WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA166 trade name]*

Pyrimethamine/Sulfadoxine 12.5mg/250mg dispersible tablets

[MA166 trade name], manufactured at Universal Corporation Limited, Kikuyu, Kenya, was included in the WHO list of prequalified medicinal products for prophylaxis against malaria, on 22 August 2022.

[MA166 trade name] is indicated for chemoprevention of malaria 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 [MA166 trade name] are pyrimethamine and sulfadoxine.

The efficacy and safety of pyrimethamine and sulfadoxine are well established based on extensive clinical experience in malaria prophylaxis.

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 pyrimethamine and sulfadoxine in malaria, the team of assessors advised that [MA166 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA166 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA166 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	22 August 2022	listed
Quality	09 August 2022	MR
Bioequivalence	16 August 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 June 2021	MR*
API	24 June 2022	MR
APIs	28 June 2022	MR
FPP	14 October 2021	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.

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