

## INSTRUCTIONS FOR USE

The following information is intended for healthcare professionals only:

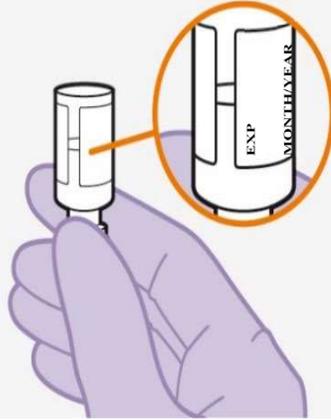
For Single Entity Vial (SEV) packs:

<p><b>Overview</b></p> <p>At each visit, one injection is required; <i>APRETUDE</i> 3 mL (600mg).</p> <p><i>APRETUDE</i> is a suspension that does not need further dilution or reconstitution.</p> <p><i>APRETUDE</i> is for intramuscular use only. It must be administered to the gluteal sites.</p> <p><b>Note:</b> The ventrogluteal site is recommended.</p>
<p> <b>Storage information</b></p>
<ul style="list-style-type: none"> <li>The storage conditions are detailed on packaging.</li> </ul> <p><b>Do not freeze.</b></p>
<p><b>For each injection, you need</b></p>
<ul style="list-style-type: none"> <li>1 vial of <i>APRETUDE</i></li> </ul>
<p><b>To prepare the injection</b></p>
<ul style="list-style-type: none"> <li>1 Luer-Lock syringe (5 mL)</li> <li>1 Luer-Lock aspiration needle or aspiration device (to draw up the suspension)</li> </ul>
<p><b>To administer the injection</b></p>
<ul style="list-style-type: none"> <li>1 additional Luer-Lock needle (use safety needle if available) of 23 gauge, 1.5 inches</li> </ul> <p>Consider the patient's build and use medical judgment to select an appropriate injection needle length.</p>
<p><b>You will also need</b></p>
<ul style="list-style-type: none"> <li>Non-sterile gloves</li> <li>2 alcohol swabs</li> <li>1 gauze pad</li> <li>A suitable sharps container</li> </ul>

## Preparation

### 1. Inspect vial

Check expiry date and medicine



- Check that the expiry date has not passed.
- Inspect the vial immediately. If you can see foreign matter, do not use the product.

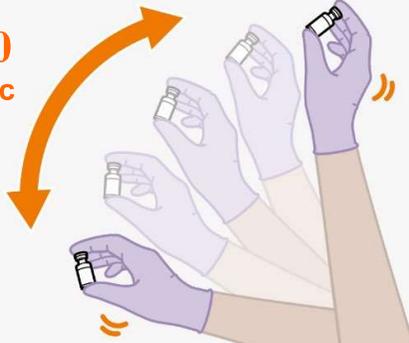
**Note:**

The *APRETUDE* vial has a brown tint to the glass.

**Do not** use if the expiry date has passed.

### 2. Shake vigorously

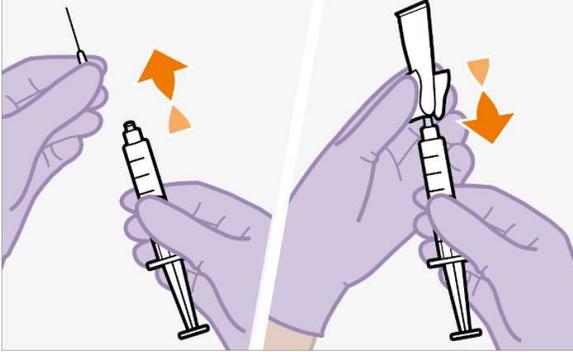
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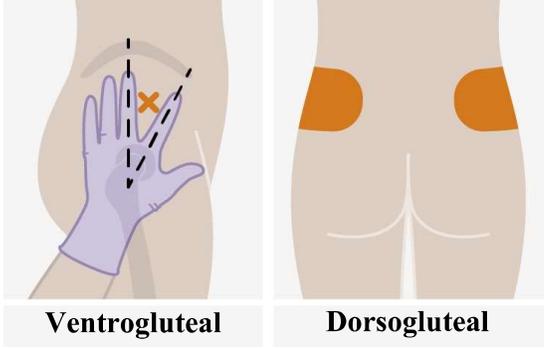
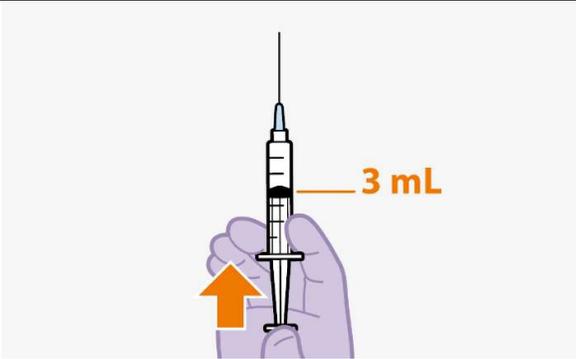


