Please refer to the Prescribing Information and adverse event reporting information at the end of this document.

HCP WELCOME BOOKLET

Your guide to implementing and administering APRETUDE▼ (cabotegravir) in your practice

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]

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

Intended for UK Healthcare professionals only
PM-GB-CBT-LBND-260004, April 2026

What is in this guide?

This booklet is designed to help prepare you for the implementation and administration of APRETUDE, and provide responses to some frequently asked questions.

Contents

Introducing APRETUDE

APRETUDE is:

- The first licensed and reimbursed long-acting PrEP to prevent HIV-1 acquisition[1,3]
- An HIV integrase strand transfer inhibitor (INSTI), administered every 2 months (after 2 initiation injections, 1 month apart, and an optional oral lead-in) by a healthcare professional (HCP) via intramuscular gluteal injection[1]

Individuals must be confirmed to be HIV-negative, in accordance with the SmPC, prior to initiating APRETUDE.[1]

APRETUDE alone does not constitute a complete regimen for the treatment of HIV-1. Therefore, if an individual acquires HIV-1 while receiving APRETUDE for PrEP, they must transition to a complete HIV-1 treatment regimen.[1]

Scan or click the QR codes below to access the following documents:

SmPC
Suspension for injection

SmPC
Film-coated tablets

Request Risk Minimisation Materials

What to know before administering APRETUDE

Efficacy

APRETUDE – The first **long-acting** injectable PrEP medication

APRETUDE demonstrated superior efficacy in reducing the risk of HIV-1 acquisition vs daily oral TDF/FTC in two head-to-head double-blind trials:[2,5,6,9,10,12]

IN CISGENDER MEN AND TRANSGENDER WOMEN WHO HAVE SEX WITH MEN (N=4,559)[12]

Efficacy analysis: Updated post-hoc blinded period

69%

Reduced rate of HIV-1 acquisition vs TDF/FTC
(0.37 vs 1.22 per 100 person-years HR [95% CI]: 0.31 [0.16–0.58], p=0.0003)*[12]

In the blinded phase of HPTN 083 (APRETUDE arm n=2,241), there were

5 **HIV-1 acquisitions**

in participants who received on-time injections[12]

In the first unblinded year of HPTN 083,

1 **additional HIV-1 acquisition**

was reported following on-time APRETUDE injections[12]

* Following the primary analysis, extended retrospective virologic testing was performed to better characterise the timing of HIV-1 acquisitions. As a result, one of the 13 incident HIV-1 acquisitions in participants receiving APRETUDE was determined to be a prevalent acquisition. The original HR (95% CI) from the primary analysis is 0.34 (0.18–0.62).[1]

IN CISGENDER WOMEN (N=3,223)[5]

Efficacy analysis: Post-hoc blinded period

90%

Reduced rate of HIV-1 acquisition vs TDF/FTC
(0.15 vs 1.85 per 100 person-years; HR [95% CI]: 0.10 [0.04–0.27], p<0.0001)*[5]

In the blinded phase of HPTN 084 (APRETUDE arm n=1,592), there were

0 **HIV-1 acquisitions**

in participants who received on-time injections[5]

In the first unblinded year of HPTN 084,

0 **HIV-1 acquisitions**

were reported following on-time APRETUDE injections[5]

* Following the primary analysis, extended retrospective virologic testing was performed to better characterise the timing of HIV-1 acquisitions. As a result, one of the four HIV-1 incident acquisitions in participants receiving APRETUDE was determined to be a prevalent acquisition. The original HR (95% CI) from the primary analysis is 0.12 (0.05–0.31).[1]

* HPTN 083 and 084 were randomised, double-blind, double-dummy, active-controlled, non-inferiority trials evaluating the safety and efficacy of APRETUDE compared with daily oral TDF/FTC for HIV-1 prevention. The primary endpoint of the studies was the rate of incident HIV-1 acquisition.[2,5,6]

Safety

THE SAFETY PROFILE of APRETUDE has been investigated in **>3,500** study participants[2,5,6]

