WHO Prequalification
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Darunavir Krka 600 mg film-coated tablets [1]

Darunavir 600 mg film-coated tablets

Darunavir Krka 600 mg film-coated tablets was submitted in 2019 by Krka, d.d., Novo mesto, to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS on 11 June 2019.

Information on the site(s) involved in the manufacture of the product and the API is available at the products listing information https://extranet.who.int/prequal/medicines/ha733.

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 http://www.ema.europa.eu/ema/) 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 Stability data SRA FPPs_March2016_newtempl.pdf

- Do not store above 30°C.
- The shelf-life at this storage condition is 36 months.
- Shelf life after first opening: 3 months

Based on the above, the WHOPAR for Darunavir refers for parts 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/documents/overview/darunavir-krka-epar-summary-public_en.pdf
Part 3	Package Leaflet	https://www.ema.europa.eu/documents/product-information/darunavir-krka-epar-product-information_en.pdf
Part 4	Summary of Product Characteristics	https://www.ema.europa.eu/documents/product-information/darunavir-krka-epar-product-information_en.pdf
Part 5	Labelling	https://www.ema.europa.eu/documents/product-information/darunavir-krka-epar-product-information_en.pdf
Part 6	Discussion	https://www.ema.europa.eu/documents/assessment-report/darunavir-krka-epar-public-assessment-report_en.pdf
Part 8	Steps taken following Authorization	https://www.ema.europa.eu/documents/procedural-steps-after/darunavir-krka-epar-procedural-steps-taken-scientific-information-after-authorisation_en.pdf

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

Summary of Prequalification Status for Darunavir Krka 600 mg film-coated tablets

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	11 June 2019	listed	12 December 2024	listed
Dossier Evaluation	May 2019	MR	December 2024	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/darunavir-krka