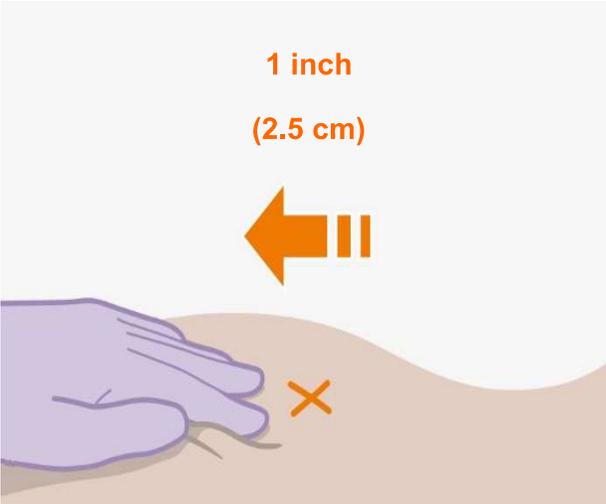
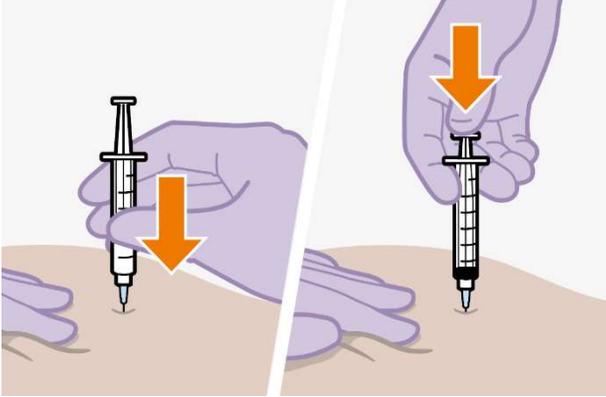
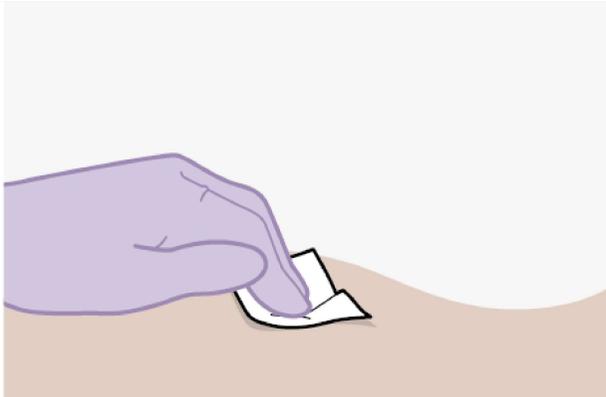
- Hold the vial firmly and vigorously shake for a full 10 seconds as shown.
- Invert the vial and check the resuspension. It should look uniform. If the suspension is not uniform, shake the vial again.
- It is also normal to see small air bubbles.
- Remove the cap from the vial.
- Wipe the rubber stopper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

