

**WHO Prequalification Programme  
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

**Ziagen 300 mg film-coated tablets<sup>1</sup>**

International Nonproprietary Name (INN):  
Abacavir (as sulfate)

**Abstract**

Ziagen 300 mg film-coated tablets, manufactured at Glaxo Wellcome Operations, Hertfordshire, UK and Glaxo GlaxoSmithKline Pharmaceuticals S.A. Poznan, Poland, was submitted to be considered for prequalification in 2001 when the product was licensed / registered in the European Union and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS on 20 March 2002.

The “Procedure for prequalification of pharmaceutical products<sup>2</sup>” 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<sup>3</sup>”.

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.

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.”

This WHOPAR refers to the information available at the approving stringent regulatory authority in terms of the assessment of the quality, efficacy and safety as well as steps taken after the prequalification ([http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000252/human\\_md\\_001179.jsp&mid=WC0b01ac058001d124](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000252/human_md_001179.jsp&mid=WC0b01ac058001d124) )

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<sup>1</sup> 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.

<sup>2</sup> [http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/TRS961\\_Annex10.pdf](http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS961_Annex10.pdf)

<sup>3</sup> [http://apps.who.int/prequal/info\\_general/documents/TRS986/TRS986\\_ANNEX-5\\_SRA-Guide.pdf](http://apps.who.int/prequal/info_general/documents/TRS986/TRS986_ANNEX-5_SRA-Guide.pdf)  
[https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification\\_February2017\\_0.pdf](https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification_February2017_0.pdf)

WHOPAR part		Reference <sup>4,5</sup>
Part 1	Summary for the Public	<a href="http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/000252/WC500050344.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/000252/WC500050344.pdf</a>
Part 3	Package Leaflets	<a href="http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000252/WC500050343.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000252/WC500050343.pdf</a>
Part 4	Summaries Product Characteristics	<a href="http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000252/WC500050343.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000252/WC500050343.pdf</a>
Part 5	Labelling	<a href="http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000252/WC500050343.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000252/WC500050343.pdf</a>
Part 6	Discussion	<a href="http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Scientific_Discussion/human/000252/WC500050162.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Scientific_Discussion/human/000252/WC500050162.pdf</a>
Part 8	Steps taken following Authorization	<a href="http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Procedural_steps_taken_and_scientific_information_after_authorisation/human/000252/WC500050345.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Procedural_steps_taken_and_scientific_information_after_authorisation/human/000252/WC500050345.pdf</a>

Parts 2a, 2b and 7 of the WHOPAR for Ziagen 300 mg film-coated tablets are included here.

Ziagen 300 mg film-coated tablets contains abacavir (as sulfate).

Its WHO recommended use is for the treatment of HIV/AIDS in combination with other antiretroviral products.

The most frequent adverse reactions observed during treatment with abacavir are anorexia, nausea, vomiting, diarrhoea, headache, fever, lethargy and rash.

Many of these adverse reactions occur commonly in patients with abacavir hypersensitivity, which is the most serious adverse reactions of abacavir. These may be life-threatening or even fatal if treatment is continued. Therefore, patients with any of these symptoms should be carefully evaluated for the presence of this hypersensitivity.

Very rarely cases of erythema multiforme, Stevens-Johnson syndrome or toxic epidermal necrolysis have been reported where abacavir hypersensitivity could not be ruled out.

The efficacy and safety profile of abacavir is well established based on the extensive clinical experience in the treatment of HIV/AIDS.

#### Summary of Prequalification Status for Ziagen 300 mg film-coated tablets

	Initial Acceptance		Requalification	
	Date	Outcome	Date	Outcome
Status on PQ list	20 March 2002	listed	28 Sept 2017	listed
Dossier Evaluation	06 Sept 2001	MR	27 March 2017	requalified

MR: meets requirements

The table represents the status of relevant completed activities only.

<sup>4</sup>[http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/epar\\_search.jsp&mid=WC0b01ac058001d125](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/epar_search.jsp&mid=WC0b01ac058001d125)

<sup>5</sup>[http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000252/human\\_med\\_001179.jsp&mid=WC0b01ac058001d124](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000252/human_med_001179.jsp&mid=WC0b01ac058001d124)