WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Prezista 150 mg film-coated tablets [1]

Darunavir (as ethanolate) 150 mg tablets

Prezista 150 mg film-coated tablets was submitted in 2012 by Janssen-Cilag International NV. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for 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/prequal/medicines/ha530

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:

- 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/prequal/sites/default/files/document_files/48 Stability data SRA FPPs_March2016_newtempl.pdf

Based on the above, the WHOPAR for Prezista 150 mg 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/documents/overview/prezista-epar-summary-public_en.pdf
Part 3	Package Leaflet	https://www.ema.europa.eu/documents/product-information/prezista-epar-product-information_en.pdf
Part 4	Summary 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	https://www.ema.europa.eu/en/documents/scientific-discussion/prezista-epar-scientific-discussion_en.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 150 mg are included here.

Prezista 150 mg contains darunavir (as ethanolate). Its WHO recommended use is for treatment and post-exposure prophylaxis of human immunodeficiency virus (HIV-1) infection.

Summary of Prequalification Status for Prezista 150 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