



GILEAD

For People Taking DESCOVY® Combination Tablets

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Introduction

This leaflet was created for people who take DESCOVY Combination Tablets. This leaflet includes information about the characteristics of DESCOVY Combination Tablets, how to take DESCOVY Combination Tablets, what to do if you forget to take DESCOVY Combination Tablets, the side effects of DESCOVY Combination Tablets, and precautions for taking DESCOVY Combination Tablets. Read this leaflet thoroughly before taking DESCOVY Combination Tablets.

A medical decision needs to be made based on your circumstances before starting the administration of DESCOVY Combination Tablets.

Listen carefully to the explanation provided by your healthcare providers (physicians, nurses and pharmacists) and follow their instructions.

If you have any questions about the administration of DESCOVY Combination Tablets, consult your healthcare providers (physicians, nurses and pharmacists).

This leaflet is a revised Japanese version of the "Patient Information of DESCOVY" which accompanies "DESCOVY Full Prescribing Information" in the U.S.

The content was compiled under the supervision of Dr. Shinichi Oka (Director of AIDS Clinical Center, National Center for Global Health and Medicine)

For People Taking DESCOVY Combination Tablets

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What are DESCOVY Combination Tablets?



DESCOVY is a medicine for HIV infection that reduces the amount of the virus in the blood¹⁾.

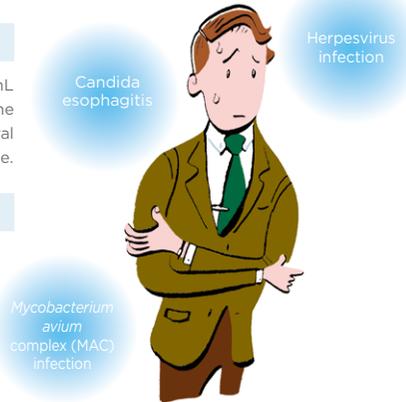
When DESCOVY Combination Tablets are administered and HIV activity in the blood is suppressed, immune-compromised patients recover some of their immune function and are less likely to acquire opportunistic infections²⁾.

Note 1) Amount of virus in the blood

The amount of virus in the blood is represented by the viral count in 1 mL of plasma. It indicates the treatment start time and/or the effects of the anti-HIV medicines. The goal of treatment is to maintain a viral concentration that is below the detection limit over a long period of time.

Note 2) Opportunistic infections

Signifies infections caused by weakly pathogenic microorganisms that do not cause infections in people with normal immune function. Opportunistic infections include candida esophagitis, herpesvirus infection, and *Mycobacterium avium* complex (MAC) infection.



Characteristics of DESCOVY Combination Tablets

DESCOVY Combination Tablets contain two types of nucleoside reverse transcriptase inhibitors. One is emtricitabine, and the other is tenofovir alafenamide. You can take two types of medicines with a once daily administration of only one tablet of DESCOVY, thus reducing the burden of administration. For actual treatment, other anti-HIV medicines are usually taken with DESCOVY Combination Tablets.

