Package leaflet: Information for the patient

Apretude 600 mg prolonged-release suspension for injection
cabotegravir

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Apretude is and what it is used for
2. What you need to know before you are given Apretude
3. How Apretude is given
4. Possible side effects
5. How to store Apretude
6. Contents of the pack and other information

1. What Apretude is and what it is used for

Apretude contains the active ingredient cabotegravir. Cabotegravir belongs to a group of anti-retroviral medicines called integrase inhibitors (INIs).

Apretude is used to help prevent HIV-1 infection in adults and adolescents weighing at least 35kg who are at an increased risk of infection. This is called **pre-exposure prophylaxis: PrEP** (see section 2). It should be used in combination with safer sex practices, such as use of condoms.

2. What you need to know before you are given Apretude

Do not use Apretude:
- if you are **allergic** *(hypersensitive)* to cabotegravir or any of the other ingredients of this medicine (listed in section 6).
- If you are **HIV positive** or you do not know if you are HIV positive**.** Apretude can only help reduce your risk of getting HIV before you are infected. **You must get tested** to make sure you are HIV negative before taking Apretude.
- if you are **taking any of the following medicines**:
  - *carbamazepine, oxcarbazepine, phenytoin, phenobarbital* (medicines to treat epilepsy and prevent fits).
  - *rifampicin* or *rifapentine* (medicines to treat some bacterial infections such as tuberculosis).

These medicines reduce the effectiveness of Apretude by decreasing the amount of Apretude in the blood.
➔ If you think these apply to you, or if you are not sure, **tell your doctor**.

Warnings and precautions

Just taking Apretude may not prevent HIV infection.

HIV infection is spread by sexual contact with someone who is HIV positive or by transfer of infected blood. Although Apretude lowers the risk of becoming infected, you can still get HIV when taking this medicine.
Other measures should be taken to further reduce your risk of getting HIV:

- **Get tested** for other sexually transmitted infections when your doctor tells you to. These infections make it easier for HIV to infect you.
- **Use a condom** when you have oral or penetrative sex.
- Do not share or re-use needles or other injection or drug equipment.
- Do not share personal items that may have blood or body fluids on them (such as razor blades or toothbrushes).

Discuss with your doctor the additional precautions needed to further decrease the risk of getting HIV.

Reduce the risk of getting HIV:

There is a risk of resistance to this medicine if you get infected with HIV. This means that the medicine will not prevent HIV infection. To minimise this risk and to prevent infection with HIV, it is important that you:

- **attend your planned appointments** to receive your Apretude injection. Talk to your doctor if you are thinking about stopping injections, as this may increase your risk of getting a HIV infection. If you do stop, or are late receiving your Apretude injection, you will need to take other medicines or precautions to reduce your risk of getting HIV and possibly developing viral resistance.

- **get tested for HIV** when your doctor tells you. You must be regularly tested to make sure that you remain HIV-1 negative while taking Apretude.

- **tell your doctor straight away** if you think you have been infected with HIV (you may get a flu-like illness). They may want to do more tests to make sure you are still HIV negative.

Apretude injection is a long-acting medicine
If you stop Apretude injections, cabotegravir will remain in your system for up to a year or more after your last injection, **but this will not be enough to protect you from becoming infected.**

It is important that you attend your planned appointments to receive Apretude injection. Talk to your doctor if you are thinking about stopping PrEP.

Once you stop Apretude injections you may need to take other medicines to reduce the risk of getting HIV infection or use other safe sex precautions.

Liver problems
Let your doctor know if you have liver problems. You may need to be more closely monitored. *(See also 'Uncommon side effects' in section 4).*

Adolescents
Your doctor will discuss your mental health with you before and while receiving Apretude. Let your doctor know if you have mental health problems. You may need to be more closely monitored *(See also section 4).*

Allergic reaction
Apretude contains cabotegravir, which is an integrase inhibitor. Integrase inhibitors, including cabotegravir, can cause a serious allergic reaction known as a *hypersensitivity reaction.* You need to know about important signs and symptoms to look out for while you're receiving Apretude.

➔ **Read the information** in 'Possible side effects' in section 4 of this leaflet.

Children and adolescents
This medicine should not be used in children or adolescents weighing less than 35 kg, because it has not been studied in these individuals.

