

APRETUDE Tablets

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. Why am I taking APRETUDE?

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. Why am I using APRETUDE?](#) in the full CMI.

2. What should I know before I take APRETUDE?

Do not take if you have ever had an allergic reaction to cabotegravir or any of the ingredients listed at the end of the CMI. Do not take 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 take 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 do I take APRETUDE?

- APRETUDE should be taken once a day. If you need to take an antacid, take it at least 2 hours before or 4 hours after you take your APRETUDE tablet.
- Take 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 do I take APRETUDE?](#) in the full CMI.

5. What should I know while taking APRETUDE?

| | |
|-----------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist |
|-----------------------------|--|

| | |
|------------------------------------|---|
| | <p>you visit that you are using APRETUDE.</p> <ul style="list-style-type: none"> • Take APRETUDE tablets every day to reduce your risk, not just when you think you have been at risk of HIV Infection. • Get tested for HIV every 2-3 months |
| Things you should not do | <ul style="list-style-type: none"> • Do not miss any doses of APRETUDE or stop taking it. Missing your dose may increase your risk of getting HIV infection. |
| Driving and using machines | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • Keep your tablets in a cool dry place where the temperature stays below 30°C. |

- Keep your tablets in the bottle until it is time to take them.

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

6. Are there any side effects?

The following very common side effects may occur when taking APRETUDE: headache, diarrhoea, 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 tablets

Active ingredient: *cabotegravir (as cabotegravir sodium)*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I taking APRETUDE?](#)
- [2. What should I know before I take APRETUDE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take APRETUDE?](#)
- [5. What should I know while taking APRETUDE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking APRETUDE?

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).

Your doctor may advise you to take APRETUDE tablets before you are given APRETUDE prolonged-released suspension for injection for the first time.

If you are being given APRETUDE prolonged-released suspension for 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. What should I know before I take APRETUDE?

Warnings

Do not take 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 take 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

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will consider the benefit to you and the risk to your baby of taking APRETUDE while you are pregnant. It is not known whether the ingredients of

APRETUDE can pass into breast milk and harm your baby.

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?](#)

Do not take APRETUDE 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.

Do not 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.

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 do I take APRETUDE?

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.
- Follow the instructions provided and take APRETUDE until your doctor tells you to stop. Always take APRETUDE exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

When to take APRETUDE

- APRETUDE should be taken once a day.
- If you need to take an antacid, take it at least 2 hours before or 4 hours after you take your APRETUDE

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

How to take APRETUDE

- 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 |
|-----------------------|--------------------------------|-------------------------|
| APRETUDE | For 1 month (at least 28 days) | 30 mg tablet once a day |

Take APRETUDE for as long as your doctor recommends. Do not stop unless your doctor advises you to.

If you will miss an APRETUDE prolonged-released suspension for 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 take one tablet a day until your next APRETUDE injection.

If you forget to take APRETUDE

APRETUDE should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember. Then continue your PrEP as before.

Do not take a double dose to make up for the dose you missed.

If you take too much APRETUDE

If you think that you have taken too much APRETUDE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking APRETUDE?

Things you should do

- 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 your dose may increase your risk of getting HIV infection.
- 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 miss any doses of APRETUDE or stop taking it. Missing doses may increase your risk of getting HIV infection.

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
- Do no risk blood transfer, do not share needles.

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

Liver problems

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.

Your liver function may need to be closely monitored.

You may need regular blood tests

While you are taking APRETUDE, your doctor may arrange regular blood tests to check for side effects. See additional information under Section [6. Are there any side effects?](#)

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APRETUDE affects you.

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.

Looking after your medicine

- Keep your tablets in a cool dry place where the temperature stays below 30°C.
- Keep your tablets in the bottle until it is time to take them.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

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

| Less serious side effects | What to do |
|--|---|
| <p>Stomach or bowel problems:</p> <p>Very common</p> <ul style="list-style-type: none">• Diarrhoea <p>Common</p> <ul style="list-style-type: none">• Feeling sick (nausea)• Vomiting• Stomach pain (abdominal pain)• Wind (flatulence) | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

| Less serious side effects | What to do |
|---|-------------------|
| <p>General disorders:</p> <p>Very common</p> <ul style="list-style-type: none"> • Headache <p>Common</p> <ul style="list-style-type: none"> • Depression • Abnormal dreams • Difficulty in sleeping (insomnia) • Dizziness • Lack of energy (fatigue) • Generally feeling unwell (malaise) <p>Skin problem:</p> <p>Common</p> <ul style="list-style-type: none"> • Rash <p>Other:</p> <p>Very common</p> <ul style="list-style-type: none"> • Feeling hot (fever) <p>Common</p> <ul style="list-style-type: none"> • Muscle pain (myalgia) <p>Uncommon</p> <ul style="list-style-type: none"> • Weight gain | |

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 |
|--|---|
| <p>Conditions you need to look out for</p> <p>Some other conditions may develop while you are taking APRETUDE:</p> <p>Allergic Reaction</p> <ul style="list-style-type: none">• 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 <p>Liver problems</p> <p>Very common</p> <ul style="list-style-type: none">• Changes in liver blood tests (increase in transaminases) | <p>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.</p> |

| Serious side effects | What to do |
|---|-------------------|
| <p>Uncommon</p> <ul style="list-style-type: none"> • 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) <p>Psychological</p> <p>Uncommon</p> <ul style="list-style-type: none"> • suicidal thoughts* • Suicidal attempt* <p>* mainly in patients who have had depression or mental health problems before.</p> <p>Skin and subcutaneous tissue disorders:</p> <p>Very rare</p> <ul style="list-style-type: none"> • Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) are serious life-threatening conditions which | |

| Serious side effects | What to do |
|---|-------------------|
| <p>usually start with flu-like symptoms. A few days later other symptoms appear including:</p> <ul style="list-style-type: none"> ○ 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

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 (as cabotegravir sodium) |
| Other ingredients (inactive ingredients) | lactose monohydrate microcrystalline cellulose hypromellose sodium starch glycolate magnesium stearate titanium dioxide macrogol |

Do not take this medicine if you are allergic to any of these ingredients.

What APRETUDE looks like

APRETUDE tablets are white, oval, film-coated tablets, debossed with 'SV CTV' on one side.

Each tablet contains 30 mg

AUST R 377442

Who distributes APRETUDE

ViiV Healthcare Pty Ltd

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Abbotsford, VIC 3067

Australia

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