

PRESCRIBING APRETUDE

Choose the option that works
for your practice



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 throughout.

Please click for full [Prescribing Information](#), including Boxed Warning, for APRETUDE.



APRETUDE

Prescribing pathways to meet your needs

ViiVConnect is committed to offering healthcare providers information and services to support the process of getting their appropriate patients started on APRETUDE. We offer you the flexibility to choose the level of ViiVConnect support your practice needs, as well as guidance for those who prefer to handle the process independently.

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

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)

Please see additional Important Safety Information throughout.

Please click for full [Prescribing Information](#), including [Boxed Warning](#), for APRETUDE.

APRETUDE prescribing pathways



ViiVConnect-supported pathway

Choose full benefits verification support for complete ViiVConnect service. ViiVConnect will:

- Perform the benefits verification upon patient enrollment
- Coordinate with TheraCom for your patient taking the optional oral lead-in to assess tolerability¹
 - TheraCom will ship the oral medication after benefits verification is complete
- Provide dedicated patient support for your practice
- Provide savings programs for commercially insured and uninsured patients*



Independently managed pathway

This option allows your office more flexibility and ownership of the process for APRETUDE, including benefits verification and navigating product acquisition.

- If your patient will be taking the optional oral lead-in, your practice will submit the prescription directly to TheraCom
- Your practice will coordinate with the specialty pharmacy (SP) or specialty distributor (SD), according to each patient's insurance requirements
- Since your office will handle this process, patient-level support through your Access Coordinator and ViiVConnect is not available
- Commercially insured patients will have access to the APRETUDE Savings Program, which could reduce their copay to as low as \$0*
- Uninsured patients will not have access to the Patient Assistance Program unless they are enrolled in ViiVConnect*

*Subject to eligibility, program terms, and conditions. ViiVConnect programs do not constitute health insurance.

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



Please see additional Important Safety Information throughout. Please click for full [Prescribing Information](#), including [Boxed Warning](#), for APRETUDE.

ViiVConnect

Apretude
cabotegravir 200 mg/mL
extended-release injectable suspension

APRETUDE

From enrollment to administration, rely on ViiVConnect

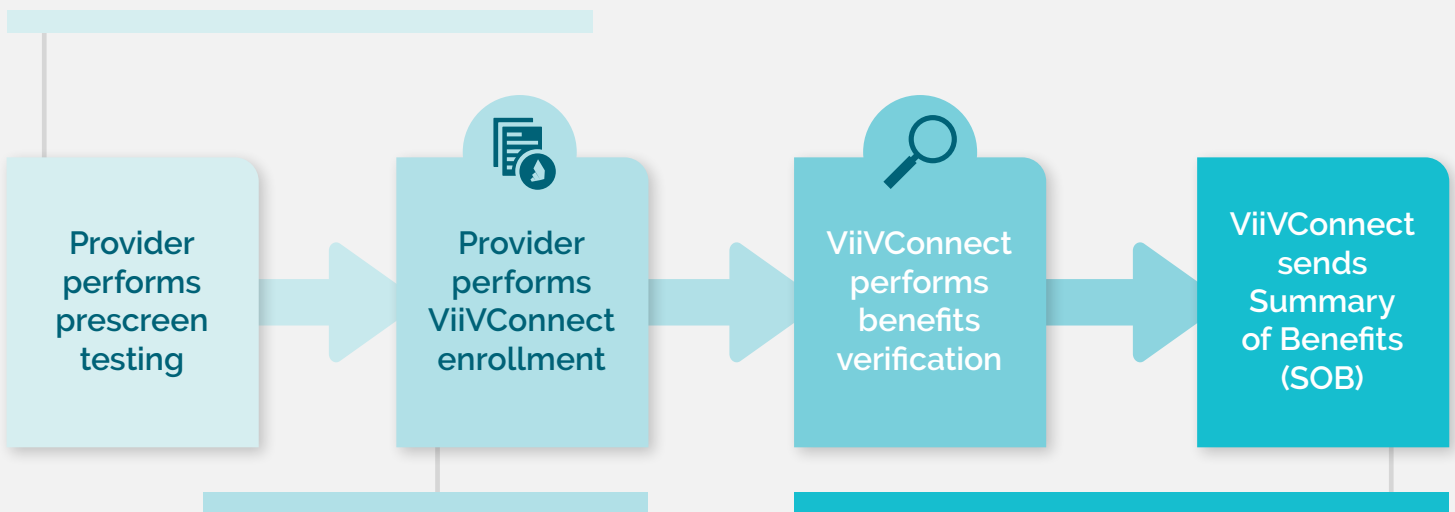


This map is meant to provide an overview of the processes that happen after prescribing APRETUDE to your patient and enrolling them in ViiVConnect.