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

### 3. Prepare syringe and needle

	<ul style="list-style-type: none"> <li>• Continue to prepare the injection in line with local guidelines.</li> <li>• Example: attach the aspiration needle to the syringe.</li> <li>• It is recommended that you inject 1 mL of air into the vial to allow the required volume to be drawn up.</li> </ul>
<b>4. Slowly draw up dose</b>	
	<ul style="list-style-type: none"> <li>• 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.</li> </ul> <p><b>Note:</b> Check that the suspension looks uniform and white to light pink.</p>
<b>5. Attach injection needle</b>	
	<ul style="list-style-type: none"> <li>• Peel open the needle packaging part way to expose the needle base.</li> <li>• Keeping the syringe upright, firmly twist the syringe onto the injection needle.</li> <li>• Attach injection needle.</li> <li>• Remove the needle packaging from the needle.</li> </ul>
<b>Injection</b>	
<b>6. Prepare injection site</b>	

 <p>The left diagram shows a hand in a purple glove pointing to the ventrogluteal site on a buttock, with dashed lines and an orange 'X' marking the location. The right diagram shows the dorsogluteal site on the upper outer quadrant of a buttock, with two orange circles marking the area.</p> <p><b>Ventrogluteal</b>      <b>Dorsogluteal</b></p>	<p>Injections must be administered to the gluteal sites. Select from the following areas for the injection:</p> <ul style="list-style-type: none"><li>• Ventrogluteal (recommended)</li><li>• Dorsogluteal (upper outer quadrant)</li></ul> <p><b>Note:</b> For gluteal intramuscular use only. <b>Do not</b> inject intravenously.</p>
<b>7. Remove extra liquid</b>	
 <p>A hand in a purple glove holds a syringe with the needle pointing up. The plunger is pushed to the 3 mL mark, indicated by an orange arrow and the text '3 mL'.</p>	<ul style="list-style-type: none"><li>• Pull off the injection needle cap.</li><li>• Hold the syringe with the needle pointing up. Press the plunger to the 3 mL dose to remove extra liquid and any air bubbles.</li></ul> <p><b>Note:</b> Clean the injection site with an alcohol swab. Allow the skin to air dry before continuing.</p>
<b>8. Stretch skin</b>	

	<p>Use the z-track injection technique to minimise medicine leakage from the injection site.</p> <ul style="list-style-type: none"><li>• Firmly drag the skin covering the injection site, displacing it by about an inch (2.5 cm).</li><li>• Keep it held in this position for the injection.</li></ul>
<b>9. Inject dose</b>	
	<ul style="list-style-type: none"><li>• Insert the needle to its full depth, or deep enough to reach the muscle.</li><li>• Still holding the skin stretched – slowly press the plunger all the way down.</li><li>• Ensure the syringe is empty.</li><li>• Withdraw the needle and release the stretched skin immediately.</li></ul>
<b>10. Assess the injection site</b>	
	<ul style="list-style-type: none"><li>• Apply pressure to the injection site using a gauze pad.</li><li>• A small bandage may be used if a bleed occurs.</li><li>• Dispose of used needles, syringe and vial according to local health and safety laws.</li></ul> <p><b>Do not</b> massage the area.</p>

**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 medication to come to 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 (86°F).

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.

**LABELLING TEXT**  
**(APRETUDE TABLETS)**

**PARTICULARS TO APPEAR ON THE CARTON [HDPE bottle]**

**NAME OF THE MEDICINAL PRODUCT**

APRETUDE 30 mg film-coated tablets  
cabotegravir

**STATEMENT OF ACTIVE SUBSTANCE(S)**

Each film-coated tablet contains 30 mg cabotegravir (as sodium).

**EXCIPIENTS WARNING(S), IF NECESSARY**

**PHARMACEUTICAL FORM AND CONTENTS**

30 film-coated tablets

**METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.  
Oral use

**OTHER SPECIAL WARNING(S), IF NECESSARY**

Keep out of the sight and reach of children.  
Medicinal product subject to medical prescription.

**PRE-PRINT INFORMATION**

Lot  
Mfg  
Exp

**STORAGE CONDITIONS**

Store at or below 30° C

**MANUFACTURING SITE ADDRESS (PACKAGING SITE ADDRESS IF DIFFERENT)**

Manufactured by:

Glaxo Operations UK Ltd (trading as Glaxo Wellcome Operations)\*  
Priory Street  
Ware  
Hertfordshire, SG12 0DJ  
United Kingdom

Packed by:

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

\*Member of the GSK group of companies.

