Visit APRETUDE.com

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

DISCOVER LONG-ACTING HIV PREVENTION

A RESOURCE FOR ASOs AND PrEP NAVIGATORS

INDICATION

APRETUDE is indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating APRETUDE (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: RISK OF DRUG RESISTANCE WITH USE OF APRETUDE FOR HIV-1 PRE-EXPOSURE PROPHYLAXIS (PrEP) IN UNDIAGNOSED HIV-1 INFECTION

Individuals must be tested for HIV-1 infection prior to initiating APRETUDE or oral cabotegravir, and with each subsequent injection of APRETUDE, using a test approved or cleared by the FDA for the diagnosis of acute or primary HIV-1 infection. Drug-resistant HIV-1 variants have been identified with use of APRETUDE by individuals with undiagnosed HIV-1 infection. Do not initiate APRETUDE for HIV-1 PrEP unless negative infection status is confirmed. Individuals who become infected with HIV-1 while receiving APRETUDE for PrEP must transition to a complete HIV-1 treatment regimen.

Please see additional Important Safety Information for APRETUDE throughout, and click here for full Prescribing Information, including Boxed Warning.

Long-acting HIV prevention
FOR YOUR CLIENTS

Why encourage your appropriate clients to start APRETUDE (cabotegravir)?

APRETUDE is the first and only long-acting, injectable pre-exposure prophylaxis (PrEP).

Designed to continuously help prevent getting HIV when taken every other month as prescribed.

No daily PrEP pills to remember or keep track of while your clients are receiving their regular APRETUDE injections.

After 2 initial injections given 1 month apart, **APRETUDE is given as few as 6 times a year**.

APRETUDE is given every other month by a healthcare provider after initiation injections have been given 1 month apart for 2 consecutive months. Your clients should stay under a provider's care while receiving APRETUDE. Your clients must receive it as scheduled. If they will miss a scheduled injection by more than 7 days, they need to call their provider right away.

IMPORTANT SAFETY INFORMATION (cont'd)
CONTRAINDICATIONS

- Do not use APRETUDE in individuals:
  - with unknown or positive HIV-1 status
  - with previous hypersensitivity reaction to cabotegravir
  - receiving carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, and rifapentine

Please see additional Important Safety Information for APRETUDE throughout, and click here for full Prescribing Information, including Boxed Warning.

APRETUDE (cabotegravir) helps lower the chance of getting HIV

- **APRETUDE should be used for PrEP to prevent getting HIV. To protect their sexual health, your clients should know their HIV status, get regular testing for other sexually transmitted infections (STIs), and use safer-sex practices like condoms to prevent other STIs.**

- **Your clients should get tested for HIV before starting APRETUDE because they must be HIV-1 negative to start. Their healthcare provider will test for HIV before each injection, or if they are diagnosed with an STI while taking APRETUDE.**

Are your clients ready to PrEP without daily pills?
Welcome to APRETUDE.

Talk with your clients about the risk of HIV-1 and whether APRETUDE may be right for them.

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS

Comprehensive Management to Reduce the Risk of HIV-1 Infection:

- Use APRETUDE as part of a comprehensive prevention strategy, including adherence to the administration schedule and safer sex practices, including condoms, to reduce the risk of sexually transmitted infections (STIs). APRETUDE is not always effective in preventing HIV-1 acquisition. Risk for HIV-1 acquisition includes, but is not limited to, condomless sex, past or current STIs, self-identified HIV risk, having sexual partners of unknown HIV-1 viremic status, or sexual activity in a high prevalence area or network. Inform, counsel, and support individuals on the use of other prevention measures (e.g., consistent and correct condom use; knowledge of partner[s] HIV-1 status, including viral suppression status; regular testing for STIs)

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CLINICAL STUDIES and SURVEY RESULTS

Among the most diverse PrEP HIV prevention trials ever conducted

2 randomized, double-blind, controlled clinical studies with nearly **8,000 at-risk HIV-1–negative participants**, including cisgender men and transgender women who have sex with men, and cisgender women.

