WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA192 trade name][*]

Pyrimethamine/sulfadoxine 25 mg/500 mg dispersible tablets

[MA192 trade name], manufactured at Ipca Laboratories Limited, Silvassa 396 230, U.T. of Dadra and Nagar Haveli and Daman and Diu, India, was included in the WHO list of prequalified medicinal products for malaria prevention on 25 April 2024.

[MA192 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. 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 [MA192 trade name] are pyrimethamine and sulfadoxine.

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

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 prevention, the team of assessors advised that [MA192 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA192 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA192 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	25 April 2024	listed
Pharmaceutical quality	12 April 2024	MR
Bioequivalence	21 April 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	24 June 2022	MR
APIs	28 June 2022	MR
FPP	27 June 2023	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

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