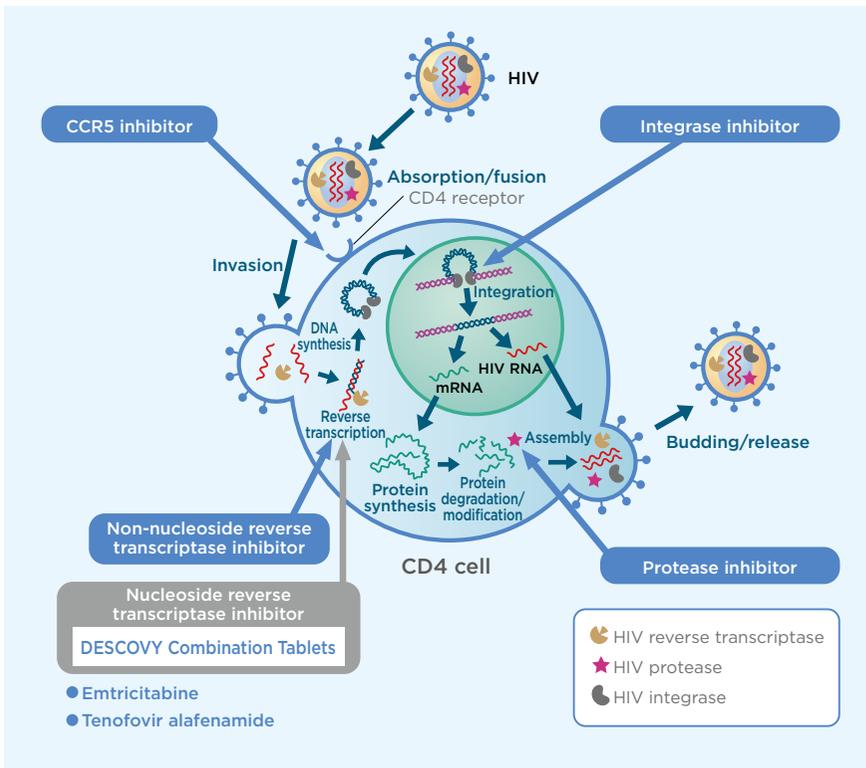
DESCOVY does not completely cure HIV infection or AIDS through short-term administration, but suppresses HIV activity through continued administration. Continued treatment is required, while taking precautions against opportunistic infections and other symptoms.

Effects of DESCOVY Combination Tablets

Emtricitabine and tenofovir alafenamide contained in DESCOVY Combination Tablets suppress the activity of HIV reverse transcriptase³⁾, which is necessary for HIV to multiply in the body, and prevent the growth of HIV.

Note 3) HIV reverse transcriptase

A type of enzyme that works when HIV multiplies in the body; A specific type of enzyme contained in the virus



In addition to nucleoside reverse transcriptase inhibitors, anti-HIV medicines include non-nucleoside reverse transcriptase inhibitors, protease inhibitors, integrase inhibitors, and CCR5 inhibitors, which respectively have different mechanisms of action. In the treatment of HIV infection, DESCOVY Combination Tablets are usually used in combination with these other medicines.

How should DESCOVY Combination Tablets be taken?

In general, take one tablet of DESCOVY once a day.

DESCOVY Combination Tablets may be taken regardless of when meals are taken.

There are two types of DESCOVY tablets (LT and HT) that contain different dosages of tenofovir alafenamide (TAF). Each of these tablets is used separately depending on other anti-HIV medicines that are concurrently administered. Make sure that you take the medicines as prescribed by your doctor.

This is a medicine you take.

DESCOVY Combination Tablets LT

Check

If administered concurrently with ritonavir or cobicistat

DESCOVY Combination Tablets HT

Check

If not administered concurrently with ritonavir or cobicistat

DESCOVY Combination Tablets LT is a gray tablet. One tablet contains emtricitabine 200 mg and tenofovir alafenamide 10 mg.



DESCOVY Combination Tablets HT is a blue tablet. One tablet contains emtricitabine 200 mg and tenofovir alafenamide 25 mg.



Taking the medicine every day is of the utmost importance for continuously suppressing the activity of the virus. If you miss taking the medicine for even a short period of time, the virus may multiply in the body or the medicine may become ineffective, and symptoms may worsen. Follow your doctor's instructions and take DESCOVY Combination Tablets and other medicines properly every day.

Do not discontinue taking DESCOVY Combination Tablets based only on your own judgment. If you have any problems, immediately contact a hospital. In addition, continue to see and consult your doctor regularly concerning your condition.