- If your patient will be taking the optional oral lead-in to assess tolerability, TheraCom will send the oral medication directly to the provider's office or to the patient, depending on preference specified during enrollment¹

Patients must have a negative HIV-1 test immediately before initiating APRETUDE or oral cabotegravir.



If Alternative Site of Administration (ASA) contact information is included on the APRETUDE Enrollment Form, ViiVConnect will send the prescription to the ASA.

After payer confirmation, ViiVConnect will call the provider's office to discuss patient coverage options and enroll them in any financial assistance programs for which they are eligible once the provider agrees to move forward.

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

Please see additional Important Safety Information throughout.

Please click for full [Prescribing Information](#), including [Boxed Warning](#), for APRETUDE.

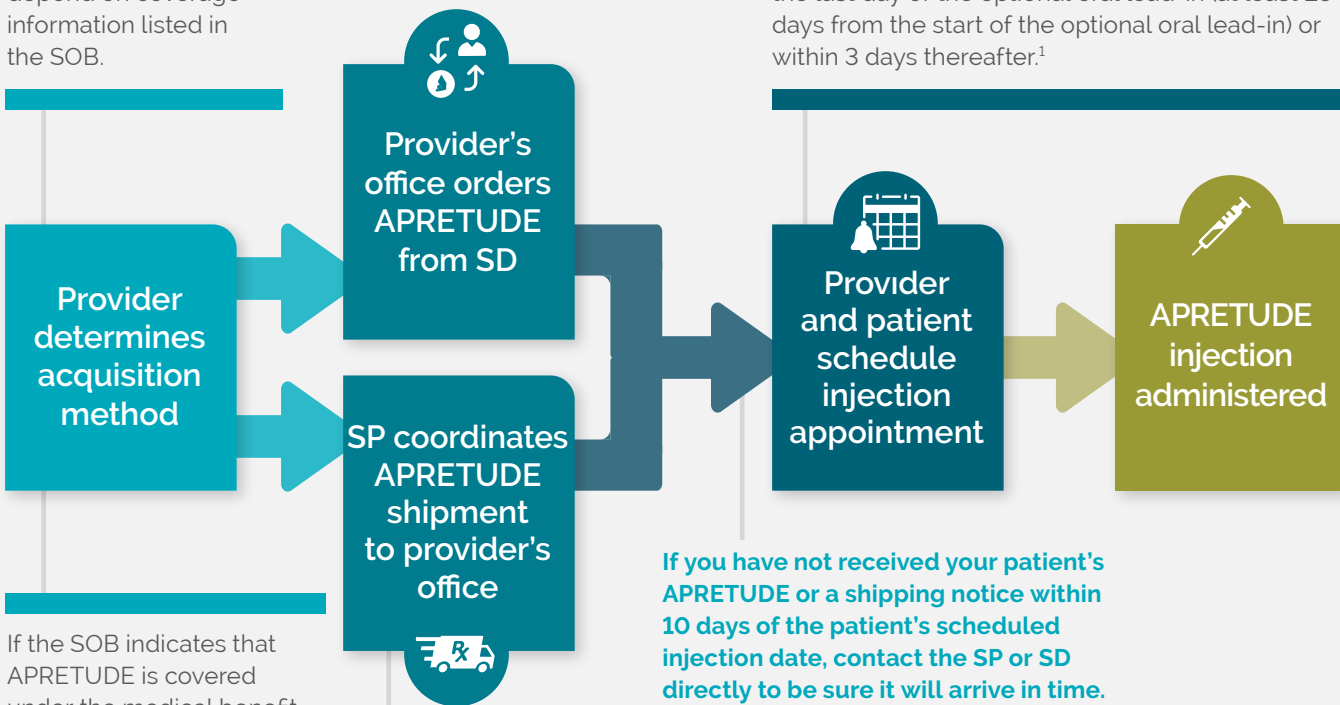
Prior Authorization and APRETUDE

The SOB may indicate that a patient's insurance company requires a Prior Authorization (PA) for APRETUDE. If this happens, ViiVConnect can help.

- ViiVConnect provides information on plan-specific requirements and paperwork, tracks PA status, and notifies provider's office of decision
- If the PA is denied, ViiVConnect provides research on appeals requirements and a sample Letter of Medical Necessity to use as a guide
- ViiVConnect cannot submit information or paperwork to the insurance company on behalf of your office

Buy and Bill (via SD) or SP acquisition may depend on coverage information listed in the SOB.

If the patient will be taking the optional oral lead-in, the injection appointment should be scheduled on the last day of the optional oral lead-in (at least 28 days from the start of the optional oral lead-in) or within 3 days thereafter.¹



If the SOB indicates that APRETUDE is covered under the medical benefit, but you would like to use SP acquisition, it may be possible to do so using Assignment of Benefits. Reach out to your Field Reimbursement Manager if you have questions about this process.