The safety of APRETUDE has been investigated in >2,000 cisgender men and transgender women who have sex with men in HPTN 083[2,6] and >1,500 cisgender women in HPTN 084[2,5,6]

- Discontinuation due to adverse events (AEs) occurred in 5.7% (n=130/2,282) of participants in HPTN 083 and 1.1% of participants (n=17/1,614) in HPTN 084[5,10]
- The most frequently reported AEs in HPTN 083 were injection site reactions (ISRs; 82%), headache (17%), and diarrhoea (14%)[2]
- The most frequently reported AEs in HPTN 084 were injection site reactions (38%), headache (23%), and transaminase increase (19%)[2]

Most ISRs were mild to moderate and the proportion of individuals reporting ISRs at each visit, and the severity, decreased over time[2,10]

- 2.4% of participants (n=50/2,117) in HPTN 083 and 0% of participants in HPTN 084 discontinued APRETUDE due to ISRs[2,5,6]
- The median duration of overall ISR events was 4 days in HPTN 083 and 8 days in HPTN 084[2]

Prescribing considerations:[1]

- APRETUDE should only be used to reduce the risk of acquiring HIV-1 in individuals confirmed to be HIV-negative
- APRETUDE alone does not constitute a complete regimen for the treatment of HIV-1 and HIV-1 resistance mutations have emerged in some individuals with undetected HIV-1 infection who were only taking APRETUDE
- Residual concentrations of APRETUDE may remain in the systemic circulation for up to 12 months or longer
- Adolescents: Suicidal ideation and suicide attempt have been reported with cabotegravir, particularly in those with pre-existing psychiatric illness Although clinical studies did not show an increased incidence of psychiatric illness in adolescents compared to adult subjects, given the vulnerability of the adolescent population, adolescents should be counselled before prescribing, and periodically while receiving APRETUDE

Choosing APRETUDE for the right people

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]

APRETUDE can benefit populations disproportionately affected by HIV-1, such as:[4–6]

- Cisgender men who have sex with men
- Transgender women who have sex with men
- Cisgender women and adolescent girls

Long-acting APRETUDE injections may also be an appropriate option for other people who could benefit from PrEP,[4,7] including those who:

- Would benefit from superior efficacy in reducing the risk of HIV-1 acquisition vs daily oral TDF/FTC[1,5,6]
- Are seeking discretion[7]
- Find it difficult to adhere to a daily oral PrEP regimen[7]
- Would require or prefer a PrEP option which does not contain tenofovir[7]
- Prefer to receive injections instead of taking tablets[7]
- Have a sexual partner with an unknown HIV status[4]
- Live in an area with a high incidence of HIV[4]

Pre-injection considerations[1]

- The effect of cabotegravir on pregnancy is unknown. Cabotegravir is not recommended during pregnancy unless the expected benefit justifies the potential risk to the foetus.

APRETUDE is contraindicated in individuals:

- With unknown or positive HIV-1 status
- With known hypersensitivity to cabotegravir or any of the excipients (mannitol [E421], polysorbate 20 [E432], macrogol [E1521], or water for injections)
- Who are currently receiving rifampicin, rifapentine, phenobarbital, phenytoin, carbamazepine or oxcarbazepine.

Note, this is not an exhaustive list. Please see the SmPC (accessible via the QR code on page 4) for further information on interactions and contraindications, warnings and precautions, adverse and serious adverse events.

APRETUDE should only be used in individuals who are confirmed to be HIV-1 negative[1]

- There is a potential risk of developing resistance to APRETUDE if an individual acquires HIV-1 either before or while taking APRETUDE, or following discontinuation. To minimise this risk, you should confirm HIV-1-negative status before each injection of APRETUDE
- Do not initiate or administer APRETUDE if signs or symptoms of acute HIV-1 infection are present, unless negative HIV-1 status is confirmed

Drug-drug interactions[1]

