WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA145 trade name]*

Pyrimethamine/sulfadoxine 25 mg/500 mg dispersible tablets

[MA145 trade name], manufactured at S Kant Healthcare Ltd, Vapi, Gujarat, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 12 April 2021.

[MA145 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 [MA145 trade name] are pyrimethamine and sulfadoxine. These APIs, in combination with each other, are well-established and documented for the preventive treatment of malaria. It has been shown that each component of the combination makes a contribution to the treatment and the 1:20 dose ratio of actives in the tablet led to the most favourable efficacy compared with other dose ratios.

The efficacy and safety of pyrimethamine/sulfadoxine combination in adults and children have been demonstrated on the basis of 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 [MA145 trade name] in malaria, the team of assessors advised that [MA145 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA145 trade name] in the list of prequalified medicinal products.

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

Summary of prequalification status for [MA145 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	12 April 2021	listed
Quality	01 April 2021	MR
Bioequivalence	06 April 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	28 November 2018	MR*:
FPP	30 April 2020	MR*
GCP/GLP (re-)inspection	29 September 2017	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.