Descovy

FACT SHEET

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Summary

Descovy is the name given to a pill containing the following two anti-HIV drugs: FTC (emtricitabine) and TAF (tenofovir alafenamide).

Descovy comes in two colour-coded strengths and can be taken with or without food. Descovy is meant to be used together with other anti-HIV drugs by people who are HIV-positive. Descovy can be used by HIV-negative men and transgender women to reduce their risk of acquiring HIV via condomless anal sex. Regardless of someone's HIV status, Descovy was generally well tolerated in clinical trials. Side effects were usually mild and temporary and included headache, tiredness or lack of energy, nausea and diarrhea.

What is Descovy?

Descovy is the name of a pill that contains the following two anti-HIV drugs:

- FTC (emtricitabine), which belongs to a class of drugs called nucleoside analogues ("nukes")
- TAF (tenofovir alafenamide), which belongs to a class of drugs called nucleotide analogues ("nukes")

It is supplied as rectangular-shaped tablets and comes in two colour-coded strengths as follows:

- Grey tablets stamped "210" on one side; these contain 200 mg FTC and 10 mg TAF
- Blue tablets stamped "225" on one side; these contain 200 mg FTC and 25 mg TAF

Descovy has different uses in different populations:

1. HIV prevention

Clinical trials have shown that Descovy significantly reduces the risk of sexual transmission of HIV in HIV-negative gay and bisexual men as well as transgender women.

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2. HIV treatment

HIV-positive people use Descovy in combination with other antiretroviral drugs to treat (but not cure) HIV.

TAF is a new formulation of an older drug called tenofovir DF (tenofovir disoproxil fumarate). In clinical trials of combination HIV therapy, TAF was found to be safe and generally well tolerated with fewer side effects than tenofovir DF.

How does Descovy work?

To explain how Descovy works, we need to first tell you some information about HIV. When HIV infects a cell, it takes control of that cell. HIV then forces the cell to make many more copies of the virus. To make these copies, the cell uses proteins called enzymes. When the activity of these enzymes is reduced the production of HIV slows.

Descovy contains two drugs, FTC, which belongs to a group of drugs called nucleoside analogues, and TAF, which belongs to a group of drugs called nucleotide analogues. FTC and TAF interfere with an enzyme called reverse transcriptase (RT), which is used by HIV-infected cells to make new viruses. Since FTC and TAF both inhibit or reduce the activity of this enzyme, Descovy causes HIV-infected cells to produce fewer viruses.

How do people with HIV use Descovy?

Descovy is used in combination with several other antiretroviral drugs, usually including drugs from different classes, such as integrase inhibitors, protease inhibitors and/or non-nucleoside reverse transcriptase inhibitors ("non-nukes"). Combinations such as this are called antiretroviral therapy, or ART. For more information on ART, see CATIE's *Your Guide to HIV Treatment*.

Neither Descovy nor any other anti-HIV medication is a cure for HIV. It is therefore important that you see your doctor regularly so that he/she monitors your health.

Evidence shows that HIV-positive people who are on ART, engaged in care, and have an ongoing undetectable viral load are substantially less likely to transmit HIV to others, be it through sex, when sharing equipment to use drugs or during pregnancy and birth. In fact, the evidence for sexual transmission shows that people on ART who maintain an undetectable viral load do not pass HIV to their sexual partners. For further information see the CATIE fact sheet *HIV treatment and an undetectable viral load to prevent HIV transmission*. However, it is still a good idea to use condoms because they can reduce your risk for getting and passing on other sexually transmitted infections.

Warnings

1. Lactic acidosis

Descovy contains FTC and TAF. Both of these medicines may be associated with a build-up of the waste product lactic acid in the blood. People who are obese or who have used nukes for many years may be at increased risk of developing lactic acidosis. Symptoms of excess amounts of lactic acid in the blood can include the following:

- nausea
- vomiting
- abdominal pain
- diarrhea
- unexpected tiredness
- unexpected muscle pain
- feeling cold, especially in the arms and legs
- feeling dizzy or light-headed

If these symptoms occur while you are taking Descovy, call your doctor right away.

2. Liver problems—enlarged liver and fatty liver

In very rare cases, people who take Descovy may develop swollen liver (hepatomegaly) or fatty liver (steatosis). Obesity and the use of nukes (nucleoside analogues) over many years may be risk factors for enlarged and fatty liver in people with HIV. People

who develop these specific liver problems may also develop the following symptoms:

- yellowing of the skin and whites of the eyes (jaundice)
- nausea
- vomiting
- abdominal pain

If any of these symptoms develop, contact your doctor right away.

