

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

**[MA163 trade name]\***

Pyrimethamine/Sulfadoxine 25mg/500mg dispersible tablets

[MA163 trade name], manufactured at Universal Corporation Limited, Kikuyu, Kenya, was included in the WHO list of prequalified medicinal products for prophylaxis against malaria, on 22 August 2022.

[MA163 trade name] is indicated for prophylaxis of malaria in children and pregnant women. 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 [MA163 trade name] are pyrimethamine and sulfadoxine.

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

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 [MA163 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA163 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [MA163 trade name]:**

<b>Initial acceptance</b>	<b>Date</b>	<b>Outcome</b>
<b>Status on PQ list</b>	22 August 2022	listed
Quality	09 August 2022	MR
Bioequivalence	16 August 2022	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
API	18 June 2021	MR*
API	24 June 2022	MR
APIs	28 June 2022	MR
FPP	14 October 2021	MR
<b>GCP/GLP (re-)inspection</b>	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	

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.