If you have not received your patient's APRETUDE or a shipping notice within 10 days of the patient's scheduled injection date, contact the SP or SD directly to be sure it will arrive in time.

The SP will contact the patient for the copay and consent to ship medication. Patients should be made aware that this call may come from an unknown number, and they need to answer in order to prevent delays.

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

Please see additional Important Safety Information throughout.

Please click for full [Prescribing Information](#), including [Boxed Warning](#), for APRETUDE.

APRETUDE

An independent pathway from prescription to administration



Your practice may prefer to manage prescribing and acquisition for APRETUDE on your own. This map is meant to give you an overview of the processes and key considerations for each step.

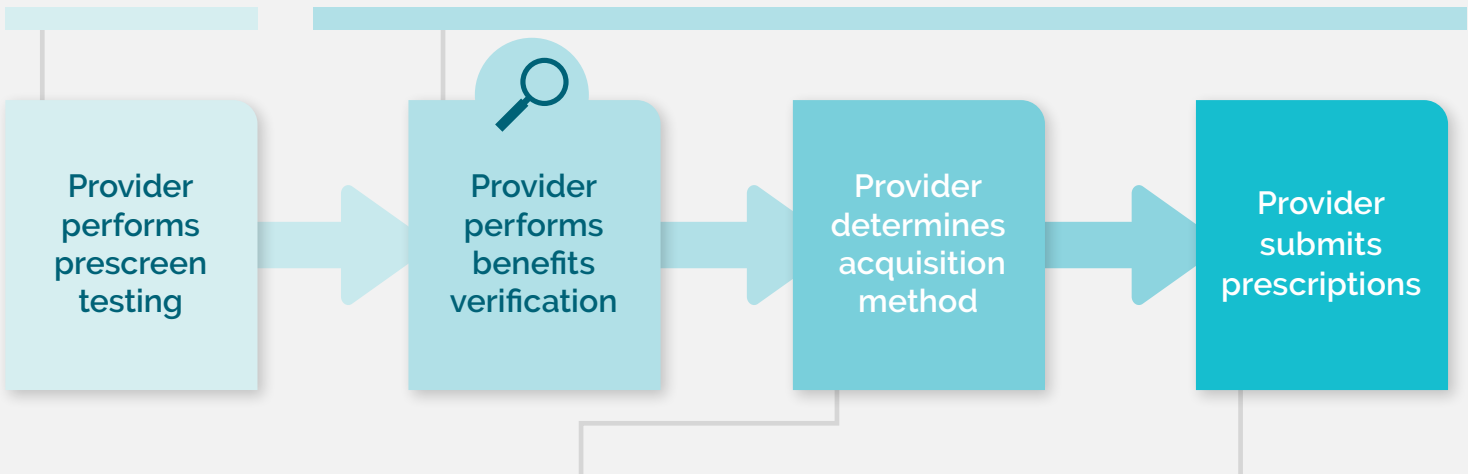
Patients must have a negative HIV-1 test immediately before initiating APRETUDE or oral cabotegravir.

Each patient's benefits must be verified either by your practice or by partnering with an SP to ensure coverage for APRETUDE, and determine if it is covered under the **medical benefit** or the **pharmacy benefit**.

Essential things to confirm during your benefits verification include:

- Any prior authorization (PA) or predetermination requirements
- If using an SP, confirm that it can fulfill the APRETUDE prescription under the patient's insurance

You can refer to the **Understanding the Summary of Benefits** resource for more benefits verification guidelines.



If coverage is under the pharmacy benefit, in many cases, an SP will be used to acquire APRETUDE. If coverage is under the medical benefit, you will usually need to Buy and Bill through an SD. **Some payers may cover APRETUDE under both medical and pharmacy benefits**, allowing you more flexibility when acquiring APRETUDE.

If APRETUDE is covered under the medical benefit, but you would like to use SP acquisition, it may be possible to do so using **Assignment of Benefits**.



