Apretude
cabotegravir 200 mg/mL
extended-release injectable suspension
for PrEP pre-exposure prophylaxis

SUPPORTING INDIVIDUALS IN UNDERSTANDING LONG-ACTING PrEP

APRETUDE is indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in high-risk adults and adolescents, weighing at least 35 kg.[1]

This information does not replace the Package Leaflet for this medicine. This document is intended only for use by UK healthcare professionals (HCPs) to help them prepare for discussions about long-acting PrEP with appropriate individuals. It should not be shown directly to the individual, caregivers, or other members of the general public. HCPs are advised to consult the prescribing information and SmPC before prescribing APRETUDE.

Please refer to the Prescribing Information and adverse event reporting Guidance on the back page of this document.

Introducing individuals to long-acting PrEP to prevent HIV-1

- Long-acting APRETUDE (cabotegravir) is an HIV-1 integrase strand transfer inhibitor (INSTI) indicated in combination with safer sex practices for PrEP to reduce the risk of sexually acquired HIV-1 infection in high-risk adults and adolescents, weighing at least 35 kg[1]
- APRETUDE is administered as a single 600 mg gluteal intramuscular injection every 2 months (after 2 initiation injections, 1 month apart, and an optional oral lead-in) by an HCP[2]
- The efficacy and safety of APRETUDE was studied in a diverse range of HIV-negative people, including cisgender men and transgender women who have sex with men, and cisgender women[2–4]

To learn more about APRETUDE, scan the QR code to access our website

Who might benefit from long-acting APRETUDE?

APRETUDE injections could be an appropriate option for a variety of individuals, including those who:

- Are seeking discretion[5]
- Find it difficult to adhere to a daily oral PrEP regimen[5]
- Would require or prefer a PrEP option which does not contain tenofovir[5]
- Prefer to receive injections instead of tablets[5]
- Have a sexual partner with an unknown HIV status[6]
- Live in an area with a high prevalence of HIV[6]

APRETUDE is contraindicated in individuals:

- With known hypersensitivity to cabotegravir or any of the excipients in the tablets or injection formula[1,9]
- Who are currently receiving rifampicin, rifapentine, phenobarbital, carbamazepine, oxcarbazepine or phenytoin[1,9]
- Individuals with an unknown or positive HIV-1 status[2]

Key points to discuss with individuals before starting APRETUDE

Individuals will need to be tested for HIV before starting APRETUDE, and before every injection.[1]

See section 4.2. of Summary of Product Characteristics for more guidance on testing requirements

All medications can have side effects. Ask individuals if there have been any changes to their health or wellbeing and inform them that a list of potential side effects can be found in the Package Leaflet.[1]

If a decision is made to stop APRETUDE, appropriate alternative PrEP options should be discussed.[1]

Explain that there are two options for starting APRETUDE. An optional oral lead-in may be used prior to the initiation of APRETUDE injections to ensure it is appropriate to proceed with APRETUDE injections, or alternatively, individuals can start directly with APRETUDE injections.[1]

Individuals may experience some discomfort following an injection, such as soreness, a lump at the injection site, swelling, or redness. You can reassure individuals by informing them that injection site reactions typically improve on their own after a few days and tend to occur less frequently the longer they remain on treatment.[3,4] In addition, please also advise individuals to inform their healthcare team if any other adverse events occur.[1]

An open conversation may help to educate individuals on the importance of adhering to their Target Injection Dates. Reiterate that meeting the Target Injection Date (a set date in the month in which the injection is received) will help to reduce their risk of HIV-1 acquisition and the development of INSTI resistance. However, there is some flexibility (injections may be given up to 7 days before or after the target injection date, if needed).[1] In case of missed injections, refer to Apretude SmPC for injection dosing recommendations.

Key steps to take before prescribing APRETUDE

Initial evaluation

- [ ] Individual carefully selected to agree to the required dosing schedule[1]
- [ ] Individual confirmed to be HIV-negative using an HIV-ribonucleic acid (RNA)-based test and combined antigen/antibody test, prior to initiating APRETUDE[1]
- [ ] Individual's HIV-1 status reconfirmed if clinical symptoms consistent with acute viral infection are present, and recent (<1 month) exposures to HIV-1 are suspected[1]

Counselling

- [ ] Individual understands the importance of attending all of their injection appointments and getting tested regularly for HIV-1[1]
- [ ] Individual informed that APRETUDE does not constitute a complete HIV-1 prevention regimen and should should be used in combination with safer sex practices[1]
- [ ] Individual advised to inform their HCP if they have any concerns or develop any side effects[1]
- [ ] Individuals are to read Package Leaflet for more information[1]
- [ ] Educational Risk Minimisation Materials are available for HCPs, for more guidance and information. Individuals starting APRETUDE can be given the guide for individuals at risk and appointment reminder card (only after APRETUDE has been prescribed). Follow the QR code below to request access[1]

There are a range of resources available for individuals who have been prescribed APRETUDE:

Follow this link to request Educational Risk Minimisation Materials, intended for HCPs

Responding to questions from APRETUDE users

1. 'Can I self-administer my injection?'

