WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Riamet® / Coartem® Dispersible tablets [1]

Artemether/Lumefantrine 20mg/120mg Dispersible Tablets

RIAMET® Dispersible was submitted in 2008 by. Novartis Pharma AG to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of malaria on 27 February 2009.
Information on the site(s) involved in the manufacture of the product and the APIs is available at the products listing information (https://extranet.who.int/pqweb/medicine/3910)

The "Procedure for prequalification of pharmaceutical products[2]" defines specific evaluation mechanisms for products approved by regulatory authorities, which apply similar stringent standards for quality, safety and efficacy as those required by WHO.

The prequalification of this product by the WHO Prequalification Team: Medicines (PQTm), is based on the approval by the Swiss Agency for Therapeutic Products "Swissmedic" (https://www.swissmedic.ch/swissmedic/en/home.html), in line with the "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities" [3].

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Programme.

However, according to the SRA guideline WHO may request additional data when considered necessary for the safe use of the product in regions relevant for prequalified products and such information may be included in the WHOPAR as a separate piece of information. In order to safeguard product quality throughout its entire intended shelf-life in hot and very humid areas, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant[4].

Based on the submitted stability data WHO PQTm considers the following storage condition appropriate for the product when distributed in regions with zone III, IVa and IVb climatic conditions, based on available stability information:

> Do not store above 30°C. Protect from moisture and store in the original pack.
>
> Avoid excursions above 30°C. The shelf-life at this storage condition is 24 months

[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.
[2] http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS961_Annex10.pdf
[3] http://apps.who.int/prequal/info_general/documents/TRS986/TRS986_ANNEX-5_SRA-Guide.pdf
[4] https://extranet.who.int/pqweb/sites/default/files/documents/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

This WHOPAR refers to the information available at the approving stringent regulatory authority's website resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval.
(https://www.swissmedicinfo.ch/ Swissmedic number 58528)

For details on the uses of this product, for relevant efficacy and safety information see the summary of product characteristics and the patient information leaflet.
The English language version of the patient information leaflet, the summary of product characteristics and the labelling, as certified to be "Swissmedic" approved texts, are included in this WHOPAR.

This WHOPAR for RIAMET® Dispersible is comprised of parts 2, 3. 4. 5 and 7

RIAMET® Dispersible contains lumefantrine and the artemisinin derivative artemether.

RIAMET® Dispersible 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 artemether as well as to lumefantrine.

The efficacy and safety profile of artemether/lumefantrine is well established based on the extensive clinical experience in the treatment of malaria.

Summary of Prequalification Status for RIAMET® Dispersible

	Initial Acceptance			
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list,	27 February 2009	listed	17 Sept 2019	listed
Dossier Evaluation	January 2009	MR	17 Sept 2019	verified
PQ: prequalification MR: meets requirements				

The table represents the status of relevant completed activities only.