WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA196 trade name]*

Primaquine 15 mg tablets

[MA196 trade name], manufactured at Ipca Laboratories Limited, Village Athal, Silvassa, U.T. of Dadra and Nagar Haveli and Daman and Diu, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 17 July 2025.

[MA196 trade name] is indicated for treatment of radical cure (prevention of relapse) of *Plasmodium vivax* and *Plasmodium ovale* malaria, in adults and children. It is also used 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 [MA196 trade name] is primaquine.

The efficacy and safety of primaquine 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 in malaria, the team of assessors advised that [MA196 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA196 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA196 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	17 July 2025	listed
Pharmaceutical quality	27 June 2025	MR
Bioequivalence	04 July 2025	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	23 February 2024	MR
API	23 June 2024	MR
FPP	27 June 2023	MR
GCP/GLP (re-)inspection	17 January 2025	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