Concomitant drug class	Effect on concentration	Recommendation
HIV-1 antiviral products (non-nucleoside reverse transcriptase inhibitor)		
Etravirine	↔ Cabotegravir	**No dose adjustment** of APRETUDE is necessary when initiating injections following etravirine use
Rilpivirine	↔ Cabotegravir	**No dose adjustment** of APRETUDE or rilpivirine is necessary when co-administered
Anticonvulsants		
Carbamazepine Oxcarbazepine Phenytoin Phenobarbital	↓ Cabotegravir	Metabolic inducers may significantly decrease cabotegravir plasma concentration. **Concomitant use is contraindicated**
Antimycobacterials		
Rifampicin	↓ Cabotegravir	Rifampicin significantly decreased cabotegravir plasma concentration which is likely to result in loss of therapeutic effect. **Concomitant use is contraindicated**
Rifapentine	↓ Cabotegravir	Rifapentine may significantly decrease cabotegravir plasma concentrations. **Concomitant use is contraindicated**
Rifabutin	↓ Cabotegravir	When rifabutin is started before or concomitantly with the **first cabotegravir initiation injection**, the recommended cabotegravir dosing schedule is **one 600 mg injection followed 2 weeks later by a second 600 mg initiation injection and monthly, thereafter**, while on rifabutin. When rifabutin is started at the time of the **second initiation injection or later,** the recommended dosing schedule is **600 mg, monthly, while on rifabutin. After stopping rifabutin,** the recommended cabotegravir dosing schedule is **600 mg every 2 months**
Oral contraceptives		
Ethinylestradiol Levonorgestrel	↔ Ethinylestradiol ↔ Levonorgestrel	**No dose adjustment** of oral contraceptives is necessary when co-administered with APRETUDE

↑ = Increase,
↓ = Decrease,
↔ = No change

No dose adjustment
Dose adjustment
Contraindicated

APRETUDE's dosing schedule[1]

Individuals should be carefully selected and agree to the required dosing schedule, and be counselled on the importance of adherence before starting APRETUDE. This conversation will help you to determine whether APRETUDE is suitable for the individual and reduce the risk of HIV-1 infection and the development of INSTI resistance. If an individual is at risk of non-adherence, they may not be suitable for APRETUDE injections for HIV prevention.[2] Individuals should be advised to read the Guide for Individuals at Risk (User Guide), and also complete the Reminder Card with details of their next APRETUDE injection.

Immediately before starting[2]

Confirm HIV-1-negative status

HIV-1 testing to be carried out:
- Prior to initiating APRETUDE or daily oral cabotegravir tablets
- At each subsequent APRETUDE injection
- When recent exposure is suspected or clinical symptoms consistent with HIV-1 (e.g., fever, fatigue, myalgia, skin rash) are present

Optional oral lead-in[1,12]

- An optional oral lead-in may be used prior to the initiation of APRETUDE to assess the tolerability of cabotegravir
- The recommended oral lead-in dose is 1 cabotegravir tablet (30 mg) once a day for approximately 1 month (at least 28 days)

Initiation injections[1]

Month 1
Month 2

- APRETUDE injections are administered by an HCP as a single 600 mg (3 mL) gluteal intramuscular injection and are given 1 month apart for the first 2 consecutive months
- Initiation injections should be administered on the last day of oral lead-in, (if used) or 3 days thereafter

Continuation injections[1]

Month 4
Month 6

- APRETUDE injections are administered every 2 months after the initiation period

APRETUDE's dosing window

It is recommended that individuals receive their APRETUDE injection on the same date every 2 months, after initiation[1] – the Target Injection Date. Talk to individuals about their routines and lifestyle to find a Target Injection Date that will fit into their life.

				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

Target Injection Date

Dosing window
7 days before or after Target Injection Date

Not recommended as Target Injection Date due to varying number of days in each month

There is a dosing window of 7 days either side of the Target Injection Date, within which APRETUDE injections can be administered.[1]

Scan or click this QR code to access APRETUDE injection schedule tool, designed to help you support individuals when planning appointments

Ongoing testing requirements

The importance of HIV-1 testing[1]

- Knowing if an individual is living with HIV ensures you can provide appropriate treatment, and minimise the risk of INSTI resistance
- Individuals should be counselled on the importance of undergoing regular HIV-1 testing to reconfirm HIV-1-negative status
- HIV-1 resistance mutations have emerged in some individuals with undetected HIV-1 infection who received APRETUDE
- Individuals who are diagnosed with HIV-1 should begin antiretroviral therapy immediately

HIV-1 testing requirements[1]

When should I test individuals for HIV-1?

