

APRETUDE FILMED COATED TABLET

Cabotegravir 30mg

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What Apretude is used for

Apretude tablet is used as a lead-in (first month) before being given Apretude injection thereafter.

Apretude is used to reduce the risk of getting HIV-1 infection in people weighing 35kg or more. This is called pre-exposure prophylaxis; PrEP.

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.

How Apretude works

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

Before you use Apretude

- When you must not use it
Do not take Apretude:

- if you're allergic (hypersensitive) to cabotegravir or to any of the other ingredients of Apretude tablet
- if you are allergic to integrase inhibitors
- 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 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.

If any of the above apply to you, tell your doctor.

- Before you start to use it

Let your doctor know if you have liver problems. Your liver function may need to be closely monitored.

- Taking other medicines

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

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

How to use Apretude

- How much to use

For adults and adolescents weighing 35 kg or more, the usual dose of Apretude is one tablet (30 mg cabotegravir) taken once a day.

- When to use it

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

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.

- How long to use it

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.

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.

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

- If you forget to use it

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 use too much (overdose)

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

While you are using it

- Things you must 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 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.
- Your doctor may arrange regular blood tests to check for side effects.

- Things you must not do

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.

- Things to be careful of

Notify doctors if you have sign of liver damage (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)

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.

Very rare side effects

These 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Apretude

- Storage

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.

- Disposal

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.

Product Description

- What it looks like

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

Apretude tablets are supplied in HDPE (high density polyethylene) bottles with child-resistant closures.

Each bottle contains 30 film-coated tablets.

- Ingredients

- Active ingredient(s)
cabotegravir (as cabotegravir sodium)

- Inactive ingredient(s)

- 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)

- MAL Number:

MAL23096001ARZ

Manufacturer

Glaxo Operations UK Ltd
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Product Registration Holder

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