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GILEAD | Medical Information

DESCOVY for PrEP® (emtricitabine and tenofovir alafenamide)

What lab tests are needed for PrEP?

This information is provided in response to your question. It is not treatment advice on how to use DESCOVY for PrEP. Please discuss this question and others you have about your medical condition or treatment with your healthcare provider.

Download the **DESCOVY Patient Information** for more details, including approved use(s) and important warnings. **www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_patient_pi.pdf**

The short answer[1]

Before you start and while you are taking DESCOVY for PrEP, or pre-exposure prophylaxis, there are several tests that your doctor will need to do to monitor your health.

Before you start taking DESCOVY for PrEP you need:

- an HIV-1 test
- a hepatitis B virus, or HBV, test
- tests to check your kidney health.

While you are taking DESCOVY for PrEP, your doctor will need to do the tests in the table below to monitor your health.

What tests should I have?	How often do I need to repeat them?
 **HIV-1**	• At least every 3 months **and** • If you find out you have a sexually transmitted infection, or STI **and** • If you think you might have been exposed to HIV-1, or if you have flu-like symptoms **and** • As often as your doctor tells you to
 **STIs**	Regularly
 **Kidney health**	Regularly

Please talk to your doctor for advice on how often you need to repeat these tests.

What is the most important information I should know about DESCOVY for PrEP?[1]

Some medications have important warnings that are designed to alert you of serious or life-threatening risks that come with taking the medication.

DESCOVY for PrEP has an important warning for: Worsening of hepatitis B virus (HBV) infection. Your healthcare provider will test you for HBV infection before or when you start treatment with DESCOVY. If you have HBV infection and take DESCOVY, your HBV may get worse (flare-up) if you stop taking DESCOVY. A “flare-up” is when your HBV infection suddenly returns in a worse way than before.

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- Do not run out of DESCOVY. Refill your prescription or talk to your healthcare provider before your DESCOVY is all gone.
- Do not stop taking DESCOVY without first talking to your healthcare provider.
- If you stop taking DESCOVY, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver, and may give you a medicine to treat hepatitis B. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking DESCOVY.

Who is DESCOVY for PrEP for?[1]

- DESCOVY for PrEP is a once-daily prescription medicine used to reduce the risk of getting HIV-1 infection in adults and teenagers who weigh at least 77 pounds (35 kg). HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).
- It is not known if DESCOVY for PrEP is effective in reducing the risk of getting HIV-1 from certain types of sex.
- DESCOVY for PrEP is not for use in people born female (assigned female at birth) who are at risk of getting HIV-1 from vaginal sex, because its effectiveness has not been studied.



You must be HIV-negative before you start and while taking DESCOVY for PrEP. Do not take DESCOVY for HIV-1 PrEP if you already have HIV-1 infection or you do not know your HIV-1 infection status.



Talk to a healthcare provider about your risk of getting HIV and if DESCOVY for PrEP is right for you. If you do not have a healthcare provider, the PrEP Locator website (www.PrEPLocator.org) can help you find a healthcare provider in your area who has experience prescribing PrEP medications.

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What should I do before taking DESCOVY for PrEP?[1]

Before you start DESCOVY for PrEP, there are several tests that your doctor will do to check your health. Please talk openly with your doctor about your sexual health.

HIV-1 Test



DESCOVY for PrEP can only help to reduce the risk of getting HIV-1 if you are HIV-negative. You must be confirmed to be HIV-negative before you start taking DESCOVY for PrEP.

- Get tested for HIV immediately before taking DESCOVY for PrEP. Some HIV tests can miss HIV-1 in people who have only recently become HIV-1-positive.
- If you have flu-like symptoms, you could have recently become HIV-1-positive. Tell your doctor if you had flu-like symptoms within the last month before starting DESCOVY for PrEP or at any time while taking it.



The symptoms of a new HIV-1 infection include: tiredness, fever, joint or muscle aches, headache, sore throat, vomiting, diarrhea, rash, night sweats, and/or enlarged lymph nodes in your neck or groin.