Other medicines and Apretude
Tell your doctor if you are taking, have recently taken or might take any other medicines, including other medicines bought without a prescription.

Some medicines can affect how Apretude works or make it more likely that you will have side effects. Apretude can also affect how some other medicines work.

Apretude must not be given with some other medicines that may affect how well the medicine works (see 'Do not use Apretude' in section 2). These include:
- *carbamazepine, oxcarbazepine, phenytoin, phenobarbital* (medicines to treat epilepsy and prevent fits).
- *rifampicin* or *rifapentine* (medicines to treat some bacterial infections such as tuberculosis).

Tell your doctor if you are taking:
- **rifabutin** (to treat some bacterial infections such as tuberculosis). You may need to receive Apretude injections more often.

➔ **Tell your doctor or pharmacist** if you are taking this medicine. Your doctor may decide that you need extra check-ups.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant**,** or are planning to have a baby, ask your doctor for advice before receiving this medicine.

Pregnancy
Apretude is not recommended during pregnancy. The effect of Apretude on pregnancy is unknown. Talk to your doctor: if you could get pregnant, if you are planning to have a baby or if you become pregnant. Do not stop attending your appointments to receive Apretude without consulting your doctor. Your doctor will consider the benefit to you and the risk to your baby of starting/continuing Apretude.

Breast-feeding
It is not known whether the ingredients of Apretude can pass into breast milk. However, cabotegravir, may pass into breast milk for up to 12 months after the last injection of Apretude. If you are breast-feeding, or thinking about breast-feeding, check with your doctor. Your doctor will consider the benefit and risks of breast-feeding for you and your baby.

Driving and using machines

Apretude can make you dizzy and have other side effects that make you less alert.
➔ **Don't drive or use machines** unless you are sure you're not affected.

3. How Apretude is given

This medicine is given as a 600 mg injection. A nurse or doctor will give you Apretude in the muscle of your buttock.

You must have a HIV-negative test before being given Apretude.

You will be given your first and second dose of Apretude one month apart. After the second dose, you will be given Apretude as a single injection once every 2 months.

Before starting treatment with Apretude injections, you and your doctor may decide first take cabotegravir tablets (called *oral lead-in* period). The lead-in period allows you and your doctor to assess whether it's appropriate to proceed with injections.
If you decide to start treatment with tablets:

- You should take one 30 mg Apretude tablet once a day, for approximately one month.
- You should have your first injection on the same day as your last tablet or no later than 3 days after.
- You will then receive an injection every 2 months

Injection Schedule for every 2 month dosing

When	Which medicine
First and second injection one month apart	Apretude 600 mg
Third injection onwards, every two months	Apretude 600 mg

If you are given too much Apretude injection
A doctor or nurse will give this medicine to you, so it is unlikely that you will be given too much. If you are worried, tell the doctor or nurse and you will be treated as needed.

If you miss a Apretude injection
Contact your doctor immediately to make a new appointment.
It is important that you keep your regular planned appointments to receive your injection and reduce the risk of getting HIV (see section 2). Talk to your doctor if you are thinking about stopping Apretude.

Talk to your doctor if you think you will not be able to receive your Apretude injection at the usual time. Your doctor may recommend you take cabotegravir tablets instead, until you are able to receive an Apretude injection again.

Don't stop receiving Apretude injections without advice from your doctor.
Keep receiving Apretude injections for as long as your doctor recommends. Don't stop unless your doctor advises you to. If you stop and you are still at risk of getting HIV your doctor must start you on another PrEP medicine within 2 months of your last Apretude injection.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions

Apretude contains cabotegravir, which is an integrase inhibitor. Integrase inhibitors including cabotegravir can cause a serious allergic reaction known as a hypersensitivity reaction.

If you get any of the following symptoms:
- skin rash
- a high temperature (*fever*)
- lack of energy (*fatigue*)
- swelling, sometimes of the face or mouth (*angioedema*), causing difficulty in breathing
- muscle or joint aches.

➔ **See a doctor straight away.** Your doctor may decide to carry out tests to check your liver, kidneys or blood, and may tell you to stop taking Apretude.

