FOR MEDIA USE ONLY

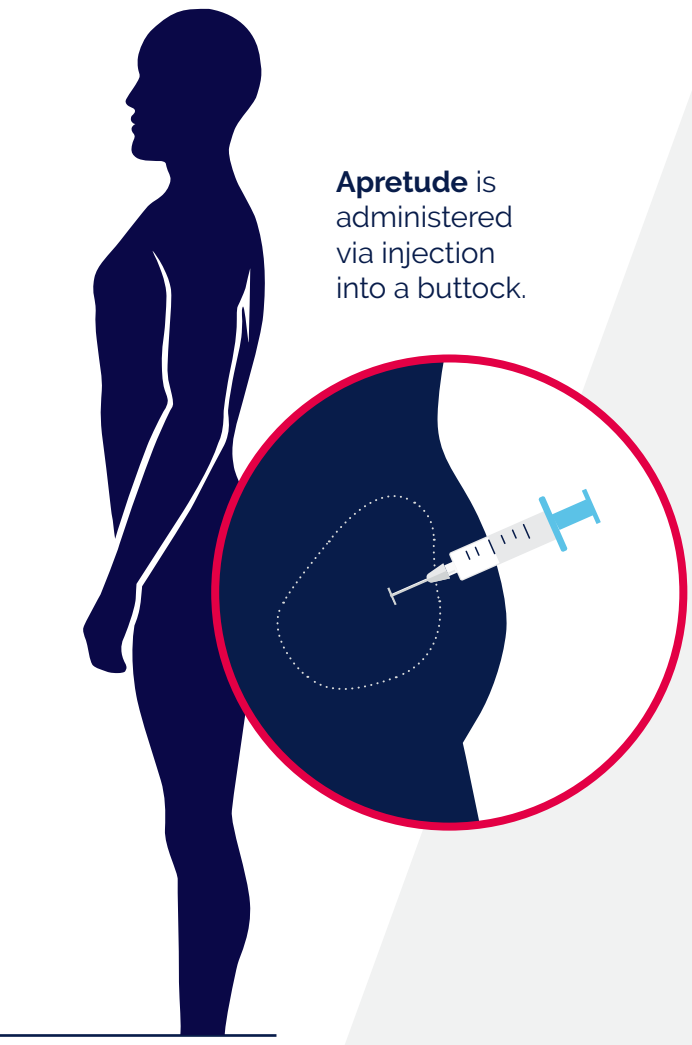
Apretude, the first and only long-acting injectable PrEP option given as few as six times per year to reduce the risk of HIV acquisition.*

Apretude is administered as a single 600-mg (3-ml) intramuscular (IM) injection into the buttocks.

** = after the initiation period*

ADMINISTRATION OF APRETUDE (CABOTEGRAVIR EXTENDED-RELEASE INJECTABLE SUSPENSION) FOR HIV PREVENTION

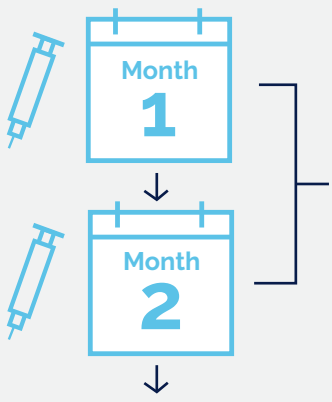
ADMINISTRATION



Apretude is administered via injection into a buttock.

Individuals must have a negative HIV test prior to initiating Apretude

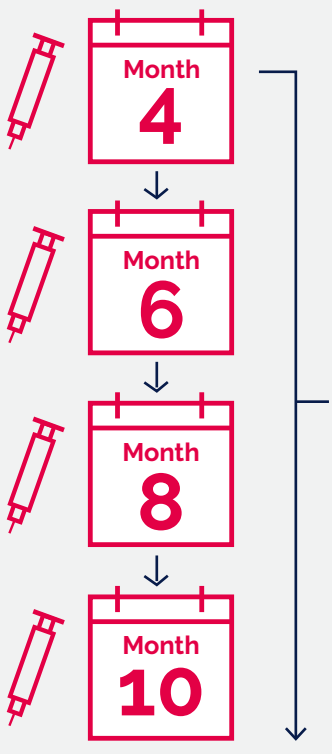
INITIATION
Step 1



Apretude is initiated with a single 600-mg (3-ml) injection given one month apart for two consecutive months.

Alternatively, Vocabria (cabotegravir oral tablets) may be administered for approx. one month prior to initiating Apretude to assess tolerability of the medicine.

CONTINUATION
Step 2



IM injections of Apretude are given **every two months after.**

ABOUT APRETUDE INJECTIONS

Apretude is an integrase strand inhibitor (INSTI) cabotegravir extended-release injectable suspension. INSTIs, like cabotegravir, inhibit HIV replication by preventing the viral DNA from integrating into the genetic material of human immune cells (T-cells). This step is essential in the HIV replication cycle and is also responsible for establishing chronic disease.

Apretude is not approved for use anywhere outside of the U.S.

Important Safety Information for Apretude

Indication and Important Safety Information for Apretude (cabotegravir 200 mg/mL extended-release injectable suspension)
Apretude is an HIV-1 integrase strand transfer inhibitor (INSTI) 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. Apretude is administered as a single 600-mg (3-mL) intramuscular (IM) injection of cabotegravir in the muscle of the buttock by a health care professional once every 2 months.

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

See full prescribing information for complete boxed warning.

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 for HIV-1 PrEP 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
- Unknown or positive HIV-1 status.
- Previous hypersensitivity reaction to cabotegravir.
- Coadministration with drugs where significant decrease in cabotegravir plasma concentrations may occur.

WARNINGS AND PRECAUTIONS
- Use APRETUDE for HIV-1 PrEP to reduce the risk of HIV-1 infection as part of comprehensive management to reduce the risk of HIV-1 acquisition.
- Potential risk of developing resistance to Apretude if an individual acquires HIV-1 either before or while taking Apretude or following discontinuation of Apretude. Reassess risk of HIV-1 acquisition and test before each injection to confirm HIV-1 negative status.
- Residual concentrations of cabotegravir may remain in the systemic circulation of individuals up to 12 months or longer.
- Hypersensitivity reactions have been reported in association with other integrase inhibitors. Discontinue Apretude immediately if signs or symptoms of hypersensitivity reactions develop.
- Hepatotoxicity has been reported in patients receiving cabotegravir. Clinical and laboratory monitoring should be considered. Discontinue Apretude if hepatotoxicity is suspected.
- Depressive disorders have been reported with Apretude. Prompt evaluation is recommended for depressive symptoms.

ADVERSE REACTIONS
The most common adverse reactions (all grades) observed in at least 1% of subjects receiving 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.

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

DRUG INTERACTIONS
- Refer to the full prescribing information for important drug interactions with Apretude.
- Drugs that induce uridine diphosphate glucuronosyltransferase (UGT1A1) may significantly decrease 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 full Prescribing Information including BOXED warning.