WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

ARTECAP[1]

International Nonproprietary Name (INN)/strength/pharmaceutical form:
Artesunate 100 mg Suppositories

Abstract

ARTECAP, 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.

ARTECAP is indicated for pre-referral treatment of suspected or proven severe malaria in patients aged between 2 months and 6 years, 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 complete 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 (API) of ARTECAP is artesunate. The API is well-established and documented for the treatment of malaria.

The most frequent adverse events observed during treatment with artesunate were vomiting, headache and convulsions.

The efficacy and safety profile of artesunate suppositories is established based on clinical experience in the treatment of malaria in children less than 7 years of age.

On the basis of data submitted and public information on the use of artesunate suppositories in antimalarial therapy, the team of assessors advised that ARTECAP is of acceptable quality, efficacy and safety to allow inclusion of ARTECAP in the list of prequalified medicinal products.

Additional important recommendation on storage of the product
Artesunate suppositories 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 distributors should take at most care to avoid excursions above 30°C during storage and transportation 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 a short term stock, generally not exceeding 6 months depending on the remaining shelf life of a given batch.

[1]Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Summary of Prequalification Status for ARTECAP:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	19 June 2018	listed
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

MR: meets requirements
NA: not applicable, not available