Very common side effects (may affect more than 1 in 10 people)
- headache
- diarrhoea
- injection site reactions:
    - very common: pain and discomfort, a hardened mass (induration), or lump (nodule)
    - common: redness (erythema), itching (pruritus), swelling, warmth, numbness (aneasthesia) or bruising, (which may include discolouration or a collection of blood under the skin)
    - uncommon: collection of pus (abscess)
- feeling hot (pyrexia)
- changes in liver function (transaminase increased), as measured in blood tests

Common side effects (may affect up to 1 in 10 people)
- depression
- anxiety
- abnormal dreams
- difficulty in sleeping (insomnia)
- dizziness
- feeling sick (nausea)
- vomiting
- stomach pain (abdominal pain)
- wind (flatulence)
- rash
- muscle pain (myalgia)
- lack of energy (fatigue)
- generally feeling unwell (malaise)

Uncommon side effects (may affect up to 1 in 100 people)
- suicide attempt
- suicidal thoughts (particularly in individuals who have had depression or mental health problems before)
- allergic reaction (hypersensitivity)
- hives (urticaria)
- swelling (angioedema), sometimes of the face or mouth, which can cause difficulty in breathing
- feeling drowsy *(*somnolence*)*
- weight gain.
- feeling lightheaded, during or following an injection (vasovagal reactions). This may lead to fainting.

- liver damage (hepatotoxicity). Signs may include yellowing of the skin and the whites of the eyes, loss of appetite, itching, tenderness of the stomach, light-coloured stools or unusually dark urine.
- Increase in blood bilirubin, a breakdown product of red blood cells, as measured in blood tests.

Very rare side effects (may affect up to 1 in 10,000 people)
- Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) are serious life-threatening conditions which usually start with flu-like symptoms. A few days later other symptoms appear including:
    - Painful red or purple skin that looks burned and peels off
    - Blisters on your skin, mouth, nose and genitals
    - Red, painful, watery eyes

➔ **Contact your doctor urgently** if you notice any of these symptoms.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Apretude

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

The doctor or nurse is responsible for storing this medicine correctly.

Do not freeze.

6. Contents of the pack and other information

What Apretude contains
The active substance is cabotegravir.

Each 3 ml vial contains 600 mg cabotegravir.

The other ingredients are:
Mannitol (E421)
Polysorbate 20 (E432)
Macrogol (E1521)
Water for injections

What Apretude looks like and contents of the pack
Cabotegravir is a white to light pink suspension, presented in a brown glass vial with a rubber stopper and an aluminium overseal with a plastic flip-cap.

Marketing Authorisation Holder
ViiV Healthcare UK Limited
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Manufacturer
Glaxo Operations UK Limited (trading as Glaxo Wellcome Operations)
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Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name **Apretude 600 mg Injection**
Reference number 35728/0062

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in April 2025.

The following information is intended for healthcare professionals only:

Apretude **600 mg** **prolonged-release suspension for injection** **cabotegravir** **For intramuscular use** **Instructions for Use** **3 ml**
Overview At each visit, one injection is required; cabotegravir 3 mL (600mg). Cabotegravir is a suspension that does not need further dilution or reconstitution.

Cabotegravir is for intramuscular use only. It must be administered to the gluteal sites.

Note: The ventrogluteal site is recommended.

Storage information

- The storage conditions are detailed on packaging.

Do not freeze.

To prepare the injection

- 1 Luer-Lock syringe (5 mL)
- 1 Luer-Lock aspiration needle or aspiration device (to draw up the suspension)

To administer the injection

- 1 additional Luer-Lock needle (use safety needle if available) of 23 gauge, 1.5 inches

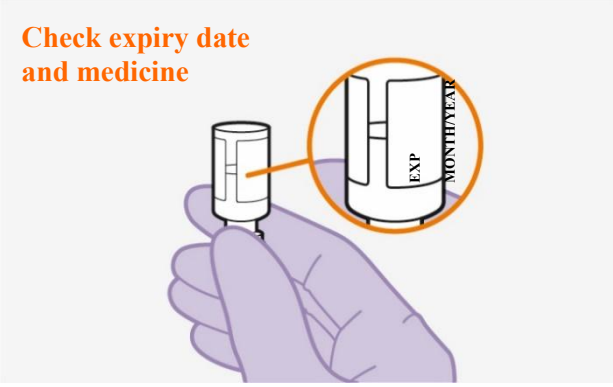
Consider the patient's build and use medical judgment to select an appropriate injection needle length.

