Descovy

FACT SHEET

Published
2019

Summary

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

Descovy comes in two, colour-coded strengths, can be taken with or without food and is meant to be used together with other anti-HIV drugs. 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:

- TAF (tenofovir alafenamide), which belongs to a class of drugs called nucleotide analogues ("nukes")
- FTC (emtricitabine), which belongs to a class of drugs called nucleoside 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 10 mg TAF and 200 mg FTC
- Blue tablets stamped "225" on one side; these contain 25 mg TAF and 200 mg FTC

Descovy is used 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

CONTACT US

by telephone
1-800-263-1638
416-203-7122

by fax
416-203-8284

by e-mail
info@catie.ca

by mail
555 Richmond Street West
Suite 505, Box 1104
Toronto ON M5V 3B1

CATIE
Canada's source for HIV and hepatitis C information

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, TAF, which belongs to a group of drugs called nucleotide analogues, and FTC, which belongs to a group of drugs called nucleoside analogues. TAF and FTC interfere with an enzyme called reverse transcriptase (RT), which is used by HIV-infected cells to make new viruses. Since TAF and FTC 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.

Studies

In clinical trials, the drugs inside Descovy have been tested in around 2,000 HIV-positive people as part of combination anti-HIV therapy. In these trials, researchers found that TAF + FTC were effective. Furthermore, TAF was found to be as good as other regimens that contained the older formulation, tenofovir DF. The medicines that are in Descovy were generally well tolerated and safe. As Descovy contains TAF, in theory, it has a reduced potential for causing side effects affecting the kidney and bones compared to regimens that included tenofovir DF. TAF + FTC were an effective part of therapy both in people new to anti-HIV therapy and in those who are treatment-experienced.

Warnings

1. Lactic acidosis

Descovy contains TAF and FTC. 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 (TAF + FTC) 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 not clear.

7. Kidney injury and dysfunction

TAF in Descovy is relatively new. 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.

8. Age

There have not been reports of people over the age of 65 experiencing any increased risk of side effects with Descovy.

Descovy, as part of combination anti-HIV therapy, has been tested in about 50 children aged between 12 and 18 years old and was found to be generally safe and effective. For further information about HIV treatment in children, speak to your infectious disease or pediatric specialist.

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.

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 10 mg TAF and 200 mg FTC, 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

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

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.

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 treatment of HIV infection in adults, in combination with other antiretroviral drugs. 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.

References

Gilead Sciences. Descovy (emtricitabine/tenofovir alafenamide tablets). *Product monograph*. 25 June, 2018.

Bahr NC, Yarlagadda SG. Fanconi syndrome and tenofovir alafenamide: A case report. *Annals of Internal Medicine*. 2019; *in press*.

Gallant JE, Daar ES, Raffi F, et al. Efficacy and safety of tenofovir alafenamide versus tenofovir disoproxil fumarate given as fixed-dose combinations containing emtricitabine as backbones for treatment of HIV-1 infection in virologically suppressed adults: a randomised, double-blind, active-controlled phase 3 trial. *Lancet HIV*. 2016 Apr;3(4):e158-65.

Boyd MA, Cooper DA. Tenofovir alafenamide: safer, but questions remain. *Lancet HIV*. 2016 Apr;3(4):e158-65.

Pozniak A, Arribas JR, Gathe J, et al. Switching to tenofovir alafenamide, coformulated with elvitegravir, cobicistat, and emtricitabine, in HIV-infected patients with renal impairment: 48-week results from a single-arm, multicenter, open-label phase 3 study. *Journal of Acquired Immune Deficiency Syndromes*. 2016 Apr 15;71(5):530-7.

Wohl D, Oka S, Clumeck N, et al. Brief Report: A randomized, double-blind comparison of tenofovir alafenamide versus tenofovir disoproxil fumarate, each coformulated with elvitegravir, cobicistat, and emtricitabine for initial HIV-1 treatment: week 96 results. *Journal of Acquired Immune Deficiency Syndromes*. 2016 May 1;72(1):58-64.

Author(s): **Hosein SR**

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.

CATIE provides information resources to help people living with HIV and/or hepatitis C who wish to manage their own health care in partnership with their care providers. Information accessed through or published or provided by CATIE, however, is not to be considered medical advice. We do not recommend or advocate particular treatments and we urge users to consult as broad a range of sources as possible. We strongly urge users to consult with a qualified medical practitioner prior to undertaking any decision, use or action of a medical nature.

CATIE endeavours to provide the most up-to-date and accurate information at the time of publication. However, information changes and users are encouraged to consult as broad a range of sources as possible. Users relying on this information do so entirely at their own risk. Neither CATIE, nor any of its partners, funders, employees, directors, officers or volunteers may be held liable for damages of any kind that may result from the use or misuse of any such information. The views expressed herein or in any article or publication accessed or published or provided by CATIE do not necessarily reflect the policies or opinions of CATIE nor the views of its partners and funders.

Permission to reproduce

Production of this document has been made possible through a financial contribution from the Public Health Agency of Canada. The views expressed herein do not necessarily represent the views of the Public Health Agency of Canada.

CATIE fact sheets are available for free at **www.catie.ca**

CATIE
Canada's source for HIV and hepatitis C information

CONTACT US

by telephone
1-800-263-1638
416-203-7122

by fax
416-203-8284

by e-mail
info@catie.ca

by mail
555 Richmond Street West
Suite 505, Box 1104
Toronto ON M5V 3B1