

APRETUDE prolonged-release suspension for injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. What is APRETUDE and what is it used for?

APRETUDE contains the active ingredient cabotegravir, which belongs to a group of antiretroviral medicines called integrase inhibitors (INIs). APRETUDE is used to reduce the risk of getting HIV infection in people weighing 35 kg or more. This is called pre-exposure prophylaxis (PrEP). For more information, see Section [1. What is APRETUDE and what is it used for?](#) in the full CMI.

2. What should I know before I am given APRETUDE?

Do not use if you have ever had an allergic reaction to cabotegravir or any of the ingredients listed at the end of the CMI. Do not use unless you have had a recent HIV test to confirm you are HIV negative.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I am given APRETUDE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APRETUDE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How APRETUDE is given to me?

- APRETUDE will be given by a nurse or doctor through an injection in the muscle of your buttock (intramuscular injection (IM)) as a single injection once every 2 months.
- You should be given APRETUDE for as long as your doctor recommends. Do not stop unless your doctor advises you to.

More instructions can be found in Section [4. How APRETUDE is given to me?](#) in the full CMI.

5. What should I know while being given APRETUDE?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using APRETUDE. • Attend your planned appointments to receive your APRETUDE injection. • Get tested for HIV every 2-3 months
Things you should not do	• Do not miss your planned appointments to receive your APRETUDE injection. Missing your dose may increase your risk of getting HIV infection.
Driving and using machines	• APRETUDE can make you dizzy and have other side effects that make you less alert. • Do not drive or use machines unless you are sure you are not affected.
Looking after your medicine	• APRETUDE injection will be given to you by a nurse or doctor who will be responsible for its storage. • APRETUDE injection should be kept in the pack until it is time to use it. It should be stored below 30°C.

For more information, see Section [5. What should I know while being given APRETUDE?](#) in the full CMI.

6. Are there any side effects?

The following very common side effects may occur when using APRETUDE: headache, diarrhoea, injection site reactions, fever. Contact your doctor promptly if you develop an allergic reaction or if you have liver problems.

Whilst very rare, Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) are serious and life-threatening. Contact your doctor straight away if you develop painful red or purple skin, blisters on your skin, mouth, nose and genitals and red, painful, watery eyes.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

APRETUDE prolonged-release suspension for injection

Active ingredient: *cabotegravir*

Consumer Medicine Information (CMI)

This leaflet provides important information about being given APRETUDE injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APRETUDE.**

Where to find information in this leaflet:

1. [What is APRETUDE and what it is used for?](#)
2. [What should I know before I am given APRETUDE?](#)
3. [What if I am taking other medicines?](#)
4. [How APRETUDE is given to me?](#)
5. [What should I know while using APRETUDE?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. What is APRETUDE and what is it used for?

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

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

2. What should I know before I am given APRETUDE?

Warnings

You must not be given APRETUDE:

- if you are allergic to cabotegravir, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can be given this medicine.
- if you are 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 seizures).
- 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.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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

If you are planning to have a baby, talk to your doctor in advance, as APRETUDE injection can stay in your system for up to 12 months or longer after the last injection of APRETUDE.

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

It is not known whether the ingredients of APRETUDE can pass into breast milk and harm your baby. APRETUDE may still pass into breast milk for 12 months after the last injection of APRETUDE.

Allergic reaction

- APRETUDE contains cabotegravir, which is an integrase inhibitor. Other 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 additional information under Section [6. Are there any side effects?](#)

You must not be given APRETUDE injection after the expiry date shown on the pack.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with APRETUDE and affect how it works or make it more likely that you will have

side effects. APRETUDE can also affect how some other medicines work.

You must not be given 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:

- 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 any of these. Your doctor may decide you need extra check-ups.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APRETUDE.

4. How APRETUDE is given to me?

How much is given

When you first start PrEP with APRETUDE, you and your doctor may decide to either:

- start PrEP directly with APRETUDE injection.
Or
- start PrEP with APRETUDE tablets. If you start with APRETUDE tablets, the doctor will advise you to:
 - o take one 30 mg APRETUDE tablet once a day, for approximately one month, then receive injections every 2 months.
 - o Your first injection should preferably be on the same day as your last tablet or no later than 3 days after.

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

When APRETUDE is given

- You will be given APRETUDE as a single injection once every 2 months.