You will also need

- Non-sterile gloves
- 2 alcohol swabs
- 1 gauze pad
- A suitable sharps container

Preparation

1. Inspect vial



- Check that the expiry date

  Do not use if the expiry date has passed

- Inspect the vial . If you can see foreign matter, do not use the product.

Note: The cabotegravir vial has a brown tint to the glass.

2. Shake vigorously

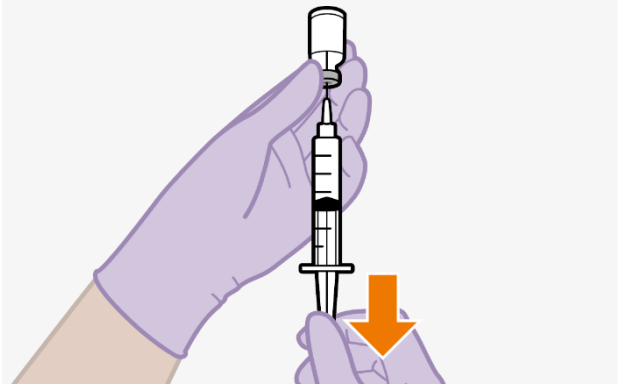
- Hold the vial firmly and vigorously shake for a full 10 seconds as shown.
- Invert the vial and check the resuspension. It should look uniform. If the suspension is not uniform, shake the vial again.
- It is normal to see small air bubbles.
- Remove the cap from the vial.
- Wipe the rubber stopper with an alcohol swab.

Do not allow anything to touch the rubber stopper after wiping it.

3. Prepare syringe and needle

	• Continue to prepare the injection in line with local guidelines. • Example: attach the aspiration needle to the syringe. • It is recommended that you inject 1 mL of air into the vial to allow the required volume to be drawn up.

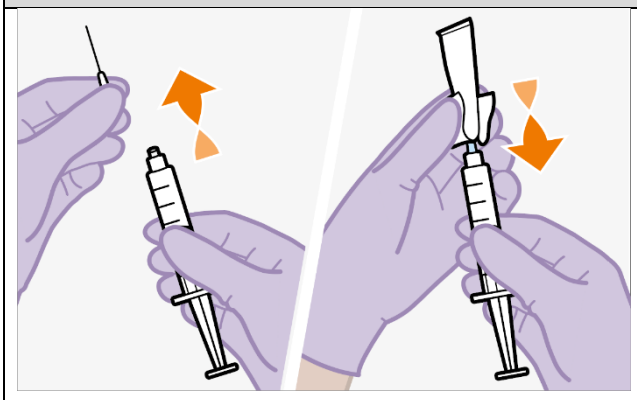
4. Slowly draw up dose



- Invert the syringe and vial, and slowly withdraw as much of the liquid as possible into the syringe. There might be more liquid than dose amount.

Note: Check that the suspension looks uniform and white to light pink.

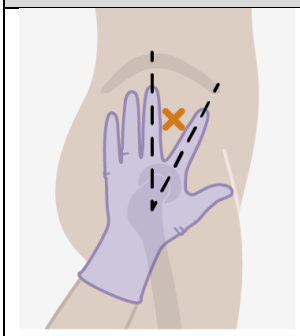
5. Attach injection needle



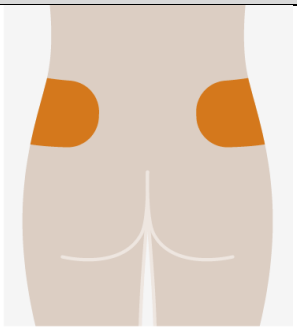
- Peel open the needle packaging part way to expose the needle base.
- Keeping the syringe upright, firmly twist the syringe onto the injection needle.
- Attach injection needle.
- Remove the needle packaging from the needle.

Injection

6. Prepare injection site



Ventrogluteal



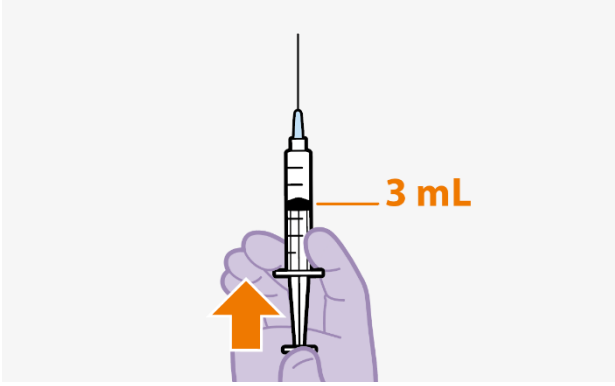
Dorsogluteal

Injections must be administered to the gluteal sites. Select from the following areas for the injection:

- Ventrogluteal (recommended)
- Dorsogluteal (upper outer quadrant)

Note: For gluteal intramuscular use only. **Do not** inject intravenously.

