WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

APRETUDE prolonged-release suspension for injection [1]

Cabotegravir 600 mg/3 mL prolonged-release suspension for injection

APRETUDE prolonged-release suspension for injection was submitted in 2023 by ViiV Healthcare Pty Ltd, Australia to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the management of HIV/AIDS on 22 December 2023.

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/ha789

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 Australian Therapeutic Goods Administration (TGA, https://www.tga.gov.au/) 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:

[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/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

- Do not store above 30°C.
- The shelf-life at this storage condition is 36 months
- In-use period: Once withdrawn into the syringe, the product must be administered within 2 hours.

This WHOPAR refers to the information available at the approving stringent regulatory authority's website resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval. https://www.tga.gov.au/resources/auspar/auspar-apretude (ARTG ID 377474)

For details on the uses of this product, for relevant efficacy and safety information see the product information (PI, information for health care provider) and the Consumer Medicines Information (CMI) as approved by TGA,

https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=&q=Apretude&r=/

This WHOPAR for Apretude is comprised of parts 2, 5 and 7.

APRETUDE prolonged-release suspension for injection contains cabotegravir.

Its WHO recommended use is for the management of HIV/AIDS.

Summary of Prequalification Status for

APRETUDE prolonged-release suspension for injection

Initial acceptance	**Date**	**Outcome**
Status on PQ list	22 December 2023	listed
Quality	December 2023	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.