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

[MA125 trade name] [1]

Amodiaquine (as hydrochloride)/Artesunate 67.5mg/25mg Tablets

## Abstract

[MA125 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.

[MA125 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 [MA125 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 [MA125 trade name] in the list of prequalified medicinal products.

**Summary of Prequalification Status for [MA125 trade name]**

| Initial acceptance | Date | Outcome |
|---|---|---|
| Status on PQ list | 15 May 2019 | listed |
| Quality | 15 May2019 | 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.