Notes

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Concomitant use of DESCOVY Combination Tablets with other medicines

Some medicines may not be administered concomitantly with DESCOVY Combination Tablets, or require precaution for concomitant use. If you take such medicines concomitantly with DESCOVY Combination Tablets, side effects may occur or therapeutic effects may decrease. Therefore, **inform and consult with your healthcare providers (physician, pharmacist, etc.) about all medicines that you are taking** (including prescription medicines, over-the-counter medicines, vitamins, herb supplements, and health foods) to take necessary measures.



Do not take DESCOVY Combination Tablets if you are taking the following anti-HIV medicines, anti-viral medicines, etc.



● Other medicines that contain emtricitabine

- Truvada® Combination Tablets
- Emtriva®
- Complera® Combination Tablets
- Stribild® Combination Tablets
- Genvoya® Combination Tablets
- Odefsey® Combination Tablets
- BIKTARVY® Combination Tablets
- Symtuza® Combination Tablets

● Other medicines that contain TDF

- Truvada® Combination Tablets
- Viread®
- Complera® Combination Tablets
- Stribild® Combination Tablets
- Tenozet®

● Other medicines that contain tenofovir alafenamide fumarate

- Genvoya® Combination Tablets
- Odefsey® Combination Tablets
- BIKTARVY® Combination Tablets
- Symtuza® Combination Tablets

● Other medicines that contain lamivudine

- Epzicom® Combination Tablets
- Combivir® Combination Tablets
- Epivir®
- Triumeq® Combination Tablets
- Zefix®

● Antiviral medicines

- Telaprevir (Telavic®)



Precautions need to be taken if you take the following medicines (or medicines containing the following ingredients) concomitantly with DESCOVY Combination Tablets.

- **Hypnotics and sedatives, anxiolytics**
- Phenobarbital (Phenobal®, etc.)

- **Antiepileptics**
- Carbamazepine (Tegretol®, etc.)
- Fosphenytoin (Fostoin®)
- Phenytoin (Aleviatin®, etc.)

- **Antibiotics**
- Rifabutin (Mycobutin®)

- **Tuberculosis preparations**
- Rifampicin (Rifadin®, etc.)

- **Antivirals**
- Aciclovir (Zovirax®, etc.)
- Ganciclovir (Denosine®)
- Valaciclovir hydrochloride (Valtrex®, etc.)
- Valganciclovir hydrochloride (Valixa®)

- **Herbal products**
- St. John's wort

Write down the medicines that you are currently taking.

*Including prescription medicines, over-the-counter medicines, vitamins, herbal supplements, health foods, etc.

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If you do not know whether or not the medicine you are taking is included in this list, ask your prescribing doctor or pharmacist.

In addition, do not start taking any new medicine while you are taking DESCOVY Combination Tablets without asking your doctor or pharmacist first.



What should you do if you miss a dose of DESCOVY Combination Tablets?

The most important thing is to take measures to prevent missing a dose.

Not missing a dose is the most important course of action for continuously suppressing HIV activity. Make out a schedule for taking DESCOVY Combination Tablets at a regular time in order to ensure that you don't forget.



Should you miss a dose of DESCOVY Combination Tablets...

If you miss a dose, take one dose of DESCOVY Combination Tablets (one tablet) as soon as possible after you realize that you have forgotten to take the medicine. Subsequently, continue taking DESCOVY Combination Tablets as scheduled.

If it is close to the time for the next administration when you realize that you have missed a dose, wait until the next administration and take one dose as scheduled.

What you must not do if you miss taking a dose!

Never take two or more doses of DESCOVY Combination Tablets (two or more tablets) at a time.

You should ask your healthcare provider (doctor or pharmacist) in advance what to do if you forget to take DESCOVY Combination Tablets.



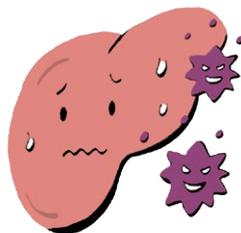
Precautions for taking DESCOVY Combination Tablets

If you are infected by hepatitis B virus

If you are infected by hepatitis B virus (HBV)⁴⁾ and take DESCOVY Combination Tablets, your hepatitis condition may relapse or rapidly deteriorate when you stop taking DESCOVY Combination Tablets. Therefore, before starting the administration of DESCOVY Combination Tablets, you need to check that you are not infected by HBV.

