WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Prezista 75 mg film-coated tablets [1]

Darunavir (as ethanolate) 75mg Tablets

The innovator product PREZISTA 75 mg film-coated tablets was submitted by Janssen Cilag International N.V in 2012 to be considered for prequalification and subsequently accepted for the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 11 September 2012. 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/pqweb/medicine/2570).

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 Team: Medicines (PQTm).

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]

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.
- The shelf-life at this storage condition is 36 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] 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/pqweb/sites/default/files/documents/48 Stability data SRA FPPs_March2016_newtempl.pdf

Based on the above, the WHOPAR for PREZISTA 75 mg film-coated tablets 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/prezista-epar-summary-public_en.pdf
Part 3	Package Leaflets	https://www.ema.europa.eu/documents/product-information/prezista-epar-product-information_en.pdf
Part 4	Summaries of Product Characteristics	https://www.ema.europa.eu/documents/product-information/prezista-epar-product-information_en.pdf
Part 5	Labelling	https://www.ema.europa.eu/documents/product-information/prezista-epar-product-information_en.pdf
Part 6	Discussion	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Scientific_Discussion/human/000707/WC500041754.pdf
Part 8	Steps taken following Authorization	https://www.ema.europa.eu/documents/procedural-steps-after/prezista-epar-procedural-steps-taken-scientific-information-after-authorisation_en.pdf

Parts 2 and 7 of the WHOPAR for PREZISTA 75 mg film-coated tablets are included here.

Summary of Prequalification Status for PREZISTA 75 mg film-coated tablets

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	11 September 2012	listed	24 November 2022	listed
Dossier Evaluation	July 2012	MR	November 2022	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/prezista