Apretude▼ Prescribing Information

Please refer to Prescribing Information as follows:

- **England, Scotland & Wales (GB)**
- **Northern Ireland (NI) – see page 3**

Prescribing Information – England, Scotland & Wales (GB)

Apretude▼ cabotegravir (30mg tablets and 600mg in 3mL prolonged-release suspension for injection).
See SmPCs before prescribing

Indication: Cabotegravir in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in high-risk adults and adolescents, weighing at least 35 kg. **Dosing:** *Adults and adolescents* carefully selected who agree to the injection schedule and are counselled about importance of adherence. Oral lead in prior to initiation of injections can be used to assess tolerability or proceed directly to injections. Individuals must be tested for HIV-1 prior to initiating cabotegravir and at each subsequent injection of cabotegravir. A combined antigen/antibody test as well as an HIV-RNA-based test should both be negative (see SmPC). For optional oral lead in: Prior to injections, once-daily oral dosing of cabotegravir for approximately 1 month (at least 28 days) with or without food. Initiation injections: single 600mg (3mL) intramuscular (gluteal) injection. If oral lead-in has been used, the first injection should be planned for the last day of oral lead-in or within 3 days thereafter. One month later, a second 600 mg intramuscular injection should be administered. Individuals may be given the second 600 mg initiation injection up to 7 days before or after the scheduled dosing date. Continuation injections: Two months after the final initiation injections and every 2 months thereafter. Single 600mg intramuscular (gluteal) 3mL injection Injections may be administered up to 7 days before or after the due date. See SmPCs for advice outside this window or missed injections. Consider the Body Mass Index (BMI) of the individual to ensure that the needle length is sufficient to reach the gluteus muscle. Caution in severe hepatic impairment or people with end-stage renal disease on renal replacement therapy. **Contraindications:** Hypersensitivity to any ingredient. Individuals with unknown or positive HIV-1 status. Concomitant use with rifampicin, rifapentine, carbamazepine, oxcarbazepine, phenytoin or phenobarbital. **Special warnings/precautions:** Apretude may not always be effective in preventing HIV-1 infection. Exact time from initiation of Apretude for HIV-1 PrEP to maximal protection against HIV-1 infection is unknown. Apretude should be used for PrEP as part of an overall HIV-1 infection prevention strategy including use of other HIV-1 prevention measures (e.g. knowledge of HIV-1 status, regular testing for other sexually transmitted infections, condom use). Individuals should be re-confirmed to be HIV negative at each subsequent injection of Apretude. 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. Potential risk of developing resistance to cabotegravir if an individual acquires HIV-1 either before or while taking Apretude, or following discontinuation of Apretude. Apretude alone does not constitute a complete regimen for treatment of HIV-1 and HIV-1 resistance mutations have emerged in some individuals with undetected HIV-1 infection who were only taking Apretude. Counsel individuals periodically on importance of adherence. Residual concentrations may remain for prolonged periods after discontinuation (see SmPC). Avoid inadvertent injection into a blood vessel. Hypersensitivity reactions. Hepatotoxicity (monitor LFTs). Counsel adolescents on risk of suicidal ideation and suicide attempt. Caution with rifabutin (see SmPCs). **Pregnancy/breast feeding:** Not recommended. **Side effects:** See SmPC for full details. Injection site reactions (common, generally mild/moderate; uncommon: abscess formation, haematoma and discolouration), headache, pyrexia (mostly reported within one week of injection), depression, anxiety, abnormal dreams, insomnia, somnolence, dizziness, suicidal ideation /suicide attempt (uncommon - particularly in patients with a pre-existing history of depression or psychiatric illness), diarrhoea, nausea, vomiting, abdominal pain, flatulence, fatigue, malaise, rash, myalgia, weight increase, hypersensitivity, angioedema, urticaria, hepatotoxicity, vasovagal reactions (in response to injections), increased transaminases, increased bilirubin. **Basic NHS costs:** £638.57 for 30 tablets (PLGB 35728/0061), £1197.02 per 600mg vial (PLGB 35728/0062); **MA holder:** ViiV Healthcare UK Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS. Further information available from: customercontactuk@gsk.com Freephone 0800 221 441.

POM

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Adverse events should be reported. For the UK, reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for **MHRA Yellowcard** in the **Google Play** or **Apple App store**. Adverse events should also be reported to GlaxoSmithKline on 0800 221441.

Prescribing Information – Northern Ireland

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See SmPCs before prescribing

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