Note: If space does not permit to include full site address, include minimum necessary address details.  
Batch releaser must be included on the Carton label as minimum.

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**QR CODE TEXT**

**PARTICULARS TO APPEAR ON THE BOTTLE LABEL [HDPE bottle]****NAME OF THE MEDICINAL PRODUCT**

APRETUDE 30 mg film-coated tablets  
cabotegravir

**STATEMENT OF ACTIVE SUBSTANCE(S)**

Each film-coated tablet contains 30 mg cabotegravir (as sodium).

**EXCIPIENTS WARNING(S), IF NECESSARY****PHARMACEUTICAL FORM AND CONTENTS**

30 film-coated tablets

**METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.  
Oral use

**OTHER SPECIAL WARNING(S), IF NECESSARY**

Keep out of the sight and reach of children.  
Medicinal product subject to medical prescription.

**PRE-PRINT INFORMATION**

Lot  
Mfg  
Exp

**STORAGE CONDITIONS**

Store at or below 30° C

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Ware  
Hertfordshire SG12 0DJ  
United Kingdom

Packed by:

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

\*Member of the GSK group of companies.

Note: If space does not permit to include full site address, include minimum necessary address details.  
Batch releaser must be included on the container label as minimum.

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Ware  
Hertfordshire SG12 0DJ  
United Kingdom

Packed by:

Glaxo Wellcome, S.A.\*  
Avda. Extremadura, 3  
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Burgos 09400  
Spain

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If applicable

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**APRETUDE INJECTION  
(SEV – SINGLE ENTITY VIAL PACK)**

**PARTICULARS TO APPEAR ON THE CARTON LABEL [Injection, Single entity vial pack]**

**NAME OF THE MEDICINAL PRODUCT**

APRETUDE 600 mg  
Prolonged-release suspension for injection  
Cabotegravir

**STATEMENT OF ACTIVE SUBSTANCE(S)**

Each 3 mL vial contains 600 mg cabotegravir (as cabotegravir free acid).

**EXCIPIENTS WARNING(S), IF NECESSARY**

**PHARMACEUTICAL FORM AND CONTENTS**

Prolonged-release suspension for injection  
600 mg/ 3mL  
1 vial (600 mg) x 25

**METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.  
For intramuscular use

**OTHER SPECIAL WARNING(S), IF NECESSARY**

Keep out of the sight and reach of children.  
Medicinal product subject to medical prescription.

**PRE-PRINT INFORMATION**

Lot  
Mfg  
Exp

**STORAGE CONDITIONS**

Store at or below 30° C  
Do not freeze.

**MANUFACTURING SITE ADDRESS (PACKAGING SITE ADDRESS IF DIFFERENT)**

Manufactured and packed by:

Glaxo Operations UK Ltd (trading as Glaxo Wellcome Operations)\*  
Harmire Road  
Barnard Castle  
County Durham, DL12 8DT  
United Kingdom

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**QR CODE TEXT**

**PARTUCULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS  
[Vial]**

**NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION**

APRETUDE 600 mg  
Cabotegravir

**METHOD OF ADMINISTRATION**

Read the package leaflet before use.  
IM

**PRE-PRINT INFORMATION (WHERE POSSIBLE)**

Lot  
Mfg  
Exp

**CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

600 mg/ 3mL

**OTHER**

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**DETAILS FOR LEAFLET**

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## GLOBAL PATIENT LEAFLET

### APRETUDE 30 mg film coated tablets cabotegravir

**Read all of this leaflet carefully before you start taking this medicine.**

Keep this leaflet. You may need to read it again. If you have any questions, ask your doctor or pharmacist.

This medicine has been prescribed for you personally. Don't pass it on to other people - it may harm them even if their symptoms seem to be the same as yours.