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS (cont'd)

Comprehensive Management to Reduce the Risk of HIV-1 Infection: (cont'd)

- Use APRETUDE only in individuals confirmed to be HIV-1 negative. HIV-1 resistance substitutions may emerge in individuals with undiagnosed HIV-1 infection who are taking only APRETUDE, because APRETUDE alone does not constitute a complete regimen for HIV-1 treatment. Prior to initiating APRETUDE, ask seronegative individuals about recent (in past month) potential exposure events and evaluate for current or recent signs or symptoms consistent with acute HIV-1 infection (e.g., fever, fatigue, myalgia, skin rash). If recent (<1 month) exposures to HIV-1 are suspected or clinical symptoms consistent with acute HIV-1 infection are present, use a test approved or cleared by the FDA as an aid in the diagnosis of acute HIV-1 infection
- When using APRETUDE, HIV-1 testing should be repeated prior to each injection and upon diagnosis of any other STIs
- Additional HIV testing to determine HIV status is needed if an HIV-1 test indicates possible HIV-1 infection or if symptoms consistent with acute HIV-1 infection develop following an exposure event. If HIV-1 infection is confirmed, then transition the individual to a complete HIV-1 treatment
- Counsel HIV-1 uninfected individuals to strictly adhere to the recommended dosing and testing schedule for APRETUDE

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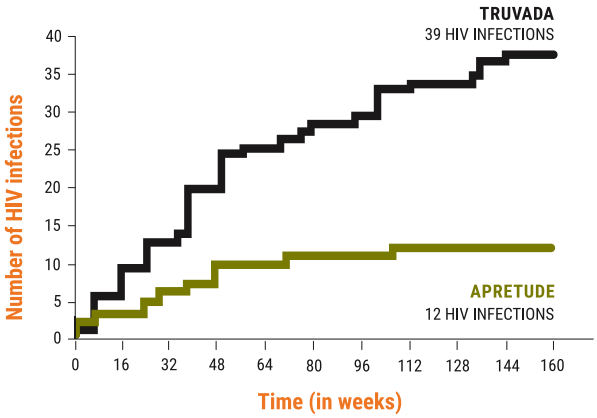
APRETUDE was proven superior at reducing the risk of getting HIV vs TRUVADA

Results may vary.

In Study 1 with 4,566 cisgender men and transgender women at risk for getting HIV:



HIV TRANSMISSIONS OCCURRED ABOUT **3x less often** WITH APRETUDE COMPARED WITH TRUVADA

Which means **better HIV protection**

After this portion of the study, participants in the US were surveyed.

96% of those who responded **chose APRETUDE over daily oral TRUVADA** as their preferred PrEP option.

When the trial was complete, participants were offered the choice of continuing the study with APRETUDE or TRUVADA. Of the 1,698 patients in the study, 803 (47%) had preference data available. Individuals preferring an oral PrEP option may have chosen to not enroll in the study.

Results may vary. Participants were on the product for a median of 1.3 years.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Potential Risk of Resistance with APRETUDE:

- There is a potential risk of developing resistance to APRETUDE if an individual acquires HIV-1 either before, while taking, or following discontinuation of APRETUDE. To minimize this risk, it is essential to clinically reassess individuals for risk of HIV-1 acquisition and to test before each injection to confirm HIV-1–negative status. Individuals who are confirmed to have HIV-1 infection must transition to a complete HIV-1 treatment. If individuals at continuing risk of HIV-1 acquisition discontinue APRETUDE, alternative forms of PrEP should be considered and initiated within 2 months of the final injection of APRETUDE

