Package leaflet: Information for the patient

Apretude 30 mg film-coated tablets
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 pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. 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 take Apretude
3. How to take Apretude
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.

Your doctor may advise you to take Apretude tablets before you are given a Apretude injection for the first time (called *oral lead-in* period, see section 3).

If you are being given Apretude injections, but you are not able to receive your injection, your doctor may also recommend that you take Apretude tablets instead, until you can receive the injection again (see section 3).

2. What you need to know before you take 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 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:

- **take Apretude tablets every day** to reduce your risk, not just when you think you have been at risk of HIV infection. Do not miss any doses of Apretude or stop taking it. Missing doses may increase your risk of getting HIV infection.

- **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 may 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.

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 less than 12 years of age or 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, phenobarbital, or phenytoin* (medicines used 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:

- **antacids (**medicines to treat indigestion and heartburn**).** Antacids can stop the medicine in Apretude tablets from being absorbed into your body. **Do not take these medicines** in the 2 hours before you take Apretude or for at least 4 hours after you take it.

➔ **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. 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.
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.

Apretude contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Apretude contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Apretude

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You must have a HIV-negative test before taking Apretude.

When you start treatment with Apretude injections, you and your doctor may decide to first start treatment with cabotegravir tablets in an oral lead-in period.
This allows your doctor to assess whether it's appropriate to proceed with injections.

If you decide to start treatment with tablets for the oral lead-in:
- You should take one 30 mg Apretude tablet once a day, for approximately one month.
- **After one month of tablets,** you should receive 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

Oral lead-in schedule

When	What medicine
Month 1	30 mg Apretude tablet once a day
At month 2 and month 3	600 mg Apretude injection each month
Month 5 onwards	600 mg Apretude injection every two months

If you are not able to receive your Apretude injection, your doctor may recommend you take Apretude tablets instead, until you can receive an injection again.

How to take the tablets
Apretude tablets should be swallowed with a small amount of water. They can be taken with or without food.
Do not take antacids (medicines to treat indigestion and heartburn) during the 2 hours before you take a Apretude tablet or for at least 4 hours after you take it, as this can stop Apretude tablets being absorbed into your body and make it less effective.

If you take more Apretude than you should
If you take too many tablets of Apretude, **contact your doctor or pharmacist for advice** and you will be treated as needed. If possible, show them the Apretude tablet bottle.

If you forget to take Apretude
If you notice within 12 hours of the time you usually take Apretude, take the missed tablet as soon as possible. If you notice after 12 hours, then skip that dose and take the next dose as usual.
Do not take a double dose to make up for a forgotten tablet.

If you vomit less than 4 hours after taking Apretude, take another tablet. If you vomit more than 4 hours after taking Apretude you should not take another tablet until your next scheduled dose.

Don't stop taking Apretude without advice from your doctor
Take Apretude for as long as your doctor recommends. Don't stop unless your doctor advises you to.

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
- feeling hot (*pyrexia*)
- changes in liver function (transaminases 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 and 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.

- 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 pharmacist. 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.

This medicine does not require any special temperature storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Apretude contains

The active substance is cabotegravir. Each tablet contains 30 mg cabotegravir.

The other ingredients are:

<u>Tablet core</u>
Lactose Monohydrate
Microcrystalline Cellulose (E460)
Hypromellose (E464)
Sodium Starch Glycolate
Magnesium Stearate

<u>Tablet coating</u>
Hypromellose (E464)
Titanium Dioxide (E171)
Macrogol (E1521)

What Apretude looks like and contents of the pack
Apretude film-coated tablets are white, oval, film-coated tablets, debossed with 'SV CTV' on one side.

The film-coated tablets are provided in bottles closed with child-resistant closures.

Each bottle contains 30 film-coated tablets.

Marketing Authorisation Holder
ViiV Healthcare UK Limited
79 New Oxford Street
London
WC1A 1DG
United Kingdom

Manufacturer
Glaxo Wellcome, S.A.
Avda. Extremadura, 3
Aranda De Duero
Burgos 09400
Spain

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 30mg Tablets**
Reference number 35728/0061

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

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