Injection Schedule for every 2 month dosing

Which medicine	When	
	First and second injections one month apart	Third injection onwards, every two months.
APRETUDE	3 mL (600 mg)	3 mL (600 mg)

How APRETUDE is given

- A nurse or doctor will give you APRETUDE through an injection in the muscle of your buttock (intramuscular injection [IM]).

If you miss an APRETUDE injection

Contact your doctor immediately to make a new appointment

It is important that you keep your regular planned appointments to receive your APRETUDE injection to reduce the risk of getting HIV. 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 APRETUDE tablets instead, until you are able to receive an APRETUDE injection again.

If you are given too much APRETUDE

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.

Do not stop receiving APRETUDE injections without advice from your doctor.

You should be given APRETUDE for as long as your doctor recommends. Don't stop unless your doctor advises you to. If you miss an appointment to receive your injection, contact your doctor right away to make a new appointment.

5. What should I know while being given APRETUDE?

Things you should do

- It is important that you attend your planned appointments to receive your APRETUDE injections. Talk to your doctor if you are thinking about stopping injections as this may increase your risk of getting HIV infection. If you do stop or are late receiving your APRETUDE injections, 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 every 2-3 months.

Call your doctor straight away if you:

- think you were 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.

Remind any doctor, dentist or pharmacist you visit that you are using APRETUDE.

Things you should not do

- Do not stop or be late receiving your APRETUDE injection. APRETUDE injection is a long-acting medication, so if you stop, cabotegravir will remain in your system for up to a year or more after your last injection. It is important that you attend your planned appointments to receive APRETUDE injection and talk to your doctor if you are thinking about stopping PrEP. You may need to take other medicines to reduce the risk of getting HIV infection or use other safe sex precautions if you stop APRETUDE injections.

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:

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

Let your doctor know if you have liver problems. Signs of liver problems include yellowing of the skin and the whites of eyes, loss of appetite, itching, tenderness of the stomach, light coloured stools or unusually dark urine.

You may need regular blood tests

Driving or using machines

APRETUDE may cause dizziness in some people and have other side effects that make you less alert. Do not drive or use machines unless you are sure you are not affected.

APRETUDE injection will be given to you by a doctor or a nurse who will be responsible for its storage.

APRETUDE injections should be kept in the pack until it is time to use it. It should be stored below 30°C.

Your healthcare professional will be responsible for discarding APRETUDE injections..

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about 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.

Less serious side effects	What to do
Stomach or bowel problems: Very common • Diarrhoea Common • Feeling sick (nausea) • Vomiting • Stomach pain (abdominal pain) • Wind (flatulence) General disorders: Very common • Headache Common • Depression • Abnormal dreams • Difficulty in sleeping (insomnia) • Dizziness • Lack of energy (fatigue) • Generally feeling unwell (malaise) Skin problem: Common • Rash Injection site reactions: Very common • Pain & tenderness, a hardened mass or lump Common • Redness, itching, swelling, warmth, numbness or bruising (which may include discolouration or a collection of blood under the skin) Uncommon • An abscess (collection of pus) Other: Very common • Feeling hot (fever)	Speak to your doctor if you have any of these less serious side effects and they worry you. Tell your doctor or pharmacist if you experience severe or troublesome reactions at the site where you are given your injection

Less serious side effects	What to do
Common - Muscle pain (myalgia) Uncommon - Weight gain - Feeling lightheaded, during or following an injection. This may lead to fainting	

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Serious side effects

Serious side effects	What to do
Conditions you need to look out for Some other conditions may develop while you are taking APRETUDE: Allergic Reaction - 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 Liver problems Very common - changes in liver blood tests (increase in transaminases) Uncommon - 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) Psychological Uncommon - suicidal thoughts* - Suicidal attempt* * mainly in patients who have had depression or mental health problems before. Skin and subcutaneous tissue disorders:	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
Very rare - 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	

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Very rare: may affect up to 1 in 10,000 people

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What APRETUDE contains

Active ingredient (main ingredient)	Cabotegravir
Other ingredients (inactive ingredients)	mannitol polysorbate 20 macrogol 3350 water for injections

You must not be given this medicine if you are allergic to any of these ingredients.

What APRETUDE looks like

APRETUDE prolonged-release suspension for injection is a white to light pink suspension. Each 3 mL vial contains 600 mg cabotegravir.

AUST R 377474

Who distributes APRETUDE

ViiV Healthcare Pty Ltd

Level 4, 436 Johnston Street

Abbotsford, VIC 3067

Australia

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