WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA131 trade name][1]

International Nonproprietary Name (INN):
Dihydroartemisinin /piperaquine (as phosphate) 40mg/320mg Tablets

Abstract

[MA131 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 19 November 2019.

[MA131 trade name] is indicated for the treatment of uncomplicated malaria in adults, children and infants. [MA131 trade name] is active against all *Plasmodium* parasites that cause malaria in humans. 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 [MA131 trade name] are dihydroartemisinin and piperaquine. The APIs are well-established and documented for the treatment of malaria.

The efficacy and safety profile of the combination of APIs in [MA131 trade name] is well established based on the extensive clinical experience in the treatment of malaria.

On the basis of data submitted and public information on the use of [MA131 trade name] in tuberculosis, the team of assessors advised that [MA131 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA131 trade name] in the list of prequalified medicinal products.

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

Summary of Prequalification Status for [MA131 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	19 Nov 2019	listed
Quality	25 Oct 2019	MR
Bioequivalence	05 Nov 2019	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
APIs	04 May 2018	MR
FPP	19 Oct 2018	MR
GCP/GLP (re-)inspection	23 Feb 2018	MR

MR: meets requirements
NA: not applicable, not available