

Cost & Resources

Clinical Studies & Survey Results

Why APRETUDE?

ASK ABOUT



Apretude

cabotegravir 200 mg/mL
extended-release injectable suspension

Please see **Important Safety Information** throughout this brochure, including an important warning.
Please see **Patient Information** about APRETUDE.

Visit [APRETUDE.com](https://www.apretude.com)

Bring on APRETUDE (cabotegravir), long-acting protection from HIV

Why APRETUDE?



The first and only long-acting, injectable pre-exposure prophylaxis (PrEP) for reducing the risk of getting HIV.



Continuously helps reduce the risk of getting HIV when taken every other month.



No daily PrEP pills to keep track of while you are receiving your regular APRETUDE injections.



APRETUDE is given 6x a year after 2 once-monthly starter doses.

APRETUDE is given every other month by a healthcare provider after initiation injections have been given 1 month apart for 2 consecutive months. Stay under a provider's care while receiving APRETUDE. You must receive it as scheduled. If you will miss a scheduled injection by more than 7 days, call your provider right away.

What is APRETUDE?

APRETUDE is a prescription medicine used for HIV-1 PrEP to reduce the risk of getting HIV-1 infection in adults and adolescents who weigh at least 77 pounds (at least 35 kg).

IMPORTANT SAFETY INFORMATION

What is the most important thing I should know about APRETUDE?

Important information for people who receive APRETUDE for pre-exposure prophylaxis (PrEP) to help reduce their risk of getting human immunodeficiency virus-1 (HIV-1) infection:

Before receiving APRETUDE to reduce your risk of getting HIV-1, you must be HIV-1 negative to start APRETUDE. Do not receive APRETUDE unless you are tested and confirmed to be HIV-1 negative.

• **Some HIV-1 tests can miss HIV-1 infection in a person who has recently become infected.**

Tell your healthcare provider if you had a flu-like illness within the last month before starting or at any time while receiving APRETUDE. Symptoms of new HIV-1 infection include: tiredness; joint or muscle aches; sore throat; rash; enlarged lymph nodes in the neck or groin; fever; headache; vomiting or diarrhea; or night sweats

Please see Important Safety Information throughout this brochure, including an important warning on the risk of drug resistance if you become HIV positive. Please see Patient Information about APRETUDE.

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APRETUDE helps to lower the risk of getting HIV.

- To further reduce your risk of getting HIV and other sexually transmitted infections (STIs), it's important to know your HIV status, get tested regularly for other STIs, and practice safer sex by using condoms.
- Get tested for HIV prior to starting APRETUDE because you must be HIV-1 negative to start. Your healthcare provider will test you for HIV before each injection, as well as if you are diagnosed with an STI while taking APRETUDE.
- It is important that you receive APRETUDE as scheduled. Talk to your healthcare provider about your risk of HIV-1 to see if APRETUDE for PrEP may be right for you.


IMPORTANT SAFETY INFORMATION (cont'd)

What is the most important thing I should know about APRETUDE? (cont'd)

While you are receiving APRETUDE for HIV-1 PrEP:

- APRETUDE does not prevent other sexually transmitted infections (STIs). Practice safer sex by using a latex or polyurethane condom to reduce the risk of getting STIs
- You must stay HIV-1 negative to keep receiving APRETUDE for HIV-1 PrEP
 - Know your HIV-1 status and the HIV-1 status of your partners. If you think you were exposed to HIV-1, tell your healthcare provider right away
 - Your risk of getting HIV-1 is lower if your partners with HIV-1 are taking effective treatment
 - Get tested for HIV-1 with each APRETUDE injection or when your healthcare provider tells you. You should not miss any HIV-1 tests. If you become HIV-1 infected and continue receiving APRETUDE because you do not know you are HIV-1 infected, the HIV-1 infection may become harder to treat

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Long-acting APRETUDE (cabotegravir) or a once-daily PrEP: Which is right for you?