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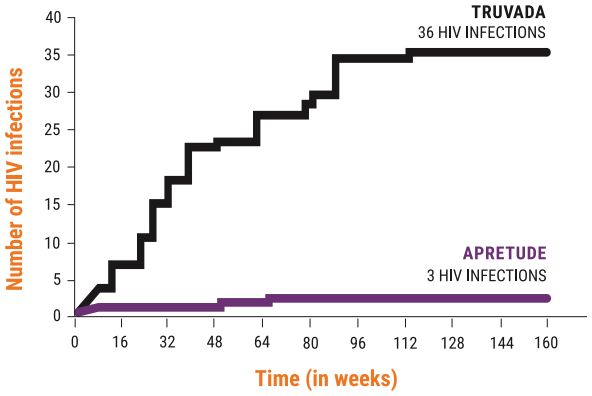
Learn more about the diversity of participants in the clinical trials at **APRETUDE.com/about-apretude/clinical-trials/**

In Study 2 with 3,224 cisgender women at risk for getting HIV:



HIV TRANSMISSIONS OCCURRED **12x less often** WITH APRETUDE COMPARED TO TRUVADA

Which means **better HIV protection**

Results may vary.

Participants were on the product for a median of 1.2 years.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Long-Acting Properties and Potential Associated Risks with APRETUDE:

- Residual concentrations of cabotegravir may remain in the systemic circulation of individuals for prolonged periods (up to 12 months or longer). Take the prolonged-release characteristics of cabotegravir into consideration and carefully select individuals who agree to the required every-2-month injection dosing schedule because non-adherence or missed doses could lead to HIV-1 acquisition and development of resistance

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STARTING APRETUDE (cabotegravir)

- Ask your clients if they think **APRETUDE may be a good fit for them**, and find out if they have **discussed APRETUDE with their healthcare provider**.

- Your clients need to be **tested to confirm their HIV-1 negative status** before **each injection**.

- Your clients may need **help with scheduling their first injection** and **checking their insurance coverage**.

- The provider may decide to begin with **a month of daily oral cabotegravir starter pills (optional oral lead-in)** to see how your client's body reacts before they start receiving an injection. **These pills contain the same drug that is in APRETUDE.**

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity Reactions:

- Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with APRETUDE
- Discontinue APRETUDE immediately if signs or symptoms of hypersensitivity reactions develop. Clinical status, including liver transaminases, should be monitored and appropriate therapy initiated

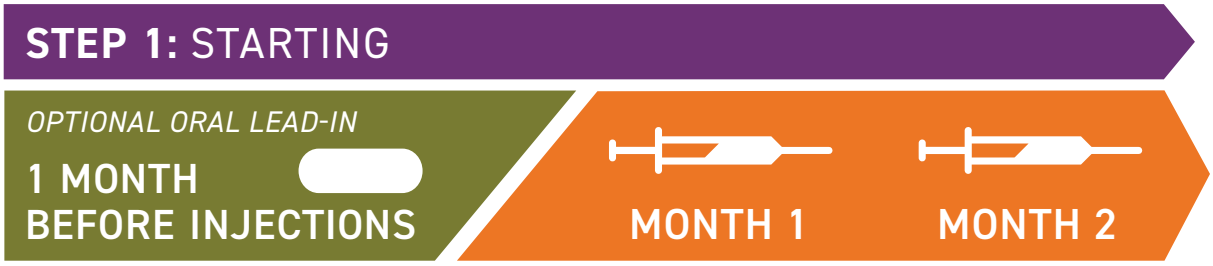
Hepatotoxicity:

