WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Kaletra[1]

Lopinavir/Ritonavir 200mg/50mg Tablets

The innovator product Kaletra (Lopinavir/Ritonavir 200mg/50mg Tablets), was submitted in 2006 by Abbott Laboratories Ltd. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS on 30 October 2006.
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/pqweb/medicine/2447)

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 of Medicines Programme (PQP) is based on the approval by a stringent regulatory authority (SRA), namely 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, 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:

HDPE bottle packs:

- Do not store above 30°C.
- The shelf-life at this storage condition is 36 months.

Blister packs:

- Do not store above 25°C.
- The shelf-life at this storage condition is 36 months.

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* Formerly: AbbVie Ltd, UK

[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] 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%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

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	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/000368/WC500039044.pdf
Part 3	Package Leaflets	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000368/WC500039043.pdf
Part 4	Summaries Product Characteristics	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000368/WC500039043.pdf
Part 5	Labelling	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000368/WC500039043.pdf
Part 6	Discussion	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Scientific_Discussion/human/000368/WC500039040.pdf
Part 8	Steps taken following Authori-zation	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Procedural_steps_taken_and_scientific_information_after_authorisation/human/000368/WC500039046.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	30 Oct 2006	listed	04 April 2018	listed
Dossier Evaluation	25 Sept 2006	MR	04 April 2018	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