WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA193 trade name]*

Pyrimethamine/sulfadoxine 25mg/500mg tablets

[MA193 trade name], manufactured at S Kant Healthcare, G.I.D.C. Phase III, Vapi, Gujarat, India, was included in the WHO list of prequalified medicinal products for intermittent preventive treatment of malaria as part of antenatal care for women in pregnancy in malaria-endemic areas and 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 on 02 May 2024.

[MA193 trade name] is indicated for intermittent preventive treatment of malaria in pregnancy and perennial malaria chemoprevention of 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 [MA193 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 preventive treatment of malaria in pregnancy and perennial malaria chemoprevention of children.

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 preventive treatment of malaria in pregnancy and perennial malaria chemoprevention of children, the team of assessors advised that [MA193 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA193 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA193 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.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	02 May 2024	listed
Pharmaceutical quality	23 April 2024	MR
Bioequivalence	30 April 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	22 June 2021	MR*
FPP	16 June 2022	MR
GCP/GLP (re-)inspection	15 June 2023	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