WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA124 trade name]*

Artesunate 100 mg Rectal Soft Capsule

[MA124 trade name], manufactured at Cipla Limited, Kurkumbh, Pune, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 22 February 2018.

[MA124 trade name] is indicated for pre-referral treatment for suspected or proven severe malaria in children under 6 years of age, who are unable to take oral medication or obtain injectable antimalarial treatment. The patient should be immediately referred to a facility where accurate diagnosis and comprehensive treatment with effective antimalarials can be instituted. 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 [MA124 trade name] is artesunate. The API is well-established and documented for the treatment of malaria.

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 rectal capsules in antimalarial therapy, the team of assessors advised that [MA124 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA124 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.

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

Summary of Prequalification Status for [MA124 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	22 Feb 2018	Listed
Quality	25 Jan 2018	MR
Bioequivalence	08 Feb 2018	MR
Safety, efficacy	NA	
GMP (re-)inspection		
API	18 Jan 2018	MR
FPP	15 March 2016	MR
GCP/GLP (re-)inspection	01 Feb 2014	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 NA: not applicable, not available PQ: prequalification	
The table represents the status of relevant completed activities only		

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