

# Apretude

## Summary

Apretude is the name given to the drug cabotegravir when it is used to reduce the risk of HIV infection. Apretude comes in tablets and a long-acting liquid for injection. Apretude belongs to a group or class of anti-HIV drugs called integrase inhibitors. Using Apretude prior to potential HIV exposure is called pre-exposure prophylaxis (PrEP).

Apretude is meant for people who are HIV-negative. Below are additional points to note about this drug:

- When initiating Apretude, your healthcare provider will discuss whether or not to begin using Apretude with a cabotegravir pill taken once daily for about four weeks. This is called the oral lead-in. This can be useful to assess if side effects occur. In general, clinical trials have found Apretude to be well-tolerated. If there are no problems with the oral lead-in then your doctor can prescribe Apretude injections.
- Note that the manufacturer of Apretude, ViiV Healthcare, has given doctors the option to skip the oral lead-in and go directly to injections of Apretude.
- Apretude is always injected into the buttocks by a healthcare provider.
- For the first two months of injections, Apretude is given via one injection deep into the buttocks once per month. After this, the drug is injected every two months, also into the buttocks.
- Regular clinic visits are necessary for continued injections and monitoring.

Both the pills and injectable Apretude are generally well-tolerated. Common side effects from Apretude include

# FACT SHEET

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injection site reactions (redness, swelling, pain), as well as headache, diarrhea and feeling hot. These side effects are generally mild to moderate and are usually temporary.

### How does cabotegravir (in Apretude) work?

Cabotegravir works by interfering with an enzyme called integrase. This enzyme is needed by HIV to make copies of itself. Using these drugs significantly reduces HIV's ability to infect cells and make copies of itself. In clinical trials, Apretude was at least 99.5% effective at preventing HIV infection in people who received the drug on time.

### How do people use Apretude?

After discussion with their healthcare provider, some people may decide to begin Apretude by taking a pill of cabotegravir once daily for one month. Each pill contains 30 mg of cabotegravir and it can be taken with or without food. Taking these pills for a month is called the oral lead-in period. If no problems have occurred during this time, a healthcare provider subsequently gives them an injection once a month for two consecutive months. The injections are given deep into the buttocks. Each injection contains 3 mL of a suspension containing 600 mg of cabotegravir.

After this, injections are given once every two months.

Over the long-term, regular visits (every two months) to a healthcare provider are necessary for injections. Regular lab tests will also be necessary, including ongoing HIV testing. If you cannot attend your next appointment let your healthcare provider know right away.

Speak to your healthcare provider about when the protective effects of Apretude begin.

## Warnings

### Anxiety and depression

Although not common in clinical trials, a very small proportion of people who took cabotegravir (Apretude) developed irritability, anxiety, depression and/or negative thoughts. These problems seemed more likely to happen if people had such problems in the past (prior to taking Apretude). If you are taking Apretude and think that you may have developed anxiety or depression, speak to your doctor or nurse right away. Your doctor or nurse can help determine if you have anxiety or depression and if there is any relationship between them and the medicines that you are taking.

Symptoms of anxiety and depression can include the following:

- becoming easily upset or angry
- feeling fearful
- excessive worry
- difficulty falling asleep or staying asleep, or waking up prematurely
- unexpected feelings of sadness
- recurrent nightmares
- prolonged feelings of sadness, anger or depression
- feeling hopeless
- loss of pleasure in everyday activities
- unexpectedly feeling tired or experiencing a lack of energy
- strange thoughts

If you have any of these feelings, contact your doctor or nurse right away.

If you have thoughts of harming yourself or others, dial 911 right away.

There are many treatment options available for anxiety and depression – your healthcare provider can tell you more about them.

## Immediate reactions after injection

Apretude is meant to be injected deep into muscle. It is released slowly and for a prolonged period (a couple of months) after injection into muscle. When it is not injected into muscle, some short-term problems can occur because a large quantity gets into the blood. Some of the problems include the following reactions:

- problems breathing
- agitation
- abdominal cramps
- flushing of the skin
- sweating
- numbness of the mouth
- feeling lightheaded or faint

Tell your doctor or nurse right away if you have any of these symptoms soon after an injection of Apretude. These problems should start to clear after a few minutes.

## Pregnancy

Apretude has not been widely studied in pregnant people. The manufacturer recommends that Apretude “should be used in pregnant women only if the potential benefits outweigh the potential risks to the fetus.” If you want to become pregnant, talk to your healthcare provider. The safety of Apretude on the fetus is not known.

## Hepatitis B virus

Apretude cannot protect you from hepatitis B virus. Check with your healthcare provider to find out if you have been vaccinated against hepatitis B and whether the vaccine is still effective. If you have not been vaccinated against hepatitis B, talk to your healthcare provider about getting vaccinated. If you have hepatitis B, ask about your treatment options.

## Side effects

### General

In clinical trials, Apretude (pills and injections) were well tolerated, generally safe and effective. However, as with any treatment, there were side effects but these were uncommon and included the following:

- fever or feeling hot
- headache
- diarrhea

For the vast majority of people who took Apretude, these side effects were mild and temporary. If you develop side effects and they become bothersome or persist, speak to your healthcare provider.

### Injection site reactions

There will be some discomfort, redness/swelling and pain at the site of injection of Apretude. In clinical trials, the vast majority of cases where such side effects occurred were of mild or moderate intensity. Also, these side effects usually resolve in a few days. Some people take over the counter medicines for a day or two to minimize discomfort, headache or pain. However, if pain and discomfort at the injection site persist, speak to your nurse or doctor.

About 15% of people who used Apretude in clinical trials developed a small bump or nodule at the site of injection. Nodules may take longer to diminish but they should have resolved by the time of the next injection. In studies of Apretude, the risk of nodules forming diminished over time, as people continued to receive Apretude.