HBV Test



Your doctor will test you for HBV before you start taking DESCOVY for PrEP. If you have HBV and take DESCOVY for PrEP, your HBV may flare up if you stop taking it.

- A “flare up” is when your HBV suddenly returns in a worse way than before.
- Do not stop taking DESCOVY for PrEP without talking to your doctor first.

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If you have HBV and stop taking DESCOVY for PrEP, your doctor will need to do blood tests regularly for several months to check your HBV.

Kidney health tests



Your doctor should do blood and urine tests to check how well your kidneys work.

What should I do while taking DESCOVY for PrEP?[1]

While you are taking DESCOVY for PrEP, there are several tests that your doctor will do to check your health. Exactly how often these tests need to be repeated may depend on your health and your circumstances. Please talk openly with your doctor about your sexual health. Your doctor will be able to advise you when and how often you need these tests.

HIV-1 test



You must stay HIV-negative to keep taking DESCOVY for PrEP. While taking DESCOVY for PrEP, you should have an HIV test:

- at least every 3 months, **and**
- if you are diagnosed with an STI, **and**
- if you think you may have been exposed to HIV-1, or if you have flu-like symptoms, **and**
- as often as your doctor tells you to.

Your doctor can talk with you about all the ways to help reduce the risk of getting HIV.

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- If you do become HIV-1-positive, you need more medicine than DESCOVY alone to treat HIV-1. DESCOVY by itself is not a complete treatment for HIV-1.
- If you have HIV-1 and take only DESCOVY, over time your HIV-1 may become harder to treat. Speak to your doctor to discuss your treatment options.

STI tests



While you are taking DESCOVY for PrEP, you should have regular STI tests. Having certain STIs can make it easier for you to get HIV-1.

- DESCOVY for PrEP does not protect you from other STIs. Practice safer sex, including using latex or polyurethane condoms, to help prevent STIs.

Please speak to your doctor for more information about all the ways to help reduce the risk of getting STIs and how often you should be tested.

Kidney health tests



Your doctor should do blood and urine tests to check how well your kidneys are working while you are taking DESCOVY for PrEP.

- Your doctor may tell you to stop taking DESCOVY for PrEP if you develop new or worse kidney problems.

Glossary

AIDS (acquired immunodeficiency syndrome): most advanced stage of HIV infection.

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HBV (hepatitis B virus) infection: a type of virus (HBV) that can cause serious liver infection.

HIV (Human Immunodeficiency Virus): HIV (human immunodeficiency virus) is a virus that attacks the body's immune system. If HIV is not treated, it can lead to AIDS (acquired immunodeficiency syndrome).

Pre-exposure prophylaxis (PrEP): means routinely taking prescription medicine before you're exposed to HIV to help reduce your chances of getting it.

Sexually transmitted infection (STI): A sexually transmitted infection which can be spread through skin-to-skin contact and body fluids during oral, vaginal, and anal sex.

References

1. Enclosed. Gilead Sciences, Inc., DESCOVY® (emtricitabine/tenofovir alafenamide) tablets, for oral use. U.S. Prescribing Information. Foster City, CA.

More information about DESCOVY

If you would like more detailed information about DESCOVY, please visit: www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi.

This is the US FDA-approved Prescribing Information, including the Patient Labeling, for DESCOVY. It will tell you about the uses, warnings, and other important safety information about DESCOVY.

Important note

Gilead Sciences, Inc. is providing this letter in response to your unsolicited request for medical information. Some of the information included in this letter may not be covered in the US FDA-approved Prescribing Information for DESCOVY. Gilead Sciences, Inc. does not intend this letter to be used as medical advice and does not promote use of DESCOVY in a way that has not been approved by the FDA. Please discuss this question and others you may have about your medical condition or treatment with your HCP.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:
☎1-866-MEDI-GSI (1-866-633-4474) or www.patient.askgileadmedical.com/

Reporting side effects

Please report all adverse events to:
Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or www.accessdata.fda.gov/scripts/medwatch

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