WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA179 trade name]*

Pyrimethamine/Sulfadoxine 25 mg/500 mg dispersible tablets

[MA179 trade name], manufactured at Guilin Pharmaceutical Co., Ltd, Guangxi, China, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 30 July 2023.

[MA179 trade name] is indicated to prevent malaria in children aged less than 12 months and in adults during pregnancy. [MA179 trade name] is also indicated for perennial malaria chemoprevention of children at high risk of severe malaria in areas of moderate to high perennial malaria transmission, where sulfadoxine-pyrimethamine is effective. 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 [MA179 trade name] are pyrimethamine and sulfadoxine.

The efficacy and safety of pyrimethamine and sulfadoxine are well established based on extensive clinical experience in the treatment 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 pyrimethamine and sulfadoxine in malaria, the team of assessors advised that [MA179 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA179 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA179 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	30 July 2023	listed
Quality	11 July 2023	MR
Bioequivalence	15 July 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	26 September 2021	MR
FPP	05 October 2021	MR
GCP/GLP (re-)inspection	23 February 2018	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.

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