WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA123 trade name]*

Artesunate 100 mg soft gelatin rectal capsules

[MA123 trade name], manufactured at Strides Pharma Science Limited, Anekal Taluk, Bangalore, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 19 June 2018.

[MA123 trade name] is currently indicated for pre-referral treatment for suspected or proven severe malaria in children less than 6 years of age, where complete treatment of severe malaria or obtaining a single dose of intramuscular artesunate injection is not possible. 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 ingredient of [MA123 trade name] is artesunate.

The efficacy and safety of 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 artesunate, the team of assessors advised that [MA123 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA123 trade name] in the list of prequalified medicinal products.

Additional important recommendation on storage of the product

Artesunate rectal capsule products are generally less stable above 30°C and in particular at the WHO accelerated storage condition (40°C/75%RH). To this end, procurers and distributers should take utmost care to avoid excursions above 30°C during storage and transport of the product. However, it is understood that this storage requirement may not always be adhered to when the product is handled by community health workers (CHWs) located in areas where the ambient temperature is usually above 30°C. Therefore, procurers and distributors need to ensure that the product is distributed to CHWs located in such areas only as short-term stock, generally not exceeding 4-6 months depending on the remaining shelf life of a given batch.

Summary of prequalification status for [MA 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	19 June 2018	Listed
Pharmaceutical quality	09 May 2018	MR
Bioequivalence	29 My 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	15 Feb 2018	MR
FPP	17 June 2016	MR
GCP/GLP (re-)inspection	18 Feb 2013	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	9 May 2024