HIV-1 testing must be carried out at these timepoints:

- Prior to initiating APRETUDE or oral cabotegravir
- With each subsequent APRETUDE injection
- When recent exposure is suspected or clinical symptoms consistent with HIV-1 (e.g., fever, fatigue, myalgia, skin rash) are present

What should I do?

- A combined antigen/antibody test as well as an HIV-ribonucleic acid (RNA)-based test, should both be negative
  - Prescribers are advised to perform both tests, even if the result of the HIV-RNA-based test will become available after APRETUDE injection
  - If a combined testing strategy including both tests is not available, ensure testing follows local guidelines

Sexually transmitted infection (STI) testing requirements[1]

- APRETUDE should be used as part of an overall HIV infection prevention strategy, which includes other HIV prevention measures (e.g., regular testing for STIs, condom use, knowledge of HIV status)

Information to discuss pre-injection

- What to expect during the injection process
- Common adverse events (AEs)
- That APRETUDE may not always be effective in preventing HIV-1 infection, and there are relevant additional precautions individuals should use to further reduce the risk of HIV-1 acquisition, including:[1]
  - Getting tested for other STIs when advised to
  - Using condoms
  - Not sharing or re-using needles or other injection or drug equipment
  - Not sharing personal items that may have blood or bodily fluids on them (such as razor blades or toothbrushes)

Readiness checklist prior to prescribing APRETUDE

Have you established:

- ☑ The additional resources you may require for APRETUDE administration?
- ☑ A protocol for appointment scheduling and setting reminders for individuals?

Do you have:

- ☑ Clinical staff who are trained to administer APRETUDE as per the Instructions For Use?
- ☑ Available storage capacity in your practice?
- ☑ A treatment room to administer the injection?

If you need further support, please visit the ViiV Exchange website or speak to your sales representative.

Instructions for administering APRETUDE injections

APRETUDE pack contents

Each pack contains:[1]

- 1 x vial of APRETUDE 600 mg / 3 mL prolonged-release suspension for injection[1]
- Instructions For Use leaflet[1]

Items required for the injection

You will also need the following items that are not included in the APRETUDE pack for the preparation and administration of APRETUDE:[1]

- 1 Luer-Lock syringe (5 mL)
- 1 Luer-Lock aspiration needle or aspiration device (to draw up the suspension)
- 1 additional Luer-Lock needle (use safety needle if available) of 23 gauge, 1.5 inches
- Non-sterile gloves
- 2 alcohol swabs
- 1 gauze pad
- A suitable sharps container

Important considerations:[1]

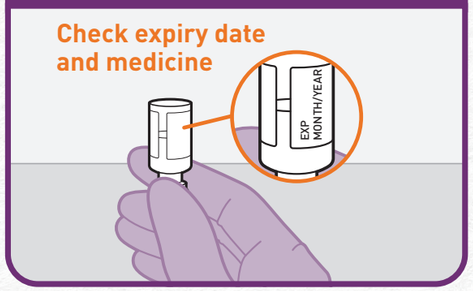
- Consider the body mass index (BMI) of the individual to determine whether the length of the needle is sufficient to reach the gluteal muscle

How to store APRETUDE:[1]

- Do not freeze the vial
- Do not store above 25°C
- APRETUDE does not require refrigeration

How to prepare APRETUDE injections[1]

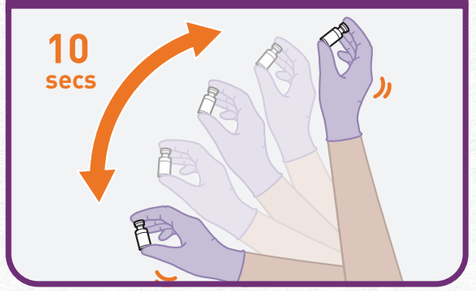
1 Inspect the vial



- Check the expiry date
- **Do not** use if the expiry date has passed
- Inspect the vial immediately. If you see foreign matter, do not use the product