3. Other liver problems—hepatitis viruses

Descovy is not approved for treating people with hepatitis B virus (HBV). Also, the safety and effectiveness of Descovy in people co-infected with HIV and HBV is not known.

The drugs inside Descovy (FTC + TAF) have anti-HBV activity. Co-infected people who take Descovy and then stop it may notice symptoms of their hepatitis B infection worsen. Symptoms of worsening HBV infection can include the following:

- yellowing of the skin and whites of the eyes (jaundice)
- nausea
- vomiting
- abdominal pain
- stools turn light in colour
- persistent loss of appetite

These symptoms are sometimes called flares. If you have this co-infection, talk to your doctor before you start Descovy. If you later need to change your therapy, remind your doctor that you have hepatitis B.

People who are co-infected with HIV and hepatitis-causing viruses (including hepatitis C virus) and who take combination anti-HIV therapy (ART) can be at increased risk for liver injury. It is important to have regular blood tests so that your doctor can assess the health of your liver. If lab tests reveal that you do not have hepatitis B, speak to your doctor about getting a vaccine to protect you from it. There is no vaccine for preventing hepatitis C virus infection.

4. Pancreatitis

The manufacturer warns that "caution should be exercised" when using Descovy in patients with a history of pancreatitis (inflammation of the pancreas gland) or who are at risk for pancreatitis. There have been reports of pancreatitis in some people who have used nucleoside analogues.

According to the U.S. National Institutes of Health (NIH) the most common risk factor for pancreatitis is alcoholism. Other risk factors can include the following:

- a close relative (mother, father, brother or sister) with pancreatitis
- cystic fibrosis
- excessive levels of calcium in the blood
- very high levels of cholesterol or triglycerides in the blood

Symptoms of pancreatitis can include the following:

- nausea
- vomiting
- abdominal pain
- weight loss
- diarrhea
- oily stools

If you have these symptoms, contact your doctor right away.

5. Women and pregnancy

In clinical trials with Descovy, the proportion of women enrolled was relatively small. However, no side effects were more common in women than in men.

The safety of Descovy for the fetus is not known. The manufacturer recommends: "Descovy should not be used in pregnant women unless the potential benefits outweigh the potential risks to the fetus."

If you are taking Descovy and are thinking about becoming pregnant or are pregnant speak to your doctor.

6. Bones

Descovy contains TAF. Although TAF is supposed to be safer for bones than the older formulation tenofovir DF, in clinical trials, a substantial proportion of people who used the medicines in Descovy as part of combination anti-HIV therapy still had about a 3% decrease in bone mineral density in the hip and spine. In these clinical trials the proportion of participants who lost more than 3% of their bone mineral density was as follows:

- combination anti-HIV therapy containing tenofovir DF – 27% of participants
- combination anti-HIV therapy that included medicines contained in Descovy – 17% of participants

The long-term effect of Descovy on bones is emerging from observational studies. The drug generally does not cause long-term bone thinning.

7. Kidney injury and dysfunction

Descovy contains TAF. In some people with pre-existing kidney injury who switched from the older formulation (tenofovir DF) to the newer formulation TAF, kidney injury did not resolve.

In very rare cases, TAF can cause severe kidney injury.

General side effects

1. Common side effects

In clinical trials Descovy was generally well tolerated. General side effects included the following:

- headache
- tiredness or lack of energy
- nausea
- diarrhea

These side effects are usually temporary and mild.

2. Weight gain

In HIV-negative people

Descovy contains TAF. Studies in HIV-negative people have found that use of TAF is associated with weight gain. The increased weight is usually modest – about 2 kilos over the course of two years. If you find that your weight has increased significantly, speak to your doctor or nurse. There may be multiple reasons for weight gain in people regardless of the use of TAF (see below for more details) or HIV status.

In HIV-positive people

Some studies with HIV-positive people who used TAF as part of combination treatment found that weight gain occurred. In some people the increased weight gain was modest – a few kilos – while in others it was more substantial. Research suggests that some HIV-positive people with the following features or characteristics tend to gain weight when on ART:

- women
- people of African, Black or Caribbean descent
- people whose CD4+ cell count fell below the 200 cell/mm^3 level at some point in the past.