7. Remove extra liquid



- Pull off the injection needle cap.
- Hold the syringe with the needle pointing up. Press the plunger to the 3 mL dose to remove extra liquid and any air bubbles.

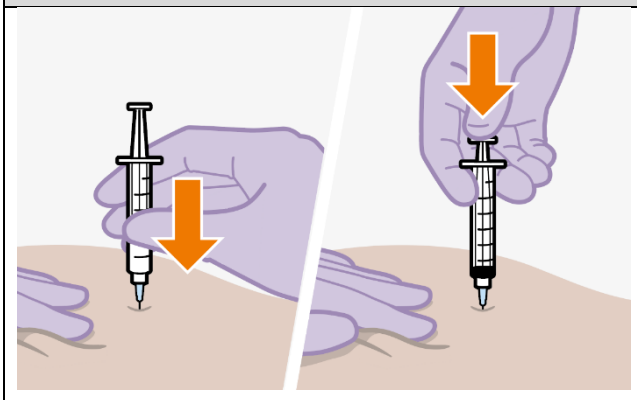
Note: Clean the injection site with an alcohol swab. Allow the skin to air dry before continuing.

8. Stretch skin

Use the z-track injection technique to minimise medicine leakage from the injection site.

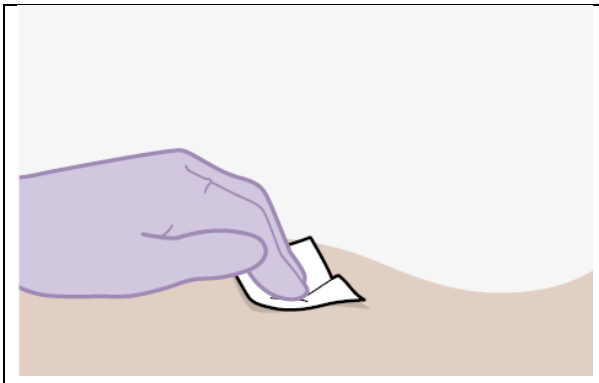
- Firmly drag the skin covering the injection site, displacing it by about an inch (2.5 cm).
- Keep it held in this position for the injection.

9. Inject dose



- Insert the needle to its full depth, or deep enough to reach the muscle.
- Still holding the skin stretched – slowly press the plunger all the way down.
- Ensure the syringe is empty.
- Withdraw the needle and release the stretched skin immediately.

10. Assess the injection site

	• Apply pressure to the injection site using a gauze pad. • A small bandage may be used if a bleed occurs. • Dispose of used needles, syringe and vial according to local health and safety laws. **Do not** massage the area.

Questions and Answers

1. **If the pack has been stored in the refrigerator, is it safe to warm the vial up to room temperature more quickly?**

   You should wait at least 15 minutes before you are ready to give the injection to allow the medicine to reach room temperature.

   It is best to let the vial come to room temperature naturally. However, you can use the warmth of your hands to speed up the warm-up time, but make sure the vial does not get above 30°C.

   Do not use any other heating methods.

2. **How long can the medicine be left in the syringe?**

   It is best to inject the (room temperature) medicine as soon as possible after drawing it up. However, the medicine can remain in the syringe for up to 2 hours before injecting.

   If the medicine remains in the syringe for more than 2 hours, the filled syringe and needle must be discarded.

3. **Why do I need to inject air into the vial?**

   Injecting 1 mL of air into the vial makes it easier to draw up the dose into the syringe.

   Without the air, some liquid may flow back into the vial unintentionally, leaving less medicine than intended in the syringe.

4. **Why is the ventrogluteal administration approach recommended?**

   The ventrogluteal approach, into the gluteus medius muscle, is recommended because it is located away from major nerves and blood vessels. A dorso-gluteal approach into the gluteus maximus muscle is acceptable, if preferred by the health care professional. The injection should not be administered in any other site.