As you and your doctor weigh which PrEP option is right for you, a good first step can be to look at the dosing instructions to compare how APRETUDE is taken vs a once-daily pill.

IMPORTANT SAFETY INFORMATION (cont'd)

What is the most important thing I should know about APRETUDE? (cont'd)

While you are receiving APRETUDE for HIV-1 PrEP: (cont'd)

- **You must stay HIV-1 negative to keep receiving APRETUDE for HIV-1 PrEP (cont'd)**
 - Get tested for other STIs. These infections make it easier for HIV-1 to infect you
 - Talk to your healthcare provider about ways to reduce your HIV-1 risk
 - Do not miss any injections of APRETUDE. Missing injections increases your risk of getting HIV-1 infection

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How you prefer to take PrEP may be an important consideration.

Per the Centers for Disease Control and Prevention (CDC), it is very important to take your PrEP as prescribed to effectively help protect against HIV.



APRETUDE

Continuous protection with as few as 6 injections a year*

*After 2 initiation injections given 1 month apart by your healthcare provider. You must receive it as scheduled. If you will miss a scheduled injection by more than 7 days, call your provider right away.



A daily PrEP pill
Daily oral doses required

» Remember:

Skipping or forgetting to take a dose may make your PrEP less effective.


IMPORTANT SAFETY INFORMATION (cont'd)

Who should not receive APRETUDE?

Do not receive APRETUDE if you:

- **already have HIV-1 or do not know your HIV-1 status.** If you are HIV-1 positive, you need to take other medicines to treat HIV-1. APRETUDE can only help reduce your risk of getting HIV-1 infection **before** you are infected. **If you have HIV-1 and receive only APRETUDE, over time, your HIV-1 may become harder to treat**
- are allergic to cabotegravir
- are taking certain medicines: carbamazepine; oxcarbazepine; phenobarbital; phenytoin; rifampin; or rifapentine

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CLINICAL STUDIES

Among the most diverse PrEP studies ever conducted.



Who participated?

The nearly 8,000 participants included HIV-negative cisgender men, transgender women, and cisgender women at risk for getting HIV.



How were the studies conducted?

Randomized, double-blind, controlled clinical trials were used to make the results of the study less likely to be biased. In these clinical trials, participants were randomly assigned to receive either APRETUDE + TRUVADA placebo or TRUVADA + APRETUDE placebo. Participants and investigators did not know which medicine was being administered.

» Ready to see the results?

Scroll to the next page.


IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of APRETUDE?

APRETUDE may cause serious side effects:

- **Allergic reactions.** Call your healthcare provider right away if you develop a rash with APRETUDE. **Stop receiving APRETUDE and get medical help right away if you develop a rash with any of the following signs or symptoms:** fever; generally ill feeling; tiredness; muscle or joint aches; trouble breathing; blisters or sores in mouth; blisters; redness or swelling of the eyes; swelling of the mouth, face, lips, or tongue

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APRETUDE (cabotegravir) was proven superior at reducing the risk of getting HIV vs TRUVADA



Study 1:

» 4,566 HIV-1-negative cisgender men and transgender women at risk for getting HIV

50% of US participants identified as **Black/African American men**

18% of US participants identified as **Hispanic/Latino**

12% of global participants identified as **transgender women**

Nearly two-thirds of participants were under 30. The median age was 26


IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of APRETUDE? (cont'd)

APRETUDE may cause serious side effects: (cont'd)

