WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA141 trade name]*

Dihydroartemisinin /Piperaquine (as phosphate) 20mg/160mg Dispersible Tablets

[MA141 trade name] manufactured at Guilin Pharmaceutical Co., Ltd, Guangxi, China was included in the WHO list of prequalified medicinal products for treatment of malaria on 19 November 2019.

[MA141 trade name] is indicated for the treatment of uncomplicated malaria in children. 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 [MA141 trade name] are dihydroartemisinin and piperaquine.

The efficacy and safety profile of dihydroartemisinin and piperaquine are well established based on extensive clinical experience in uncomplicated malaria in children. 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 [MA141 trade name] for treatment of malaria, the team of assessors advised that [MA141 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA141 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [MA141 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	19 Nov 2019	listed
Quality	25 Oct 2019	MR
Bioequivalence	29 Oct 2019	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	04 May 2018	MR
API	04 May 2018	MR
FPP	17 Oct 2018	MR
GCP/GLP (re-)inspection	NA	NA

MR: meets requirements
NA: not applicable, not available

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