

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Kaletra 200 mg/50 mg film-coated tablets¹

Lopinavir/Ritonavir 200mg/50mg film-coated tablets

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/prequal/medicines/ha381>)

The Marketing Authorization was transferred in 2012 to “AbbVie Ltd” and to “AbbVie Deutschland GmbH & Co. KG” in 2018.

The “Procedure for prequalification of pharmaceutical products²” 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/homepage>)) in line with the “Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities”³.

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 Applicant⁴.

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 48 months.

Blister packs:

- Do not store above 25°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.

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%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	https://www.ema.europa.eu/en/documents/overview/kaletra-epar-summary-public_en
Part 3	Package Leaflet	https://www.ema.europa.eu/documents/product-information/kaletra-epar-product-information_en.pdf
Part 4	Summary of Product Characteristic	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-procedural-steps-taken-scientific-information-after-authorisation_en.pdf

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

Kaletra contains lopinavir co-formulated with ritonavir as a pharmacokinetic enhancer. Its WHO recommended use is with other antiretroviral medicinal products for the treatment of HIV/AIDS.

Summary of Prequalification Status for Kaletra 200 mg/50 mg film-coated tablets

	Initial Acceptance		Requalification		Requalification	
	Date	Outcome	Date	Outcome	Date	Outcome
Status on PQ list	30 Oct 2006	listed	04 April 2018	listed	11 March 2025	listed
Dossier Evaluation	Sept 2006	MR	April 2018	requalified	March 2025	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