WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA147 trade name][*]

Amodiaquine (as hydrochloride) 150mg dispersible tablets +
Pyrimethamine/Sulfadoxine 25mg/500mg dispersible tablets

[MA147 trade name], manufactured at S Kant Healthcare Ltd., Mumbai, India, was included in the WHO list of prequalified medicinal products for malaria prevention on 12 April 2021.

[MA147 trade name] is indicated for malaria prevention 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 [MA147 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 prevention 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 and sulfadoxine in malaria prevention, the team of assessors advised that [MA147 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA147 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA147 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.

Summary of prequalification status for [MA147 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	12 April 2021	listed
Quality	01 April 2021	MR
Bioequivalence	07 April 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	04 May 2018	MR
APIs	28 November 2018	MR*
FPP	31 April 2020	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