Note: The vial has a brown tint to the glass

2 Shake the vial vigorously

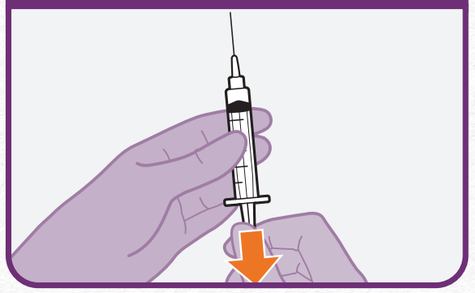


- Firmly hold the vial and shake vigorously for a full 10 seconds as shown
- Invert the vial and check the resuspension. It should look uniform. If the suspension is not uniform, shake the vial again
- It is normal to see small air bubbles
- Remove the cap from the vial
- Wipe the rubber stopper with an alcohol swab

Notes:

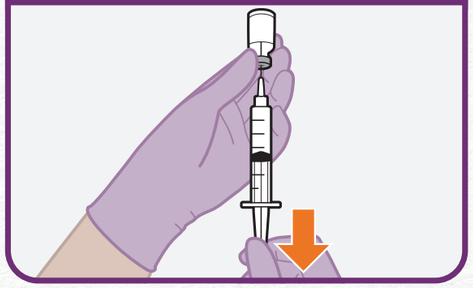
- The suspension does not require further dilution or reconstitution
- **Do not** allow anything to touch the rubber stopper after wiping it

3 Prepare the syringe and needle



- Continue to prepare the injection in line with local guidelines
- **Example:** Attach the aspiration needle to the syringe
- It is recommended that you inject 1 mL of air into the vial to allow the required volume to be drawn up

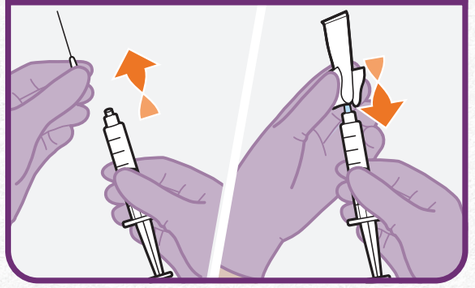
4 Slowly draw up the dose



- Invert the syringe and vial, and slowly withdraw as much of the liquid as possible into the syringe. There might be more liquid than the dose amount
- Once APRETUDE has been drawn into the syringe, it can remain there for **up to 2 hours** before injecting. Administer the injection as soon as possible
- Discard the filled syringe if APRETUDE has remained in there for **more than 2 hours**

Note: Check that the suspension looks uniform and white to light pink

5 Attach the injection needle

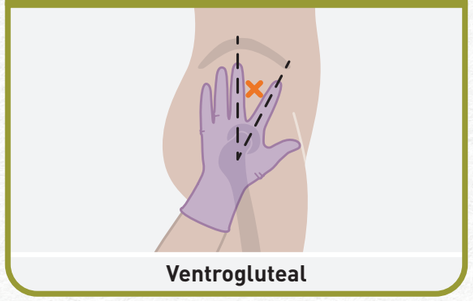


- Peel open the needle packaging part way to expose the needle base
- Keeping the syringe upright, firmly twist the syringe onto the injection needle
- Attach the injection needle
- Remove the needle packaging from the needle

Note: Consider the individual's build and use medical judgment to select an appropriate injection needle length

How to administer APRETUDE injections[1]

1 Prepare the injection site

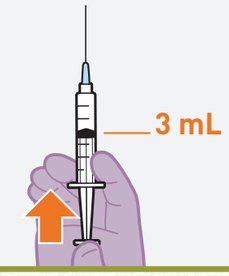


Ventrogluteal

- Injections must be administered to the gluteal sites. Select from the following areas for the injection:
  - Ventrogluteal (recommended)
  - Dorsogluteal (upper outer quadrant)

