

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Ziagen 20 mg/ml oral solution¹

Abacavir (as sulfate) 20 mg/mL oral solution

Ziagen 20 mg/ml oral solution was submitted in 2001 by GlaxoSmithKline Inc. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS on 20 March 2002.

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/ha107>)

The name of the supplier changed to “ViiV Healthcare BV” 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.

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 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:

- Do not store above 25°C.
- The shelf-life at this storage condition is 24 months
- After first opening of the container: 2 months

Based on the above, the WHOPAR for Ziagen refers for parts 1, 3, 4, 5, 6 and 8 to the previously issued public assessment report as follows:

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=8aac767d_2

⁴ https://extranet.who.int/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_nwtempl.pdf

WHOPAR part		Reference ⁵
Part 1	Summary for the Public	https://www.ema.europa.eu/en/documents/overview/ziagen-epar-medicine-overview_en.pdf
Part 3	Package Leaflet	Ziagen, INN-abacavir (europa.eu)
Part 4	Summary of Product Characteristics	https://www.ema.europa.eu/en/documents/product-information/ziagen-epar-product-information_en.pdf
Part 5	Labelling	Ziagen, INN-abacavir (europa.eu)
Part 6	Discussion	https://www.ema.europa.eu/en/documents/scientific-discussion/ziagen-epar-scientific-discussion_en.pdf
Part 8	Steps taken following Authorisation	https://www.ema.europa.eu/en/documents/procedural-steps-after/ziagen-epar-procedural-steps-taken-and-scientific-information-after-authorisation_en.pdf

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

Ziagen contains abacavir. Its WHO recommended use is with other antiretroviral medicinal products for the treatment of HIV/AIDS.

Summary of Prequalification Status for Ziagen 20 mg/ml oral solution

	Initial Acceptance		Requalification		Requalification	
	Date	Outcome	Date	Outcome	Date	Outcome
Status on PQ list	20 March 2002	listed	27 June 2019	listed	15 May 2025	listed
Dossier Evaluation	Sept 2001	MR	June 2019	requalified	May 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/ziagen>
EMA/H/C/000252