WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA159 trade name]*

Pyrimethamine/sulfadoxine 25 mg/500 mg dispersible tablets

[MA159 trade name], manufactured at Macleods Pharmaceuticals Limited, Kachigam, Daman, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 1 July 2021.

[MA159 trade name] is indicated for intermittent preventive treatment of malaria as part of antenatal care for women in pregnancy in malaria-endemic areas. It 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.

The active pharmaceutical ingredients of [MA159 trade name] are pyrimethamine and sulfadoxine. These APIs, in combination with each other, are well-established and documented for the preventive treatment of malaria.

The efficacy and safety of pyrimethamine/sulfadoxine combination in adults and children have been demonstrated based on extensive clinical experience in malaria chemoprevention.

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/sulfadoxine in malaria, the team of assessors advised that [MA159 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA159 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA159 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	01 July 2021	listed
Quality	14 June 2021	MR
Bioequivalence	23 June 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	27 August 2020	MR*
FPP	22 October 2018	MR*
GCP/GLP (re-)inspection	09 September 2020	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.