#### **In this leaflet**

- 1. What APRETUDE is and what it is used for**
- 2. Before you take APRETUDE**
- 3. How to take APRETUDE**
- 4. Possible side effects**
- 5. How to store APRETUDE**
- 6. Further information**

#### **1. What APRETUDE is and what it is used for**

**APRETUDE is used to reduce the risk of getting HIV-1 infection in people weighing 35kg or more (see Section 2). This is called pre-exposure prophylaxis; PrEP.**

*APRETUDE* contains the active ingredient cabotegravir, which belongs to a group of anti-retroviral medicines called *integrase inhibitors* (INIs).

Your doctor may advise you to take *APRETUDE* tablets before you are given a *APRETUDE* injection for the first time.

If you are being given *APRETUDE* injection 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.

#### **2. Before you take APRETUDE**

##### **Don't take APRETUDE**

- if you're allergic (*hypersensitive*) to cabotegravir or to any of the other ingredients of *APRETUDE* (listed in Section 6).

- If you're taking any of these medicines as they may affect the way *APRETUDE* works:
  - **rifampicin or rifapentine** (to treat some bacterial infections such as tuberculosis).
  - **phenytoin, phenobarbital, carbamazepine or oxcarbazepine** (also known as anticonvulsants used to treat epilepsy and prevent fits).
- **Unless you have had a recent HIV test to confirm you are HIV negative.** *APRETUDE* can only help reduce your risk of getting HIV before you are infected so, you must get tested to make sure you don't already have HIV infection before taking *APRETUDE*.
- → **If these apply to you**, tell your doctor.

### Conditions you need to look out for

*APRETUDE* can cause serious side effects. You must look out for certain symptoms while you are taking *APRETUDE* and tell your doctor.

#### Allergic reaction

*APRETUDE* contains cabotegravir, which is an integrase inhibitor. Integrase inhibitors 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*. See 'Allergic Reactions' in **Section 4**.

### Take special care with *APRETUDE*

#### Just taking *APRETUDE* may not stop you getting HIV.

You can still get HIV when taking this medicine, although *APRETUDE* lowers the risk. HIV infection is spread by sexual contact with someone who has the infection or by transfer of infected blood. To reduce your risk of getting HIV:

- **Use a condom** when you have oral or penetrative sex.
- **Don't risk blood transfer** — for example, don't share needles.

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

#### While taking *APRETUDE* tablets to reduce the risk of getting HIV:

- **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 every 2-3 months.**

- **If you think you were infected with HIV (you may get a flu-like illness), tell your doctor straight away.** 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. Your liver function may need to be closely monitored. (*See also 'Liver problems' in section 4*).

### Other medicines and APRETUDE

**Tell your doctor or pharmacist if you're taking any other medicines**, if you've taken any recently, or if you start taking new ones. This includes herbal medicines and 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.

Don't take *APRETUDE* with these medicines:

- **carbamazepine, oxcarbazepine, phenobarbital, or phenytoin** (also known as anticonvulsants used to treat epilepsy and prevent seizures).
- **rifampicin or rifapentine** (to treat some bacterial infections such as tuberculosis).

**Tell your doctor** if you are taking any of the medicines *in the following list*:

- medicines called **antacids**, to treat **indigestion** and **heartburn** (*see also Section 3*).

**Tell your doctor or pharmacist** if you are taking any of these. Your doctor may decide that you need extra check-ups.

### Pregnancy and breast-feeding

If you are **pregnant**, or **think you could be**, or if you are **planning to have a baby**, **don't take APRETUDE** without checking with your doctor. **Your doctor** will consider the benefit to you and the risk to your baby of taking *APRETUDE* while you're pregnant.

If you are thinking about breast-feeding, check with your doctor who will consider the benefits and risks to you and your baby.

**It is not known** whether the ingredients of *APRETUDE* can pass into breast milk and harm your baby.

- ➔ **Talk to your doctor immediately**, if you're breast-feeding, or thinking about breast-feeding.

### 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.

## While you're taking APRETUDE

### You may need regular blood tests

While you're taking *APRETUDE*, your doctor may arrange regular blood tests to check for side effects. There is more information about these side effects in **Section 4** of this leaflet.

## 3. How to take APRETUDE

**Always take APRETUDE exactly as your doctor has told you to.** Check with your doctor or pharmacist if you're not sure.

