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

## [MA113 trade name]*

Pyrimethamine/Sulfadoxine 25 mg/500 mg tablets

[MA113 trade name], manufactured at Guilin Pharmaceutical Co. Ltd, Guilin, China , was included in the WHO list of prequalified medicinal products for the prophylaxis of malaria in children and pregnant women on 31 October 2018.

[MA113 trade name] is indicated for intermittent preventive treatment of malaria as part of antenatal care for women in pregnancy in malaria-endemic areas and it is also indicated for perennial malaria chemoprevention of children at high risk of severe malaria in areas of moderate to high perennial malaria transmission. 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 [MA113 trade name] are pyrimethamine and sulfadoxine.

The efficacy and safety of pyrimethamine and sulfadoxine are well established based on extensive clinical experience in the treatment of malaria chemoprevention, in adults and children.

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 pyrimethamine and sulfadoxine in malaria, the team of assessors advised that [MA113 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA113 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [MA113 trade name]:**

| **Initial acceptance** | **Date** | **Outcome** |
|---|---|---|
| **Status on PQ list** | 31 October 2018 | Listed |
| Quality | 12 October 2018 | MR |
| Bioequivalence | 16 October 2018 | MR |
| Safety, efficacy | NA | NA |
| **GMP (re-)inspection** | | |
| API | 25 March 2016 | MR |
| API | 25 March 2016 | MR |
| FPP | 23 March 2016 | MR |
| **GCP/GLP (re-)inspection** | NA | NA |

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

The table represents the status of relevant completed activities only.

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