WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Eurartesim 320 mg/40 mg film-coated tablets [1]

Dihydroartemisinin/Piperaquine tetraphosphate 40mg/320mg tablets

Eurartesim 320 mg/40 mg film-coated tablets was submitted in 2012 by Sigma-Tau Industrie Farmaceutiche Riunite SpA to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of malaria on 09 October 2015.

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/prequal/medicines/ma094.

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 European Medicines Agency (EMA https://www.ema.europa.eu/en/medicines) 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:

[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] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs961-annex10-who-procedure-prequalification.pdf?sfvrsn=85029f47_2

[3] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs986-annex5.pdf?sfvrsn=8aae767d_2

[4] https://extranet.who.int/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

*Formerly
Sigma-Tau Industrie
Farmaceutiche Riunite SpA

- Do not store above 30°C.
- Store in the original package in order to protect from light and moisture.
- Avoid excursions over 30°C.
- The shelf-life at this storage condition is 24 months.

Based on the above, the WHOPAR for Eurartesim refers for parts 1, 3, 4, 5, 6 and 8 to the previously issued public assessment report as follows:

WHOPAR part		**Reference**[5]
Part 1	Summary for the Public	https://www.ema.europa.eu/en/documents/overview/eurartesim-epar-summary-public_en.pdf
Part 3	Package Leaflet	https://www.ema.europa.eu/en/documents/product-information/eurartesim-epar-product-information_en.pdf
Part 4	Summary of Product Characteristics	https://www.ema.europa.eu/en/documents/product-information/eurartesim-epar-product-information_en.pdf
Part 5	Labelling	https://www.ema.europa.eu/en/documents/product-information/eurartesim-epar-product-information_en.pdf
Part 6	Discussion	https://www.ema.europa.eu/en/documents/assessment-report/eurartesim-epar-public-assessment-report_en.pdf
Part 8	Steps taken following Authorisation	https://www.ema.europa.eu/en/documents/procedural-steps-after/eurartesim-epar-procedural-steps-taken-and-scientific-information-after-authorisation_en.pdf

Parts 2 and 7 of the WHOPAR for Eurartesim are included here.

Eurartesim contains piperaquine tetraphosphate (as the tetrahydrate) and dihydroartemisinin.

Its WHO recommended use is for the treatment of malaria.

Summary of Prequalification Status for Eurartesim 320 mg/40 mg film-coated tablets

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	09 October 2015	listed	08 January 2025	listed
Dossier Evaluation	October 2015	MR	January 2025	requalified
PQ: prequalification MR: meets requirements				

The table represents the status of relevant completed activities only.

[5] https://www.ema.europa.eu/en/medicines/human/EPAR/eurartesim
EMEA/H/C/001199
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