WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Kaletra [1]

Lopinavir/Ritonavir 80mg/20mg oral solution

Kaletra (Lopinavir/Ritonavir 80mg/20mg oral solution), was submitted in 2001 by Abbott Laboratories Ltd. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the management of HIV/AIDS on 20 March 2002.

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/ha098)

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:

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* Formerly: AbbVie Ltd, UK

[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

- Store in a refrigerator (2°C – 8°C).
- In use storage: If kept outside of the refrigerator, do not store above 25°C and discard any unused contents after 42 days (6 weeks). It is advised to write the date of removal from the refrigerator on the package.
- Avoid exposure to excessive heat.
- The shelf life at this storage condition is 24 months."

This WHOPAR 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/kaletra-epar-summary-public_en.pdf
Part 3	Package Leaflets	https://www.ema.europa.eu/documents/product-information/kaletra-epar-product-information_en.pdf
Part 4	Summaries Product Characteristics	https://www.ema.europa.eu/documents/product-information/kaletra-epar-product-information_en.pdf
Part 5	Labelling	https://www.ema.europa.eu/documents/product-information/kaletra-epar-product-information_en.pdf
Part 6	Discussion	https://www.ema.europa.eu/documents/scientific-discussion/kaletra-epar-scientific discussion_en.pdf
Part 8	Steps taken following Authorization	https://www.ema.europa.eu/documents/procedural-steps-after/kaletra-epar-procedu steps-taken-scientific-information-after-authorisation_en.pdf

This WHOPAR for Kaletra is comprised of parts 2 and 7

Summary of Prequalification Status for Kaletra

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	20 March 2002	listed	05 Dec 2016	listed
Dossier Evaluation	06 Sept 2001	MR	02 Dec 2016	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/kaletra
Agency product number: EMEA/H/C/000368