How to Order

APRETUDE

APRETUDE 600-mg/3-mL kit

Extended-release injectable suspension: cabotegravir 600 mg/3 mL*

NDC – 49702-264-23

*Please click Prescribing Information for APRETUDE for more information on dosing and administration.

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.

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 throughout.
Please click for full Prescribing Information, including Boxed Warning, for APRETUDE.

Get support from ViiVConnect
Visit ViiVConnect.com

Call to speak to an Access Coordinator
1-844-588-3288 (toll-free)
Monday-Friday, 8AM-11PM (ET)

ViiVConnect

Apretude
cabotegravir 200 mg/mL
extended-release injectable suspension

Available via specialty pharmacy or Buy & Bill

Specialty pharmacy network for APRETUDE

The following specialty pharmacies currently participate in the specialty pharmacy network for APRETUDE. Fulfillment may vary based on individual health insurance plans.

Accredo Health Group, Inc
Phone: (877) 856-4670
Fax: (888) 302-1028
Hours of Operation: Monday-Friday: 7AM-10PM (CT)
Saturday: 7AM–4PM (CT) | Sunday: Closed

AHF Pharmacy
Phone: (877) 429-0708
Fax: (833) 814-1322
Hours of Operation: Monday-Friday: 8AM-8PM (ET) | Saturday-Sunday: Closed

AllianceRx Walgreens Pharmacy
Phone: (888) 347-3416
Fax: (877) 231-8302
Hours of Operation: Monday-Friday: 8AM-8PM (ET)
Saturday: 8AM-5PM (ET) | Sunday: Closed

Avita Pharmacy
Phone: (866) 437-6717
Fax: (803) 358-3034
Hours of Operation:
Monday-Friday: 8AM-6PM (ET)
Saturday-Sunday: Closed

BioPlus Specialty Pharmacy
Phone: (866) 514-8082
Fax: (800) 269-5493
Hours of Operation: Monday-Friday: 8:00AM-8:00PM (ET)
Saturday-Sunday: 9:00AM-5:00PM (ET)

CenterWell Specialty Pharmacy
Phone: (800) 486-2668
Fax: (877) 405-7940
Hours of Operation: Monday-Friday: 8AM-11PM (ET)
Saturday: 8AM-6:30PM (ET) | Sunday: Closed

Coordinated Care Network
Phone: (877) 349-6330
Fax: (877) 770-4107
Hours of Operation: Monday-Friday: 8:30AM-5PM (ET)
Saturday-Sunday: Closed

Curant Health
Phone: (866) 460-8040
Fax: (866) 437-8411
Hours of Operation: Monday-Friday: 8:30AM-5:30PM (ET)
Saturday-Sunday: Closed

CVS Specialty Pharmacy
Phone: (855) 801-8262
Fax: (866) 279-1993
Hours of Operation: Monday-Friday: 8AM-8PM (ET)
Saturday-Sunday: Closed

Kroger Specialty Pharmacy
Phone: (800) 228-3643
Fax: (866) 539-1092
Hours of Operation: Monday-Friday: 8AM-6PM (PT)
Saturday-Sunday: Closed

Mail-Meds Clinical Pharmacy
Phone: (800) 939-2022
Fax: (855) 523-0910
Hours of Operation: Monday-Friday: 8:30AM-5:30PM (ET)
Saturday-Sunday: Closed

MediLink RxCare Specialty Pharmacy
Phone: (609) 956-1900
Fax: (609) 521-4001
Hours of Operation: Monday-Friday: 8:30AM-5:00PM (ET)
Saturday-Sunday: Closed

Optum Specialty Pharmacy
Phone: (855) 427-4682
Fax: (877) 342-4596
Hours of Operation: Monday-Friday: 8:30AM-10PM (ET)
Saturday: 9AM-5:30PM (ET) | Sunday: Closed

Specialty distributor network for APRETUDE

ASD Specialty Healthcare
(800) 746-6273

Besse Medical
(800) 543-2111

Cardinal Health Specialty
Acute (855) 855-0708
Provider (877) 453-3972

CuraScript Specialty Distribution
(800) 942-5999

McKesson Medical-Surgical
(800) 446-3008

McKesson Plasma and Biologics
(877) 625-2566

McKesson Specialty
(800) 482-6700

Morris & Dickson Specialty Distribution, LLC
(800) 388-3833

Oncology Supply
(800) 633-7555

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)

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
600-mg/3-mL kit*

Extended-release injectable suspension: cabotegravir 600 mg/3 mL†

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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

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*The APRETUDE dosing kits have standard 1½-inch safety needles. If 2-inch safety needles are required to reach the gluteus muscle, please order by visiting: http://www.fisherhealthcare.com/2inchsafetyneedle. This information is provided for your reference only. ViiV Healthcare does not warrant or endorse Thermo Fisher or its offerings.

†Please click Prescribing Information for APRETUDE for more information on dosing and administration.

ViiVConnect

Apretude
cabotegravir 200 mg/mL
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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

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

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

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

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 ≥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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