WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Eurartesim film-coated tablets[1]

International Nonproprietary Name (INN)
Dihydroartemisinin/Piperaquine tetraphosphate 40mg/320mg tablets

Abstract

The "Procedure for Assessing the Acceptability, in principle, of Pharmaceutical Products for purchase by United Nations Agencies"[2] defines different evaluation mechanisms for innovator products and multisource (generic) products. In relation to this the "Guidance note to Applicants (Manufacturers) on the compilation of the WHO Public Assessment Report"[3] defines that for an innovator product that was approved by a medicines regulatory authority in one of the ICH regions and for which a public assessment report was published by the approving authority, the WHOPAR will for parts 1, 3, 4, 5, 6 and 8 refer to this public assessment report.

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, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant.
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. Store in the original package in order to protect from light and moisture.
Avoid excursions over 30°C.

Eurartesim film-coated tablets, manufactured at Sigma-Tau Industrie Farmaceutiche Riunite SpA, was submitted to be considered for prequalification in 2012 when the product was licensed / registered in at least one of the ICH regions and subsequently accepted for the WHO list of prequalified medicinal products for the treatment of malaria on 09 Oct 2015.

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

[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.

[2] http://apps.who.int/prequal/info_general/documents/TRS961/TRS961_Annex10.pdf
[3] http://apps.who.int/prequal/WHOPAR/WHOPARGUIDE/WHOPAR_Guid_Appl_v2-5.pdf

WHOPAR part		Reference[4, 5]
Part 1	Summary for the Public	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/001199/WC500118117.pdf
Part 3	Package Leaflets	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001199/WC500118113.pdf
Part 4	Summaries Product Characteristic	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001199/WC500118113.pdf
Part 5	Labelling	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001199/WC500118113.pdf
Part 6	Discussion	http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinic_-_Initial_authorisation/human/001199/ WC500108010.pdf
Part 8	Steps taken following Authorization	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Procedural_steps_taken_and_scientific_information_after_authorisation/huma/001199/WC500127852.pdf

Parts 2a/b and 7 of the Eurartesim film-coated tablets WHOPAR are included here.

Summary of the Prequalification Status for Eurartesim film-coated tablets:

	Initial Acceptance			
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	09 Oct 2015	listed		
Dossier Evaluation	01 Oct 2015	MR		

MR: meets requirements
NA: not applicable
The table represents the status of relevant completed activities only.

[4] http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/epar_search.jsp&mid=WC0b01ac058001d125
[5] http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001199/human_med_001450.jsp&mid=WC0b01ac058001d124