# WHO Prequalification Programme
# WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

## [MA125 trade name]*

Amodiaquine (hydrochloride)/artesunate 67.5 mg/25 mg tablets

[MA125 trade name], manufactured at Macleods Pharmaceuticals Limited, Kachigam, Daman, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 15 May 2019.

[MA125 trade name] is indicated for uncomplicated malaria due to *Plasmodium falciparum* 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 [MA125 trade name] are amodiaquine (hydrochloride) and artesunate.

The efficacy and safety of amodiaquine (hydrochloride) and artesunate 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 amodiaquine (hydrochloride) and artesunate in malaria, the team of assessors advised that [MA125 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA125 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [MA125 trade name]:**

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

| **Initial acceptance** | **Date** | **Outcome** |
|---|---|---|
| **Status on PQ list** | 15 May 2019 | listed |
| Pharmaceutical quality | 15 May2019 | MR |
| Bioequivalence | 22 July 2016 | MR |
| Safety, efficacy | NA | NA |
| **GMP (re-)inspection** | | |
| API | 04 May 2018 | MR |
| FPP | 05 Dec 2017 | MR |
| **GCP/GLP (re-)inspection** | 14 July 2017 | 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

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