Note 4) Hepatitis B virus (HBV)

Hepatitis B virus causes chronic hepatitis B. HBV continues to multiply in hepatocytes, but does not kill cells directly. Therefore, it must be noted that even healthy people can be carriers of HBV. It is estimated that 1.5 million Japanese people are infected by HBV.



If you have symptoms of lactic acidosis

When you take a nucleoside reverse transcriptase inhibitor such as DESCOVY Combination Tablets, blood lactate level may become high and you may develop lactic acidosis. Lactic acidosis is very serious and life-threatening. If you have the following symptoms, immediately contact the hospital.

- Feel very weak or tired
- Have unusual muscle pain
- Have trouble breathing
- Have a fast or irregular heartbeat
- Feel cold, numbness, or pain, especially in your arms and legs
- Feel dizzy or lightheaded
- Have stomach pain with nausea or vomiting

If liver dysfunction occurs

When you take a nucleoside reverse transcriptase inhibitor such as DESCOVY Combination Tablets, you may develop fat in your liver (**steatosis**) and your liver may become enlarged (**hepatomegaly**). Immediately contact the hospital if you have any of the following symptoms.

- Your skin or the whites of your eyes turn yellow (jaundice)
- Urine color is thicker than before
- Stool color is whiter than before
- Loss of appetite for several days or longer
- Have nausea
- Have pain, aching, or tenderness on the right side of your stomach area



What are the side effects of DESCOVY Combination Tablets?

After administration of DESCOVY Combination Tablets, the following serious adverse effects may occur:

- Recurrence or worsening of the hepatitis B, lactic acidosis, fatty liver, or hepatomegaly symptoms described in “Precautions for taking DESCOVY Combination Tablets” (page 10)
- Changes in body fat⁵⁾
- Changes in your immune system⁶⁾
- Kidney problems⁷⁾
- Bone problems⁸⁾

Note 5) Changes in body fat

When you take anti-HIV medicines such as DESCOVY Combination Tablets, your body may put on fat on the chest or abdomen or from the neck to the upper back, or it may lose fat from the legs, arms, or face.

Note 6) Changes in your immune system

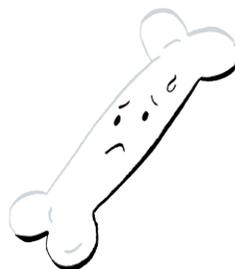
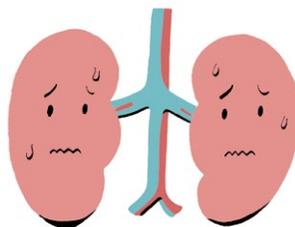
After the rapid improvement in your immunity following the administration of anti-HIV medicines, you may feel abnormalities in your body as your immune system functions.

Note 7) Kidney problems

Anti-HIV medicines may cause kidney problems. In clinical studies, DESCOVY Combination Tablets had less of an impact on kidney lab test results than the comparator medicine, TRUVADA Combination Tablets. However, DESCOVY Combination Tablets may cause additional kidney problems, including kidney failure and dysfunction, or worsen existing kidney problems. Blood and urine tests are required both before and during administration of DESCOVY Combination Tablets. Your doctor may tell you to stop taking DESCOVY Combination Tablets if your kidney function worsens during administration of DESCOVY.

Note 8) Bone problems

Bone problems may occur as a result of HIV infection or the effect of DESCOVY Combination Tablets or other medicines. If a bone problem is suspected, you may need to take a bone density test, etc.



Before administration of DESCOVY Combination Tablets, make sure to tell your healthcare provider if any of the following apply to you.