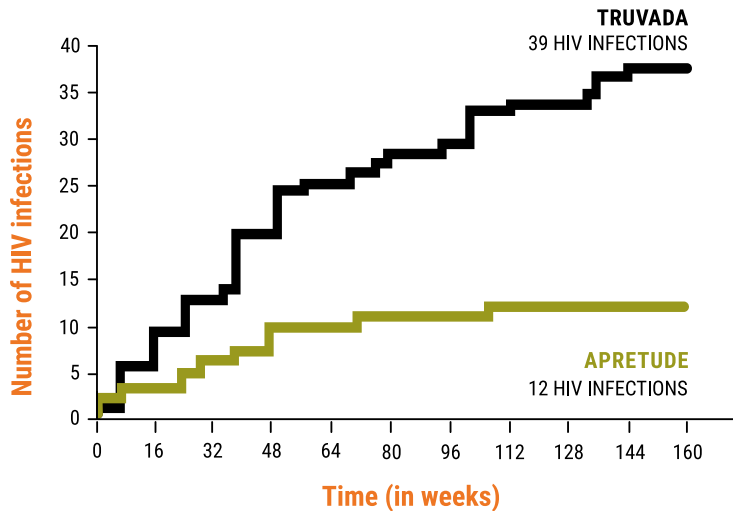
- **Liver problems.** Liver problems have happened in people with or without a history of liver problems or other risk factors. **Call your healthcare provider right away if you have any of the following symptoms:** your skin or the white part of your eyes turns yellow; dark or "tea-colored" urine; light-colored stools; nausea or vomiting; loss of appetite; pain, aching, or tenderness on the right side of your stomach area; or itching
- **Depression or mood changes.** Call your healthcare provider or get emergency medical help right away if you develop any of the following symptoms: feeling sad or hopeless; feeling anxious or restless; have thoughts of hurting yourself (suicide) or have tried to hurt yourself

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Results for Study 1

More people stayed HIV negative on APRETUDE vs TRUVADA during the study.



HIV TRANSMISSIONS OCCURRED ABOUT
3x
LESS OFTEN
WITH APRETUDE COMPARED WITH TRUVADA

Which means better HIV protection

Participants were on the product for a median of 1.3 years.

Results may vary.

After this portion of the study, participants in the US were surveyed.



96% of those who responded chose **APRETUDE** over daily oral TRUVADA as their preferred PrEP option.

When the trial was complete, participants were offered the choice of continuing the study with APRETUDE or TRUVADA. Of the 1,698 patients in the study, 803 (47%) had preference data available. Individuals preferring an oral PrEP option may have chosen to not enroll in the study.


IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of APRETUDE? (cont'd)

The most common side effects of APRETUDE include:

- Pain, tenderness, hardened mass or lump, swelling, bruising, redness, itching, warmth, loss of sensation at the injection site, abscess, and discoloration; diarrhea; headache; fever; tiredness; sleep problems; nausea; dizziness; passing gas; stomach pain; vomiting; muscle pain; rash; loss of appetite; drowsiness; back pain; or upper respiratory infection
- These are not all the possible side effects of APRETUDE. Call your healthcare provider for medical advice about side effects

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Study 2:

» 3,224 HIV-1-negative cisgender women at risk for getting HIV



3,224 women

in Sub-Saharan Africa
participated



Nearly half


were younger than 25

IMPORTANT SAFETY INFORMATION (cont'd)

Before receiving APRETUDE, tell your healthcare provider about all your medical conditions, including if you:

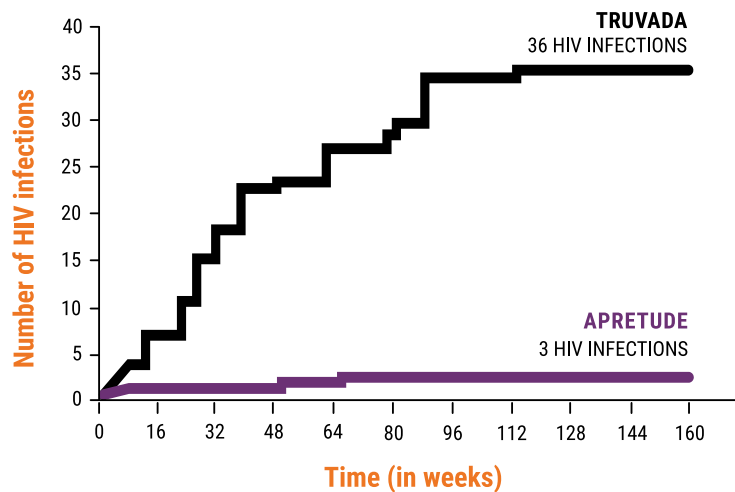
- have ever had a skin rash or an allergic reaction to medicines that contain cabotegravir
- have or have had liver problems
- have ever had mental health problems
- have or ever had kidney problems

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Results for Study 2

Significantly more women stayed HIV negative on APRETUDE vs TRUVADA during the study.