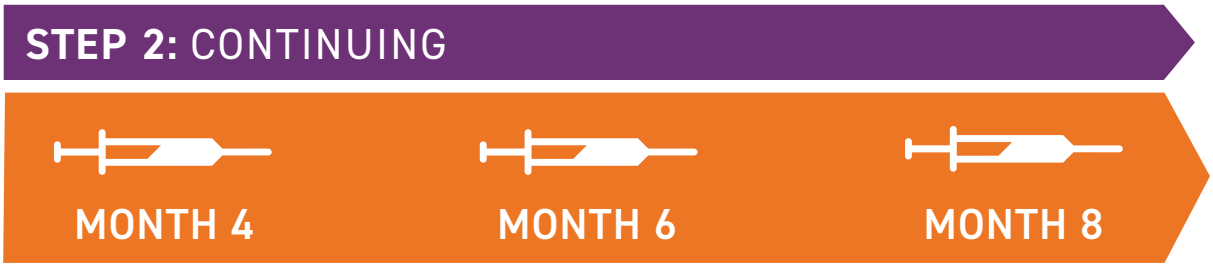
- Hepatotoxicity has been reported in a limited number of individuals receiving cabotegravir with or without known pre-existing hepatic disease or identifiable risk factors
- Clinical and laboratory monitoring should be considered and APRETUDE should be discontinued if hepatotoxicity is suspected and individuals managed as clinically indicated

Please see additional Important Safety Information for APRETUDE throughout, and click here for full Prescribing Information, including Boxed Warning.

STARTING APRETUDE (cabotegravir) (cont'd)

The first 2 APRETUDE injections are **1 month apart.** After that, the injections are **every other month.**





IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS (cont'd)

Depressive Disorders:

- Depressive disorders (including depression, depressed mood, major depression, persistent depressive disorder, suicidal ideation or attempt) have been reported with APRETUDE
- Promptly evaluate patients with depressive symptoms

Risk of Reduced Drug Concentration of APRETUDE Due to Drug Interactions:

- The concomitant use of APRETUDE and other drugs may result in reduced drug concentration of APRETUDE
- Refer to the full Prescribing Information for steps to prevent or manage these possible and known significant drug interactions, including dosing recommendations. Consider the potential for drug interactions prior to and during use of, and after discontinuation of APRETUDE; review concomitant medications during use of APRETUDE

Please see additional Important Safety Information for APRETUDE throughout, and click here for full Prescribing Information, including Boxed Warning.

COST SUPPORT

You can confirm client copay information and whether they are insured or uninsured at **viivconnect.com or by calling 1-844-588-3288 (toll free) Monday-Friday, 8AM-11PM (ET).** Multilingual options are available.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥1%, all grades) with APRETUDE were injection site reactions, diarrhea, headache, pyrexia, fatigue, sleep disorders, nausea, dizziness, flatulence, abdominal pain, vomiting, myalgia, rash, decreased appetite, somnolence, back pain, and upper respiratory tract infection.

DRUG INTERACTIONS

- Refer to the full Prescribing Information for important drug interactions with APRETUDE
- Drugs that induce UGT1A1 may significantly decrease the plasma concentrations of cabotegravir

USE IN SPECIFIC POPULATIONS

- **Lactation:** Assess the benefit-risk of using APRETUDE to the infant while breastfeeding due to the potential for adverse reactions and residual concentrations in the systemic circulation for up to 12 months or longer after discontinuation
- **Pediatrics:** Not recommended in individuals weighing less than 35 kg

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APRETUDE (cabotegravir) Savings Program:

Eligible patients may pay **as little as a $0 copay** per fill on select prescribed ViiV Healthcare medications. Learn about eligible medications and their yearly coverage amounts at apretudecopayprogram.com

The amount your clients pay for APRETUDE will largely depend on their insurance coverage, so your clients should contact their provider, who will know the details of the plan. The healthcare provider's office, insurance provider, and ViiVConnect can help your clients better understand out-of-pocket costs. ViiVConnect is a resource to help your clients understand their coverage options and see their estimated copay. Visit **viivconnect.com** to complete the enrollment form for your clients.

IMPORTANT SAFETY INFORMATION

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CONTRAINDICATIONS

- Do not use APRETUDE in individuals:
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PrEP AND INSURANCE

APRETUDE (cabotegravir) is NOW covered by most private insurers and most Medicaid plans*

Commercial patients may be eligible for a $0 copay

*For those with coverage under the medical benefit. Insurance plans vary. Advise your client to contact ViiVConnect or their healthcare provider to see what this means for them.

