



## Guide for Prescribers

### Apretude▼ (cabotegravir) for HIV-1 pre-exposure prophylaxis (PrEP)

- Apretude is indicated in combination with safe sex practices for PrEP to reduce the risk of sexually acquired HIV-1 infection in high-risk adults and adolescents weighing at least 35 kg
- Before prescribing Apretude, it is essential that you read this document in conjunction with the EU SmPC [placeholder for local SmPC or EU SmPC] and Prescriber Checklist document
- This Guide for Prescribers provides further information to ensure the appropriate use of Apretude aimed at minimising the risk of HIV-1 seroconversion, development of resistance and medication errors, including treatment noncompliance

## Key information regarding the use of Apretude for PrEP

- Apretude should only be used to reduce the risk of acquiring HIV-1 in individuals confirmed to be HIV negative
- Prior to starting Apretude, the individuals should be carefully selected and agree to the required dosing schedule
- Individuals must be tested for HIV-1 prior to initiating Apretude and at each subsequent injection of Apretude
- Do not initiate (or re-initiate) Apretude for PrEP if signs or symptoms of acute HIV-1 infection are present, unless negative infection status is confirmed
- Apretude should be used for PrEP as part of an overall HIV-1 infection prevention strategy including the use of other HIV-1 prevention measures (e.g., knowledge of HIV-1 status, regular testing for other sexually transmitted infections, condom use)
- 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 of Apretude
- Individuals who are diagnosed with HIV-1 should immediately begin antiretroviral therapy
- Individuals should be counselled periodically to strictly adhere to the recommended injection dosing schedule in order to reduce the risk of HIV-1 infection and the potential development of resistance

# Risk of HIV-1 drug resistance development in individuals with undiagnosed HIV-1 infection

Apretude is contraindicated in individuals with unknown or positive HIV-1 status.

- 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 of Apretude. To minimise this risk, it is essential to confirm HIV-1 negative status at each subsequent injection of Apretude
- A combined antigen/antibody test, as well as an HIV-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, testing should follow local guidelines
- If clinical symptoms consistent with acute viral infection are present and recent (<1 month) exposures to HIV-1 are suspected, HIV-1 status should be reconfirmed
- Individuals who are diagnosed with HIV-1 should immediately begin antiretroviral therapy
  - 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
- Alternative forms of non-long-acting PrEP should be considered following discontinuation of Apretude injection for those individuals that remain at risk of HIV acquisition, which should be initiated within 2 months of the final Apretude injection
- Cabotegravir may remain in the systemic circulation for prolonged periods (up to 12 months or longer) and this should be taken into consideration when Apretude is discontinued in individuals who remain at risk of HIV acquisition

## Apretude for PrEP should be used as part of a comprehensive prevention strategy

Apretude may not always be effective in preventing HIV-1 infection.

- Apretude should be used for PrEP as part of an overall HIV-1 infection prevention strategy including the use of other HIV-1 prevention measures (e.g., knowledge of HIV-1 status, regular testing for other sexually transmitted infections, condom use)
- Counsel individuals at high risk about the relevant additional precautions they should consider to further reduce their risk of acquiring HIV

## Strict adherence to the recommended dosing regimen is important to reduce the risk of HIV-1 infection and the potential development of resistance

Prior to starting Apretude, individuals should be carefully selected and agree to the required dosing schedule. Individuals who may be at risk of non-adherence may not be suited to Apretude injections for HIV prevention.

- Individuals should be counselled periodically to strictly adhere to the recommended injection dosing schedule in order to reduce the risk of HIV-1 infection and the potential development of resistance
- Individuals receiving Apretude tablets for oral lead-in should be counselled to take their tablets regularly
- 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

### **Missed Doses**

- Individuals who miss a scheduled injection visit should be reassessed to ensure resumption of PrEP remains appropriate

### **Planned missed doses**

- Individuals may be given injections up to 7 days before or after the date of the scheduled injection date
- If a delay of more than 7 days from a scheduled injection date cannot be avoided it will be a missed dose, therefore, 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 therapy should be taken approximately 2 months (+/- 7 days) after the last injection of cabotegravir
  - For oral PrEP durations greater than 2 months, an alternative PrEP regimen is recommended
- Injection dosing should be resumed on the day oral dosing completes or within 3 days

### **Unplanned missed doses**

#### **Injections**

- If the second injection is missed and time since first injection is >2 months, restart the individual on one 600 mg initiation injection, followed by a second 600 mg initiation injection 1 month later. Then follow the every 2 month injection dosing schedule
- If the third or subsequent injection is missed and time since prior injection is >3 months, restart the individual on one 600 mg initiation injection, followed by a second 600 mg initiation injection 1 month later. Then follow the every 2 month injection dosing schedule
- Alternative non-long-acting forms of PrEP should be considered following discontinuation of Apretude for those individuals at continuing risk of HIV acquisition and initiated within 2 months of the final Apretude injection

#### **Tablets**

- If the individual misses a dose of Apretude tablets, the individual 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 simply resume the usual dosing schedule

ViiV Healthcare. Adverse events should be reported.

**[Placeholder: please insert local safety reporting information here]**