WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA177 trade name]*

Dihydroartemisinin/Piperaquine (as phosphate) 40 mg/320 mg tablets

[MA177 trade name], manufactured at KBN-Zhejiang Pharmaceutical Co. Limited, Building 8, (3-3) 6 Langjiayuan, Chaoyang District, Beijing, China, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 10 October 2023.

[MA177 trade name] is indicated for the treatment of uncomplicated malaria. 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 [MA177 trade name] are dihydroartemisinin and piperaquine (as phosphate).

The efficacy and safety of dihydroartemisinin and piperaquine (as phosphate) are well established based on extensive clinical experience in the treatment of uncomplicated 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 dihydroartemisinin and piperaquine (as phosphate) in malaria, the team of assessors advised that [MA177 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA177 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA177 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	10 October 2023	listed
Pharmaceutical quality	14 November 2022	MR
Bioequivalence	20 November 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	24 October 2018	MR
API	19 October 2018	MR
FPP	14 July 2023	MR
GCP/GLP (re-)inspection	03 June 2022	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