

**WHO Prequalification Programme**  
**WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

**[MA180 trade name]\***

Pyrimethamine/sulfadoxine 25mg/500mg tablets

[MA180 trade name], manufactured at Swiss Pharma Nigeria Ltd, Agege-Lagos, Ikeja, Nigeria, was included in the WHO list of prequalified medicinal products for prophylaxis of malaria on 16 August 2024.

[MA180 trade name] is indicated for malaria prophylaxis. 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 [MA180 trade name] are pyrimethamine and sulfadoxine.

The efficacy and safety of pyrimethamine and sulfadoxine are well established based on extensive clinical experience in the prophylaxis 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 [MA180 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA180 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [MA180 trade name]:**

<b>Initial acceptance</b>	<b>Date</b>	<b>Outcome</b>
<b>Status on PQ list</b>	16 August 2024	listed
Quality	10 August 2024	MR
Bioequivalence	15 August 2024	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
API	22 June 2021	MR*
FPP	08 February 2024	MR
<b>GCP/GLP (re-)inspection</b>	23 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	

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.