### How much to take

#### Adults and adolescents weighing 35 kg or more

The usual dose of *APRETUDE* is one tablet (30 mg cabotegravir) taken **once a day**.

### How to take

*APRETUDE* tablets should be swallowed whole with some liquid. *APRETUDE* tablets can be taken with or without food.

### Initial PrEP with *APRETUDE*

If you are starting PrEP with tablets, your doctor will advise you to:

- take one 30 mg *APRETUDE* tablet once a day, for approximately one month
- receive injections every 2 months.

This first month is called the oral lead-in period. It allows your doctor to assess whether it's appropriate to proceed with injections.

Which medicine	When	Dose
<i>APRETUDE</i>	<b>For 1 Month (at least 28 days)</b>	30 mg tablet once a day

### If you will miss a *APRETUDE* Injection

If you are not able to receive your injection, your doctor may recommend you take *APRETUDE* tablets instead, until you can receive an injection again. Your doctor will advise you to take one tablet a day until your next *APRETUDE* injection.

### Antacid medicines

Antacids, to treat **indigestion** and **heartburn**, can stop or reduce *APRETUDE* being absorbed into your body and make it less effective.

Antacids should be taken at least 2 hours before or 4 hours after you take *APRETUDE* . Talk to your doctor for further advice on taking acid-lowering (antacid) medicines with *APRETUDE* .

### **If you forget to take *APRETUDE***

If you miss a dose, take it as soon as you remember. Then continue your PrEP as before.

**Don't take a double dose** to make up for a missed dose.

### **If you take too much *APRETUDE***

If you take too many tablets of *APRETUDE* , **contact your doctor or pharmacist for advice**. If possible, show them the *APRETUDE* pack.

### **Don't stop *APRETUDE* without advice from your doctor**

Take *APRETUDE* for as long as your doctor recommends. Don't stop unless your doctor advises you to.

## **4. Possible side effects**

Some side effects may only be seen in your blood tests and may not appear immediately after you start taking *APRETUDE* . If you get any of these effects, and if they are severe, your doctor may advise you to stop taking *APRETUDE* .



### **Allergic Reactions**

These are uncommon in people taking *APRETUDE* . Signs include:

- skin rash
- a high temperature (*fever*)
- lack of energy (*fatigue*)
- raised and itchy rash (*hives*)
- swelling, sometimes of the face or mouth (*angioedema*), causing difficulty in breathing
- muscle or joint aches.

→ **Contact your doctor as soon as possible.** Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking *APRETUDE* .

### Very common side effects

These may affect **more than 1 in 10** people:

- Headache
- Diarrhoea
- Feeling hot (*pyrexia*)
- changes in liver blood tests (*increase in transaminases*)

### Common side effects

These may affect **up to 1 in 10** people:

- depression
- 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

These may affect **up to 1 in 100** people:

- weight gain
- liver damage (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) (*hepatotoxicity*)
- suicidal thoughts\*
- suicide attempt\*

\*Mainly in patients who have had depression or mental health conditions before.

→ **Tell your doctor or pharmacist** if you notice any of these symptoms.

## 5. How to Store *APRETUDE*

The storage conditions are detailed on the packaging.

Keep out of the sight and reach of children.

Do not take *APRETUDE* after the expiry date shown on the pack.

Don't throw away any medicines in wastewater or household waste. Ask your pharmacist how to throw away medicines no longer required. This will help to protect the environment.

## 6. Further information

### What *APRETUDE* contains

The active substance is cabotegravir (as cabotegravir sodium). Each tablet contains 30 mg cabotegravir.

The other ingredients are:

#### Tablet core:

Lactose Monohydrate  
Microcrystalline Cellulose  
Hypromellose 2910 (E464)  
Sodium Starch Glycolate (Type A)  
Magnesium Stearate

#### Tablet coating

Hypromellose (E464)  
Titanium Dioxide (E171)  
Macrogol 400 (E1521)

**What *APRETUDE* looks like and contents of the pack**

The 30 mg tablets are white, oval, film-coated tablets marked with SV CTV on one side.

tablets are supplied in HDPE (high density polyethylene) bottles with child-resistant closures. Each bottle contains 30 film-coated tablets.