However, some HIV-positive people without these features can also gain weight. The cause of increased weight in HIV-positive people is not clear because studies suggest that HIV-negative people of the same age and gender are also generally gaining weight even though they are not taking ART.

An increase of one or two kilograms in weight over the course of one year is normal when initiating ART and is what has been reported in clinical trials in the current era. However, should you gain more than this amount of weight, speak to your nurse or doctor so that your weight gain can be assessed. Doctors and nurses also take into account a person's waist size and/or body mass index (BMI) – this is a number derived by dividing their height by the square of their weight. If your nurse or doctor has found that your BMI is increasing and is outside what is considered healthy then they will investigate possible causes for an increase in weight.

There may be one or more reasons that your BMI is increasing, including the following:

Physical activity – Are you getting enough daily physical activity, including walking and climbing stairs? If not, can you begin a program of exercise? Speak to your nurse or doctor about what kind of exercise is right for you.

Sleeping problems – Rest and sleep quality are sometimes overlooked aspects of health. A large observational study in HIV-negative people found that people who have sleeping problems tend to gain weight. If you are unexpectedly gaining weight, speak to your doctor or nurse to rule out any sleep problems.

Emotional and mental health – Are there factors in your life that can affect how you respond to stressful events? For instance, when stressed, some people eat more fat and carbohydrate-rich foods as a source of comfort. Repeated engagement in excessive intake of carbohydrates and fatty foods can lead to weight gain over time. Depression can affect appetite—some people gain weight, others lose weight. If you notice weight gain along with changes in your mood, speak to your doctor or nurse.

Metabolic conditions, hormones and arthritis

Some conditions and life-stages are associated with weight gain, including the following:

- diabetes
- problems with the thyroid gland and its hormones
- being post-menopausal
- arthritis

Diet

Not everyone follows a diet that is informed by dietary guidelines. If you have access to subsidized dietary counselling (sometimes this is provided in large hospitals and clinics), you may benefit from consulting a registered dietitian. Registered dietitians can assess the quality and quantity of meals, and if necessary, provide helpful advice about making healthy changes.

Substance use

Alcohol contains calories. Is excess consumption of alcohol an issue for you? Excess consumption of alcoholic beverages could suggest unaddressed mental health and emotional issues.

Prescription medicines

Some prescription medicines (for conditions other than HIV) have the potential to cause changes in weight, particularly increased weight. It can be useful to speak to a pharmacist about all the medicines that you are taking to see if any are associated with changes in weight. You can then discuss any medicines that your pharmacist has identified with your doctor.

Bear in mind

While the above list covers some potential causes of weight gain in HIV-positive people, it is not exhaustive.

Uncommon side effects

Fewer than 1% of participants in clinical trials experienced the following side effects:

- abdominal pain
- indigestion
- flatulence
- rash
- vomiting

These side effects were generally mild and temporary.

In clinical trials of Descovy a small proportion of users developed increases in the levels of cholesterol and triglycerides in their blood.

Drug interactions

Sometimes one drug can interfere with the body's processing of another drug. Such an effect is called a drug-drug interaction or, more simply, a drug interaction. This can cause higher-than-normal

levels of one or both drugs in the blood, resulting in side effects or worsening of pre-existing side effects. Alternatively, the interference of one drug on another can cause the levels of one or both drugs to fall below normal levels. This can result in the drug(s) losing effectiveness. In the case of anti-HIV drugs, this fall in drug levels can cause HIV to develop the ability to resist one drug and, likely, other related drugs. This drug resistance limits future treatment options.

To minimize the development of drug resistance, all prescribed medicines should be taken every day, exactly as directed.

Always tell your doctor, nurse and pharmacist about **all** the drugs you are taking—prescription and over the counter, supplements or herbs, and street drugs. Pharmacists in particular can be very helpful in checking for the possibility of drug interactions. It is best to get all your prescription medicines from the same pharmacy so that they can help you keep track of potential drug interactions.

Below are lists of some actual and potential drug interactions; these lists are not exhaustive.