Source: Coverage data are provided by Managed Markets Insight & Technology, LLC, as of June 2023.

Federal law requires that many insurance plans cover certain items and services associated with PrEP.

What if your client's insurance company wants them to go on generic PrEP?

Some insurance companies may require daily oral PrEP pills first. However, if your client's healthcare provider determines that APRETUDE is a better fit for them, it may be possible to work with the insurance company to switch your client to APRETUDE. Advise your client to work with their healthcare provider.

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS

Comprehensive Management to Reduce the Risk of HIV-1 Infection:

- Use APRETUDE as part of a comprehensive prevention strategy, including adherence to the administration schedule and safer sex practices, including condoms, to reduce the risk of sexually transmitted infections (STIs). APRETUDE is not always effective in preventing HIV-1 acquisition. Risk for HIV-1 acquisition includes, but is not limited to, condomless sex, past or current STIs, self-identified HIV risk, having sexual partners of unknown HIV-1 viremic status, or sexual activity in a high prevalence area or network. Inform, counsel, and support individuals on the use of other prevention measures (e.g., consistent and correct condom use; knowledge of partner[s] HIV-1 status, including viral suppression status; regular testing for STIs)
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COULD APRETUDE (cabotegravir) BE RIGHT FOR YOUR CLIENTS?

Here are some questions you can ask to find out:

- Are you taking daily PrEP pills now?
- Do you struggle fitting a daily PrEP pill into your daily routine?
- Would you rather get your PrEP once every other month?
- Do you like the idea of continuous protection from HIV without daily PrEP pills? APRETUDE can help reduce the risk of getting HIV when taken as prescribed.
- Are you able to attend an injection appointment every other month?
- Are you concerned that people may see your PrEP pill and ask about it?

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS (cont'd)

Comprehensive Management to Reduce the Risk of HIV-1 Infection: (cont'd)

- When using APRETUDE, HIV-1 testing should be repeated prior to each injection and upon diagnosis of any other STIs
- Additional HIV testing to determine HIV status is needed if an HIV-1 test indicates possible HIV-1 infection or if symptoms consistent with acute HIV-1 infection develop following an exposure event. If HIV-1 infection is confirmed, then transition the individual to a complete HIV-1 treatment
- Counsel HIV-1 uninfected individuals to strictly adhere to the recommended dosing and testing schedule for APRETUDE

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COULD APRETUDE (cabotegravir) BE RIGHT FOR YOUR CLIENTS? (cont'd)

Q Who injects APRETUDE?

A APRETUDE is given to your clients by a trained healthcare professional by gluteal intramuscular injection every other month, after initial injections given 1 month apart for 2 consecutive months.

Q What if your client misses an appointment?

A Adherence to the injection dosing schedule is strongly recommended. APRETUDE injections have a Flexible Appointment Window—from 7 days before to 7 days after the Target Appointment Date. If your client can't make the Target Appointment Date, make sure they contact their provider right away to set up a new appointment within the Flexible Appointment Window and talk about their options.

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS (cont'd)

Potential Risk of Resistance with APRETUDE:

- There is a potential risk of developing resistance to APRETUDE if an individual acquires HIV-1 either before, while taking, or following discontinuation of APRETUDE. To minimize this risk, it is essential to clinically reassess individuals for risk of HIV-1 acquisition and to test before each injection to confirm HIV-1–negative status. Individuals who are confirmed to have HIV-1 infection must transition to a complete HIV-1 treatment. If individuals at continuing risk of HIV-1 acquisition discontinue APRETUDE, alternative forms of PrEP should be considered and initiated within 2 months of the final injection of APRETUDE

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For your clients who may benefit from long-acting HIV prevention, introduce them to APRETUDE.

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS (cont'd)

Long-Acting Properties and Potential Associated Risks with APRETUDE:

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To report SUSPECTED ADVERSE REACTIONS, contact ViiV Healthcare at 1-877-844-8872 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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