WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA133 trade name]*

Amodiaquine (hydrochloride)/artesunate 135mg/50mg tablets

[MA133 trade name], manufactured at Micro Labs Limited, Goa, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 31 October 2018.

[MA133 trade name] is indicated for the treatment of uncomplicated malaria due to Plasmodium falciparum strains which are susceptible to amodiaquine and to artesunate. 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 [MA133 trade name] are the 4-aminoquinoline amodiaquine and the artemisinin derivative artesunate.

The efficacy and safety of amodiaquine and artesunate are well established based on extensive clinical experience in the treatment of uncomplicated P. falciparum 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 [MA133 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA133 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA133 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	31 October 2018	listed
Pharmaceutical quality	20 September 2018	MR
Bioequivalence	15 October 2018	MR
Safety, efficacy	NA	MR
GMP (re-)inspection		
API	26 February 2016	MR
FPP	18 June 2016	MR
GCP/GLP (re-)inspection	16 February 2018	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

Requalification	01 October 2024