WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA151 trade name]*

Dihydroartemisinin /Piperaquine (as phosphate) 60mg/480mg Tablets

[MA151 trade name], manufactured at Guilin Pharmaceutical Co., Ltd, Oral Solid Dosage Workshop, Guilin, Guangxi, China, was included in the WHO list of prequalified medicinal products for the treatment of Malaria on 16 September 2020.
[MA151 trade name] is indicated for uncomplicated malaria in adults, children and infants. 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 [MA151 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 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 [MA151 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA151 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [MA151 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	16 September 2020	listed
Quality	08 September 2020	MR
Bioequivalence	04 September 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	04 May 2018	MR
FPP	19 October 2019	MR
GCP/GLP (re-)inspection	NA	NA

MR: meets requirements

NA: not applicable, not available

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.