

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

### [MA209 trade name]\*

#### Primaquine (as phosphate) 2.5 mg dispersible tablets

[MA209 trade name], manufactured at Guilin Pharmaceutical Co Ltd, Guilin, Guangxi, China, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 06 November 2025.

[MA209 trade name] is indicated for radical cure (prevention of relapse) of *Plasmodium vivax* and *Plasmodium ovale* malaria. It is also used in combination with an artemisinin-based combination therapy to reduce the transmissibility of *Plasmodium falciparum* infections in low-transmission areas. 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 ingredient of [MA209 trade name] is primaquine (as phosphate).

The efficacy and safety of primaquine (as phosphate) are well established based on extensive clinical experience in the treatment 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 primaquine (as phosphate), the team of assessors advised that [MA209 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA209 trade name] in the list of prequalified medicinal products.

#### Summary of prequalification status for [MA209 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	Date	Outcome
<b>Status on PQ list</b>	06 November 2025	listed
Pharmaceutical quality	28 October 2025	MR
Bioequivalence	03 October 2025	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
API	24 June 2022	MR
API	04 July 2025	MR*
FPP	16 April 2025	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	

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