Note: For gluteal intramuscular use only. Do not inject intravenously

2 Remove the extra liquid



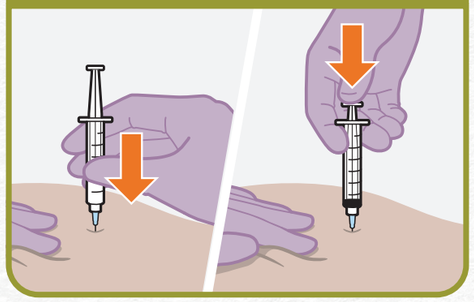
- Pull off the injection needle cap
- Hold the syringe with the needle pointing up. Press the plunger to the 3 mL dose to remove extra liquid and any air bubbles

Note: Clean the injection site with an alcohol swab. Allow the skin to air dry before continuing

3 Stretch the skin

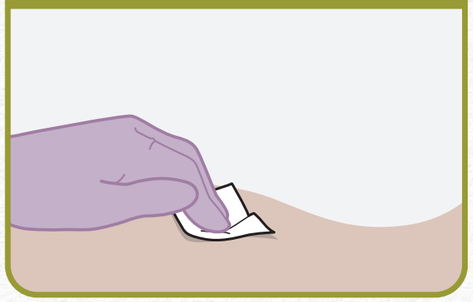
- Use the z-track injection technique to minimise medicine leakage from the injection site
  - Firmly drag the skin covering the injection site, displacing it by about an inch (2.5 cm)
  - Keep it held in this position for the injection

4 Inject the dose



- Insert the needle to its full depth, or deep enough to reach the muscle
- Consider injecting slowly to minimise discomfort
- Still holding the skin stretched, slowly press the plunger all the way down
- Ensure the syringe is empty
- Withdraw the needle and release the stretched skin immediately

5 Assess the injection site



- Apply pressure to the injection site using a gauze pad
- A small bandage may be used if a bleed occurs
- Dispose of used needles, syringe, and vial according to local health and safety laws

Note: Do not massage the area

Scan the QR code to watch the instructional administration video

APRETUDE administration video

Scan or click the QR code to view the HCP educational video which can support with cabotegravir preparation, storage and administration

Managing individuals after APRETUDE injections

Information to discuss post-injection

- Encourage individuals to schedule their next appointment, aiming for their Target Injection Date,[1] and support them in recording their next appointment on their Reminder Card or in their phone calendar
- Reiterate the importance of sticking to their dosing schedule to help reduce the risk of HIV-1 acquisition and the potential development of resistance[1]
- Make individuals aware of common AEs they may experience after the injection (see APRETUDE safety profile on page 25 for more information)

Scan or click to visit our website and explore the full safety data

Managing AEs

- Inform individuals that they may experience some discomfort following an injection, such as soreness, tenderness, or a lump at the injection site[1]
  - You can reassure individuals by informing them that injection site reactions (ISRs) typically improve on their own after a few days and tend to be less of a concern for PrEP users the longer they remain on treatment [5,6]
- If individuals experience discomfort post-injection, advise them to:
  - Take over-the-counter pain relievers if needed
  - Rest and avoid high intensity/rigorous exercise
  - Use cold packs
- Advise individuals to contact their HCP immediately if they think they are experiencing side effects or allergic reactions to the medication.[1]
- Monitor individuals closely for skin reactions such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN).[1]

Refer to question 6 of the Frequently Asked Questions section for additional tips you can give to individuals to help them feel more comfortable after their APRETUDE injections.