- Have or have had any liver problems, including HBV infection
- Have or have had any kidney problems
- Have or have had any bone problems
- Have any other medical conditions



The most common side effects from taking DESCOVY Combination Tablets are nausea, diarrhea, headache, etc.

Although there are cases where you need to discontinue DESCOVY Combination Tablets due to side effects, never discontinue the medicine or change how you take it based only on your own judgment. If you notice any physical abnormalities, contact your hospital immediately.

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Taking DESCOVY Combination Tablets during pregnancy?

The effects of DESCOVY Combination Tablets on a pregnant woman or the fetus are unknown.

Adequately consult your doctor about whether or not to take DESCOVY Combination Tablets during pregnancy. If you are pregnant or plan to become pregnant, be sure to tell your doctor before taking DESCOVY Combination Tablets.

Breast-feeding

Avoid breast-feeding, since it may result in HIV being transmitted from mother to infant.

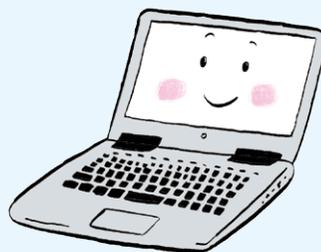
Emtricitabine contained in DESCOVY Combination Tablets may be excreted in milk. It is unknown whether tenofovir alafenamide fumarate is excreted in milk. In addition, the effects of DESCOVY Combination Tablets on the infant are unknown.

Ask your doctor about meals for infants.



If you would like to know more about HIV infection, access:

- AIDS Clinical Center, National Center for Global Health and Medicine
<https://www.acc.go.jp/> (Japanese version only) (Viewed on September 10, 2021)
- AIDS Medical Center, National Hospital Organization
Osaka National Hospital
<https://osaka.hosp.go.jp/department/khac/center/>
(Japanese version only) (Viewed on September 10, 2021)
- AIDS Prevention Information Network
<https://api-net.jfap.or.jp/>
(Japanese version only) (Viewed on September 10, 2021)



Is there anything else you should know?

Take note of the following points.

- Get regular examinations while taking DESCOVY Combination Tablets. Do not discontinue or change how to take DESCOVY Combination Tablets based on your own judgment alone without instructions from your doctor.
- Do not give DESCOVY Combination Tablets to others.

Precautions in everyday life

- Overseas research has demonstrated¹⁻⁴ that HIV transmission to a sexual partner can be prevented* by taking effective treatment that persistently suppresses the HIV RNA content to less than 200 copies per milliliter of blood. However, it has not been proven that taking the treatment will ensure complete prevention of HIV transmission.
- The partner could be infected with sexually transmitted disease such as hepatitis B, chlamydia, gonorrhea, and syphilis, or may have a type of HIV that does not respond as well to the treatment. Thus, proper use of condoms is advised when engaging in sexual activities in order to prevent becoming infected by such sexually transmitted diseases.

*Undetectable = Untransmittable; U = U

1: Rodger A, et al.: JAMA 2016; 316(2): 171

3: Bavinton BR, et al.: Lancet HIV 2018; 5(8): e438

2: Rodger AJ, et al.: Lancet 2019; 393: 2428

4: HIV Treatment Guidelines, March 2021

How to store DESCOVY Combination Tablets

- Keep DESCOVY Combination Tablets out of the reach of children.
- Keep DESCOVY Combination Tablets in its original container.
- Store DESCOVY Combination Tablets at room temperature, away from moisture. Do not store DESCOVY Combination Tablets at extremely high or low temperatures.
- Be sure to close the cap of the container after taking out a tablet for administration.
- Leave the desiccant (photo on the right) in the container during storage.



Desiccant

How to uncup the container of DESCOVY Combination Tablets

Follow the characteristic method for uncapping the container of DESCOVY Combination Tablets.

- 1) While holding down the cap,
- 2) Turn the cap to the left.



Citation: DESCOVY Full Prescribing Information (Issued: April 2016), Gilead Sciences, Inc.

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