### Weight gain

In clinical trials, people gained an average of between 1 to 2 kg of weight over about two years of using Apretude.

## Looking after your general health

Apretude significantly reduces your risk for getting HIV. However, you need to continue to look after

your general health making sure that you do the following:

- Get enough physical activity every day.
- Get enough sleep; if you have sleeping problems or do not feel rested after waking up, speak to your healthcare provider.
- Monitor your emotional and mental health; if there are problems, speak to your healthcare provider right away.
- Tell your doctor and/or nurse about all the medicines that you are taking, both prescription and over the counter.
- If possible, try and use the same pharmacy to obtain all your prescription medicines; that way your pharmacist can help keep track of the medicines that you are taking.
- Eat a nutritious diet.

## Looking after specific health issues

Talk to your doctor about whether or not you have already been vaccinated against these viruses:

- hepatitis A virus
- hepatitis B virus
- human papilloma virus (HPV)

There are vaccines that can help protect you from these viruses. There is usually no cost for the vaccines for hepatitis A and B. However, there may be a cost for the HPV vaccine depending on your age and where you live.

As part of regular clinic visits, your healthcare provider will give you lab test requisition forms for screening for HIV, syphilis, gonorrhoea, chlamydia and possibly other infections.

## Drug interactions

Some drugs (including prescribed and over-the-counter), herbs and supplements can interfere with the absorption and/or effectiveness of Apretude. Such interference is called a drug interaction. Some drugs or herbs and supplements can reduce the levels of cabotegravir (in Apretude) in your blood.

This can make Apretude less effective and increase your risk for HIV. Other drugs can raise the levels of cabotegravir in your blood, resulting in enhanced side effects or new side effects. Therefore, it is important to disclose to your doctor, nurse and pharmacist all the supplements, drugs, and herbs you are taking.

This factsheet is *not* comprehensive and only lists some of the potential and actual drug interactions with the pills and injectable formulations of cabotegravir. Speak to your pharmacist to find out more about drug interactions with Apretude.

## Drug interactions with Apretude

People taking Apretude should not use the following drugs or herbs/herbal extracts:

- antiseizure drugs – carbamazepine, oxcarbazepine, phenobarbital, and phenytoin
- antibiotics for TB (tuberculosis) or Mycobacterium complex – rifampin and rifapentine should not be used by people taking Apretude
- St. John's wort or its active ingredients hypericin and hyperforin – sometimes used to manage mild to moderate cases of depression (it is not highly effective for this purpose)

If you have been prescribed these drugs or are taking these supplements, speak to your healthcare provider about other treatment options.

## Acid-reducing agents, laxatives, metal supplements and buffered medicines

The manufacturer of Apretude, ViiV Healthcare, recommends that acid-reducing agents or supplements that contain certain metals (aluminum, calcium, or magnesium) should be taken "at least two hours before or four hours after taking Apretude tablets." Examples of these acid-reducing agents include:

- Alka-Seltzer
- Calcium and/or magnesium supplements
- Gaviscon (tablets and syrup)

- Maalox (liquid and tablets)
- Milk of Magnesia
- Pepto-Bismol and Pepto Bismol Children's
- Rolaids
- Tums

## Medication-taking

To reduce the risk of developing HIV infection, Apretude should be taken exactly as prescribed and directed. If doses are delayed, missed or not taken as prescribed, the level of cabotegravir in the blood may fall too low to protect you from HIV. If you find you are having problems taking your medications as directed, speak to your doctor, nurse or pharmacist about this. They can find ways to help you.

## Dosage

The dosing, formulation, schedule and administration of injectable therapy can seem complex at first. The drugs must be injected deep into muscular tissue in the buttocks and need to be injected by a health care professional.

Your doctor or clinic nurse will inject the drugs or refer you to a nurse who will do so. If a nurse will be injecting the drugs, note that your doctor will continue to provide your overall care, so regular doctor visits and lab tests are important.

Speak to your nurse or doctor about your schedule of visits to get future injections. If you cannot attend your next appointment for an injection, let your doctor or nurse know right away. ViiV indicates that there is some flexibility about the timing of injections by up to seven days. However, repeatedly missing appointments for injections can increase the risk of HIV infection.

## Missed doses of Apretude

If you miss a dose of Apretude pills, ViiV advises to take a dose as soon as you remember. The company further states, "if your next dose is due within 12 hours, skip the dose you missed and take the next one at your usual time. Then continue your

treatment as before. Don't take a double dose to make up for the missed dose."

It is important not to miss an injection appointment. If you miss or are going to miss an injection of Apretude, speak to your healthcare provider right away. ViiV states that in such cases, your healthcare provider "may recommend that you take Apretude tablets until you are able to take Apretude injections again." Furthermore, ViiV recommends that another HIV test be done if you miss an injection.

## Changing PrEP

If you want to stop taking Apretude first speak to your doctor or nurse. They can listen to your reasons for quitting and either advise you about resolving the issues you have raised or help you find a new regimen to reduce your risk of HIV infection. According to ViiV, small amounts of cabotegravir will remain in your body for "up to a year or more after your last injection". Speak to your healthcare provider about what this means for you.

## Bear in mind

Apretude is not for everyone and there are risks and benefits with every medicine.

If you are thinking about changing your PrEP from injections to pills, speak with your doctor or nurse to find out if these medicines are right for you.

## Availability

Apretude (cabotegravir) is licensed in Canada. Your doctor or pharmacist can tell you if and when Apretude is subsidized in your region.

## Reference

ViiV Healthcare. Apretude (cabotegravir tablets and extended release injectable suspension). *Product monograph*. 10 May, 2024.

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