APRETUDE safety profile

Discontinuation rates due to AEs were low (5.7% [n=130/2,282] of cisgender men and transgender women, and 1.1% [n=17/1,614] of cisgender women) in the HIV Prevention Trials Network (HPTN) 083 and 084 trials, respectively.[2,5,8]

AEs identified from HPTN 083 and 084, and post-marketing data*,[1]

Frequencies are defined as very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000).[1]

MedDRA System organ class	Frequency category	Adverse reactions
Immune system disorders	Uncommon	Hypersensitivity[4]
Psychiatric disorders	Common	Abnormal dreams Insomnia Depression Anxiety
	Uncommon	Suicide attempt-; Suicidal ideation- (particularly in individuals with a pre-existing psychiatric illness)
Nervous system disorders	Very common	Headache
	Common	Dizziness
	Uncommon	Somnolence
Gastrointestinal disorders	Very common	Diarrhoea
	Common	Nausea Abdominal pain Flatulence Vomiting
Hepatobiliary Disorders	Uncommon	Hepatotoxicity
Skin and subcutaneous tissue disorders	Common	Rash°
	Uncommon	Urticaria- Angioedema-
	Very rare	Stevens-Johnson syndrome-, toxic epidermal necrolysis-
Musculoskeletal and connective tissue disorders	Common	Myalgia
General disorders and administrative site conditions	Very common	Pyrexia**
	Common	Fatigue Malaise
Investigations	Very common	Transaminase increased
	Uncommon	Weight increased Blood bilirubin increased

*Abdominal pain includes the following grouped MedDRA preferred terms: upper abdominal pain and abdominal pain.
°Rash includes the following grouped MedDRA preferred terms: rash, rash erythematous, rash macular, rash maculo-papular, rash morbilliform, rash papular, rash pruritic.
**Pyrexia includes the following grouped MedDRA preferred terms: pyrexia and feeling hot.
-This adverse reaction was identified through post-marketing reporting. The frequency category is based on individuals exposed to cabotegravir in clinical studies.

Managing missed doses

Individuals may receive APRETUDE injections 7 days either side of their Target Injection Date.[2] However, if they miss their scheduled appointment by >7 days, please follow the advice below:

Planned missed injections[1]

- If a delay of >7 days cannot be avoided, oral cabotegravir 30 mg tablets may be used once daily, for a duration of up to 2 months, to replace one scheduled injection visit
  - The first dose of oral cabotegravir (or an alternative oral PrEP therapy) should be taken 2 months (+/- 7 days) after the last APRETUDE injection
  - For oral PrEP durations greater than 2 months, an alternative PrEP regimen is recommended
- APRETUDE injections should be resumed on the final day of oral PrEP, or within 3 days thereafter

Reassess suitability[1]

- Adherence to the injection schedule is strongly recommended
- Individuals who miss their scheduled injection or cabotegravir tablet should have their HIV-negative status re-confirmed and be clinically reassessed to determine suitability of resuming APRETUDE

Restarting APRETUDE after missed injections or following oral PrEP to replace an injection[1]

Second injection missed	
Time since first injection:	**Recommendation:**
≤2 months	**Resume continuation injections** Administer APRETUDE injection as soon as possible and continue with every-2-month injection schedule
>2 months	**Restart initiation injections** Administer 1 APRETUDE injection per month for the next 2 consecutive months, then follow every-2-month injection schedule
Third or subsequent injection missed	
Time since prior injection:	**Recommendation:**
≤3 months	**Resume continuation injections** Administer APRETUDE injection as soon as possible and continue with every-2-month injection schedule
>3 months	**Restart initiation injections** Administer 1 APRETUDE injection per month for the next 2 consecutive months, then follow every-2-month injection schedule

Missed doses of oral cabotegravir[11]

- If an individual misses a dose of oral cabotegravir, they should take the missed dose as soon as possible, providing the next dose is not due within 12 hours
- If the next dose is due within 12 hours, the individual should not take the missed dose and resume their regular dosing schedule

Discontinuing APRETUDE[1]

If an individual decides to discontinue APRETUDE, there are some important things to consider:

- **Prolonged release characteristics of APRETUDE**
  - Residual concentrations of APRETUDE may remain in the systemic circulation for 12 months or longer
- **Alternative PrEP options**
  - Alternative forms of PrEP should be considered for individuals at risk of acquiring HIV-1 and initiated within 2 months of the last APRETUDE injection

Frequently asked questions and additional resources

Frequently asked questions

1. 'How is APRETUDE stored?'

