

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA126 trade name]¹

Amodiaquine (as hydrochloride)/Artesunate 135 mg/50 mg Tablets

Abstract

[MA126 trade name], manufactured at Macleods Pharmaceuticals Limited, Mumbai, India was included in the WHO list of prequalified medicinal products for the treatment of malaria on 15 May 2019.

[MA126 trade name] is a so-called artemisinin-based combination therapy (ACT) for the treatment of uncomplicated cases of malaria due to *Plasmodium falciparum* strains which are susceptible to amodiaquine as well as to artesunate.

The active pharmaceutical ingredients (APIs) of [MA126 trade name] are the 4-aminoquinoline amodiaquine and the artemisinin derivative artesunate.

The efficacy and safety profile of 4-aminoquinoline amodiaquine and the artemisinin derivative artesunate is 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 artemisinin-based combination therapy in malaria, the team of assessors advised that [MA125 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA126 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [MA126 trade name]

Initial acceptance	Date	Outcome
Status on PQ list	15 May 2019	listed
Quality	15 May 2019	MR
Bioequivalence	22 July 2016	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
APIs	04 May 2018	MR
FPP	05 Dec 2017	MR
GCP/GLP (re-)inspection	14 July 2017	MR

MR: meets requirements

NA: not applicable, not available

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