HIV TRANSMISSIONS OCCURRED
12x
LESS OFTEN
WITH APRETUDE
COMPARED TO
TRUVADA

Which means
better HIV protection


Participants were on the product for a median of 1.2 years.
Results may vary.

IMPORTANT SAFETY INFORMATION (cont'd)

Before receiving APRETUDE, tell your healthcare provider about all your medical conditions, including if you: (cont'd)

- are pregnant or plan to become pregnant. It is not known if APRETUDE will harm your unborn baby. APRETUDE can remain in your body for up to 12 months or longer after the last injection. Tell your healthcare provider if you become pregnant while or after receiving APRETUDE
- are breastfeeding or plan to breastfeed. APRETUDE may pass into your breast milk. Talk with your healthcare provider about the best way to feed your baby while or after receiving APRETUDE

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COST SUPPORT



Ask your healthcare provider about your coverage options. They can work with ViiVConnect to see what your expected copay will be.



APRETUDE Savings Program

Eligible patients may pay as little as a **\$0 copay per injection** on their prescribed APRETUDE. Go to apretudecopayprogram.com to see if you are eligible.

IMPORTANT SAFETY INFORMATION (cont'd)

Before receiving APRETUDE, tell your healthcare provider about all your medical conditions, including if you: (cont'd)

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

- Some medicines may interact with APRETUDE. Keep a list of your medicines and show it to your healthcare provider and pharmacist. **Do not start a new medicine without telling your healthcare provider**

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COST SUPPORT (cont'd)

APRETUDE is NOW covered by most private insurers and most Medicaid plans*

➤ **Commercial patients may be eligible for a \$0 copay**

*For those with coverage under the medical benefit. Insurance plans vary. Contact ViiVConnect or your healthcare provider to see what this means for you.

Source: Coverage data are provided by Managed Markets Insight & Technology, LLC, as of June 2023.

IMPORTANT SAFETY INFORMATION (cont'd)

How will I receive APRETUDE?

- APRETUDE will be given to you as an injection by your healthcare provider
- APRETUDE is initially given as an injection into the muscle of your buttock 1 time every month for the first 2 months, then as an injection 1 time every 2 months
- Before receiving your first APRETUDE injection, your healthcare provider may have you take 1 oral cabotegravir tablet 1 time a day for 1 month (at least 28 days) to assess how well you tolerate cabotegravir
- APRETUDE is a long-acting medicine and may stay in your body for 12 months or longer after your last injection

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PrEP AND INSURANCE



If you're insured, all APRETUDE costs, including lab and testing fees, may be **completely covered**. Call your insurance company for more information. If your insurance covers APRETUDE, HIV testing should also be covered. Depending on your plan, this may be covered at zero cost to you. Call your doctor, insurance company, or PrEP navigator if you have questions.

What if my insurance company wants me to go on generic PrEP?

Some insurance companies may require you to go on daily oral PrEP pills first. However, if you and your healthcare provider determine that APRETUDE is a better fit for you, make sure to talk to your healthcare provider. It may be possible to work with your insurance company to switch you to APRETUDE.

IMPORTANT SAFETY INFORMATION (cont'd)

How will I receive APRETUDE? (cont'd)

- Stay under the care of a healthcare provider while receiving APRETUDE. It is important that you receive APRETUDE as scheduled
- If you miss or plan to miss a scheduled injection of APRETUDE by more than 7 days, call your healthcare provider right away to discuss your PrEP options
- If you stop receiving APRETUDE, talk to your healthcare provider about other options to reduce the risk of getting HIV-1 infection

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Ask about APRETUDE.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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