- Do not freeze[1]
- Do not store above 25°C

2. 'If the pack has been stored in the refrigerator, is it safe to warm the vial up to room temperature quickly?'

- APRETUDE does not require refrigeration but if it has been stored in the refrigerator, you should wait at least 15 minutes before you are ready to give the injection to allow the medication to reach room temperature[1]
- It is best to let the vial reach room temperature naturally. However, you can use the warmth of your hands to speed up the warm-up time. Make sure the vial does not reach above 30°C (86°F)[1]
- Do not use any other heating methods[1]

3. 'How long can APRETUDE be left in the syringe?'

- It is best to inject the room temperature medicine as soon as possible after drawing it up. However, the medicine can remain in the syringe for up to 2 hours before injecting[1]
- If the medicine remains in the syringe for more than 2 hours, the filled syringe and needle must be discarded[1]

4. 'Why do I need to inject air into the vial?'

- Injecting 1 mL of air into the vial makes it easier to draw up the medicine into the syringe[1]
- Without the air, some liquid may flow back into the vial unintentionally, leaving less medicine than intended in the syringe[1]

5. 'Why is the ventrogluteal administration approach recommended?'

- The ventrogluteal approach, into the gluteus medius muscle, is recommended because it is located away from major nerves and blood vessels. A dorsogluteal approach into the gluteus maximus muscle is acceptable, if preferred by the HCP. The injection should not be administered in any other site[1]

6. 'How do I manage ISRs?'

- Advise individuals to alleviate pressure from prolonged sitting
- Recommend applying cooling packs to the area to reduce swelling (e.g., ice wrapped in a damp cloth – ice should not be applied directly to skin)

7. 'How do I help individuals stay adherent to APRETUDE?'

- Remind individuals to strictly adhere to their injection or oral dosing schedule to reduce the risk of HIV-1 infection and the development of INSTI resistance[1]
- Advise individuals to read the APRETUDE Welcome Booklet, Package Leaflet, and Guide for Users of APRETUDE (patient RMM)
- Help individuals to book their next injection and record it on their Reminder Card

8. 'How was APRETUDE studied?'

- The HPTN 083 and 084 trials evaluated the safety and efficacy of APRETUDE compared with daily oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) for HIV-1 prevention in cisgender men and transgender women who have sex with men (HPTN 083) and in cisgender women (HPTN 084). The primary efficacy endpoint was the rate of incident HIV-1 infection, and the primary safety endpoint was grade two or higher AEs[1,5,6]
- Participants were either randomised to receive:
  - Cabotegravir initiated oral lead-in dosing with one 30 mg cabotegravir tablet and a placebo daily, for up to 5 weeks, followed by cabotegravir intramuscular injection (single 600 mg injection, at Months 1, 2, and every 2 months thereafter and a daily placebo tablet)[1,5,6]

  Or

  - TDF/FTC initiated oral TDF 300 mg/FTC 200 mg and placebo for up to 5 weeks, followed by oral TDF 300 mg/FTC 200 mg daily and placebo (intramuscular) injection (3 mL, 20% lipid injectable emulsion at Months 1, 2, and every 2 months thereafter)[1,5,6]

Resources

Scan or click the below QR code to access further support for you and your practice

APRETUDE resources website

A website containing range of resources to help you successfully integrate APRETUDE into your clinic, and equip you with the knowledge to feel confident discussing APRETUDE for pre-exposure prophylaxis (PrEP) with people in your care.

Notes

Notes

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

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.

AE, adverse event; **BMI,** body mass index; **EU,** European Union; **FAQ,** frequently asked question; **HCP,** healthcare professional; **HIV-1,** human immunodeficiency virus type 1; **HPTN,** HIV Prevention Trials Network; **INSTI,** integrase strand transfer inhibitor; **ISR,** injection site reaction; **MedDRA,** Medical Dictionary for Regulatory Activities; **PrEP,** pre-exposure prophylaxis; **RNA,** ribonucleic acid; **SmPC,** Summary of Product Characteristics; **STI,** sexually transmitted infection; **TDF/FTC,** tenofovir disoproxil fumarate/emtricitabine.

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