Drug interactions for Descovy

All of the following drugs/herbs can reduce the amount of tenofovir in your body. Therefore the manufacturer recommends that you not take the following if you are taking Descovy:

- anti-tuberculosis (TB) drugs – rifampin, rifapentine or rifabutin
- herbs – St. John's wort and its extracts (such as hypericin and hyperforin)
- anti-HIV medicine – Aptivus (tipranavir)

The manufacturer recommends that physicians prescribe a different anti-seizure drug if a patient is taking one of the following anti-seizure drugs and has also been prescribed Descovy:

- carbamazepine
- oxcarbazepine
- phenobarbital
- phenytoin

The manufacturer recommends that the smaller dose of Descovy (containing 200 mg FTC and 10 mg TAF, tablets are stamped "210" on one side) should be used with the following drugs:

- atazanavir (Reyataz) + cobicistat
- atazanavir (Reyataz) + ritonavir (Norvir)
- darunavir + cobicistat (both drugs come in one pill called Prezcobix)
- darunavir (Prezista) + ritonavir (Norvir)
- lopinavir + ritonavir (both drugs come in one pill called Kaletra)

The manufacturer notes that the following drugs may raise the concentration of TAF in the blood:

- antifungal drugs – ketoconazole (Nizoral), itraconazole (Sporanox). However, the company does not provide any advice. If you are taking these drugs speak to your doctor.

Resistance

Descovy is meant to be taken once daily. If you have problems taking Descovy exactly as directed, speak to your doctor and pharmacist. They can help you find ways to stick to your drug regimen. If you do not take Descovy once every day, the level of anti-HIV drugs in your body will be reduced. When this happens, HIV can develop the ability to resist the medicines that make up Descovy, which means that the medicines will no longer work. This could weaken your immune system and affect your body's ability to fight infections. Also, the development of HIV that is resistant to one or more of the medicines inside Descovy can reduce your future treatment options.

The U.S. Department of Health and Human Services (DHHS) has been producing comprehensive HIV treatment guidelines for many years. These guidelines recommend that patients have resistance testing done prior to starting ART. Such testing can help reveal if HIV in your body has any resistance to the drugs in Descovy.

Dosage and formulations

For HIV treatment

The manufacturer recommends that adults and adolescents who are at least 12 years and who weigh at least 35 kg can use Descovy.

Descovy can be taken with or without food.

Descovy is supplied as rectangular-shaped tablets and comes in two, colour-coded strengths as follows:

- Grey tablets stamped "210" on one side; these contain 200 mg FTC and 10 mg TAF
- Blue tablets stamped "225" on one side; these contain 200 mg FTC and 25 mg TAF

The strength of Descovy used depends on the rest of a person's anti-HIV regimen. In general, in patients who are taking HIV protease inhibitors together with the boosting agents ritonavir (Norvir) and cobicistat, the manufacturer recommends the lower strength ("210") tablets of Descovy.

The manufacturer recommends the higher strength "225" tablets when Descovy is used with other classes of anti-HIV drugs such as the following:

- non-nukes (NNRTIs) – including efavirenz (Sustiva, Stocrin), rilpivirine (Edurant)
- integrase inhibitors – including dolutegravir (Tivicay), raltegravir (Isentress)
- co-receptor blockers – maraviroc (Celsentri)

Speak to your doctor and pharmacist to find out more about your regimen and which strength of Descovy is right for you.

For reducing the risk of sexual transmission of HIV

Gilead Sciences Canada recommends that the dose of Descovy in HIV-1 uninfected men or trans women is 200/25 mg once daily with or without food.

Missed doses

The manufacturer advises the following when it comes to missed doses: "If you miss a dose of Descovy and it is less than 18 hours from the time you usually take Descovy, then take the dose. If more than 18 hours has passed from the time you usually take Descovy, then wait until the next scheduled daily dose."

Availability

Once Health Canada licenses a drug, physicians can prescribe it but patients must pay for it unless they have a private insurance plan that provides coverage. If left untreated, HIV infection leads to catastrophic disease that can affect one's ability to work. HIV treatment is also expensive. Therefore, in Canada, provincial and territorial ministries of health heavily subsidize the cost of anti-HIV medications. Each ministry has a listing of drugs for which it is prepared to pay. These listings are called formularies.

Descovy is licensed in Canada for the following uses:

- the treatment of HIV infection in adults and adolescents, in combination with other anti-HIV drugs
- the prevention of HIV infection in men and transgender women

Your doctor can tell you more about the availability and coverage of Descovy in your region. CATIE's online module Federal, Provincial and Territorial Drug Access Programs also contains information about Canadian drug coverage.

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Disclaimer

Decisions about particular medical treatments should always be made in consultation with a qualified medical practitioner knowledgeable about HIV- and hepatitis C-related illness and the treatments in question.

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