- If your patient will be taking the optional oral lead-in, send that prescription to TheraCom via **phone (844-276-6299), fax (833-904-1881), or ePrescribe**
- If you are using an SP to acquire APRETUDE and your patient will not be taking the optional oral lead-in, you will only need a single prescription for the APRETUDE injection
- If you acquire APRETUDE through Buy and Bill, you will not need a prescription for the injection, as you will order directly from the SD

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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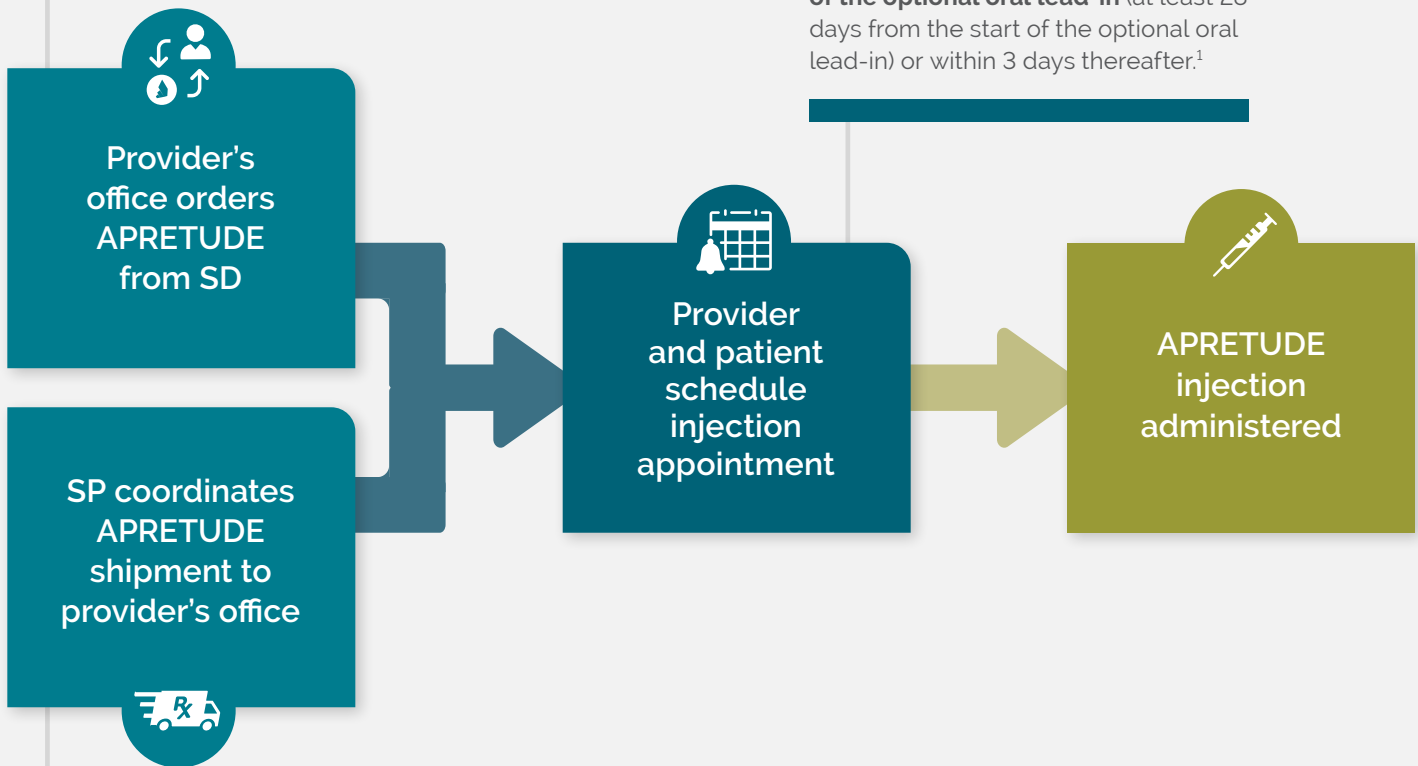
Prior Authorization and APRETUDE

Your practice will be responsible for preparing and submitting PAs, as well as determining how many injections an approved PA will cover.

You will need a contract with an SD in the APRETUDE network. Order the appropriate amount of APRETUDE and store it as directed until it is needed.

After the first dose of APRETUDE, each dose requires a confirmation of coverage, **not a full benefits verification**.

If the patient will be taking the optional oral lead-in, the injection appointment should be scheduled on the **last day of the optional oral lead-in** (at least 28 days from the start of the optional oral lead-in) or within 3 days thereafter.¹



Send the APRETUDE prescription to the selected SP (choice may depend on the patient's insurance).

- The SP will verify benefits and contact the patient for the copay and consent to ship medication. Inform your patients that this call may come from an unknown number, and they need to answer in order to prevent delays

Be sure to leave enough time for the SP to process the prescription and ship APRETUDE before the patient's scheduled injection date.

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

Please see additional Important Safety Information throughout.

Please click for full [Prescribing Information](#), including [Boxed Warning](#), for APRETUDE.

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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

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

ADVERSE REACTIONS

The most common adverse reactions (incidence $\geq 1\%$, 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

Please see additional Important Safety Information throughout.

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Reference: 1. APRETUDE [package insert]. ViiV Healthcare; 2023.



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