Only HCPs can administer APRETUDE.[1]

2. 'Can I use APRETUDE if I am pregnant or breastfeeding?'

Discuss the risks of taking APRETUDE with individuals who are pregnant or breastfeeding. In addition, advise individuals to inform you if they are pregnant, breastfeeding, think they may be pregnant, or are planning to have a baby. Apretude injection is not recommended during pregnancy unless the expected benefit justifies the potential risk to the foetus.[1]

3. 'Does PrEP prevent sexually transmitted infections (STIs)?'

All PrEP options, including APRETUDE, are only proven to help prevent HIV-1 acquisition. APRETUDE does not prevent other STIs, such as herpes, syphilis, gonorrhoea, or chlamydia.[1]

4. 'Can I take APRETUDE if I am taking other medications?'

APRETUDE should not be used with the following: carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampicin, or rifapentine. Please also advise individuals using oral cabotegravir to inform you if they are taking antacids to treat indigestion or heartburn. Antacids containing polyvalent cations have the potential to decrease oral cabotegravir absorption and should be taken at least 2 hours before or 4 hours after oral cabotegravir.[1,9]

5. 'Can I take herbal supplements while on APRETUDE?'

Some herbal supplements may interact with APRETUDE and make it less effective.[7] Therefore, it is important for people using APRETUDE to be open with you about any herbal supplements they are taking.

6. 'Can I drink alcohol / take recreational drugs while on APRETUDE?'

Based on the way it is metabolised, no interactions between APRETUDE and alcohol and recreational drugs are expected (these interactions have not been studied directly).[7] However, people using APRETUDE should let you know about anything they are currently taking.

7. 'When should I get tested for HIV while on APRETUDE?'

Individuals must be confirmed to be HIV-1 negative, before starting APRETUDE and at each continuation injection. Individuals should get tested if they think they may have been recently exposed to HIV-1, or if they develop symptoms consistent with acute HIV-1 infection, such as fever, fatigue, skin rash, or muscle pain.[1,8]

8. 'Can I get HIV while on APRETUDE?'

While APRETUDE reduces the risk of acquiring HIV-1 infection, it is not 100% effective. APRETUDE should be used alongside other HIV-1 prevention measures, such as regular testing for HIV and STIs, and condom use.[1]

9. 'How long will APRETUDE stay in my body?'

Residual concentrations of APRETUDE may remain in the body for prolonged periods (up to 12 months or longer). Those characteristics should be taken into consideration when the product is discontinued and alternative not long-acting forms of PrEP are taken, as long as or at any time the risk of acquiring HIV is present. Also, it is important for individuals to inform you if they are planning to have a baby or breastfeed.[1]

For more information, please refer to the Summary of Product Characteristics (scan below)

Please scan or click on the QR code to access prescribing information

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellowcard in the Google Play or Apple App store. Adverse events should also be reported to GSK via the GSK Reporting Tool or on 0800221441.

HCP, healthcare professional; **HIV-1,** human immunodeficiency virus type 1; **INSTI,** integrase strand transfer inhibitor; **PrEP,** pre-exposure prophylaxis; **RNA,** ribonucleic acid; **SmPC,** summary of product characteristics; **STI,** sexually transmitted infection.

1. APRETUDE (cabotegravir) 600 mg suspension for injection Summary of Product Characteristics (SmPC).
2. Data on file from Global Data Sheet, REF-210867.
3. Landovitz RJ et al. N Engl J Med. 2021;385(7):595–608.
4. Delany-Moretlwe S et al. Lancet. 2022;399:1779–1789.
5. Clement ME et al. Presented at the Conference on Retroviruses and Opportunistic Infections (CROI). 19–22 February 2023. Seattle, Washington. 994.
6. UNAIDS. UNAIDS Global AIDS Update 2022. Available at: https://www.unaids.org/sites/default/files/media_asset/2022-global-aids-update_en.pdf. Accessed: October 2025.
7. HIV drug interactions. Alcohol and recreational drug interactions. Available at: https://www.hiv-druginteractions.org/checker. Accessed: October 2025.
8. https://www.nhs.uk/conditions/hiv-and-aids/, Accessed October 2025.
9. APRETUDE (cabotegravir) 30 mg film-coated tablets Summary of Product Characteristics (SmPC).

ViiV Healthcare, 79 New Oxford Street, London, W1CA 1DG.

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