September 2025.

[MA198 trade name] is indicated for chemoprophylaxis 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 [MA198 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 chemoprophylaxis 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 amodiaquine (as hydrochloride), pyrimethamine/sulfadoxine in malaria, the team of assessors advised that [MA198 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA198 trade name] in the list of prequalified medicinal products.

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

Summary of prequalification status for [MA198 trade name]:

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

Initial acceptance	**Date**	**Outcome**
Status on PQ list	17 September 2025	listed
Pharmaceutical quality	04 September 2025	MR
Bioequivalence	09 September 2025	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	24 June 2022	MR
API	12 June 2024	MR
APIs	04 July 2025	MR*
FPP	08 December 2023	MR*
GCP/GLP (re-)inspection	24 May 2024	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