

Descovy

WHAT IS DESCOVY?

Descovy is a drug used as part of <u>antiretroviral therapy (ART)</u> and as <u>pre-exposure prophylaxis (PrEP)</u>. Descovy contains two <u>antiretroviral drugs (ARVs)</u> combined in one tablet:

- emtricitabine (FTC, Emtriva)
- tenofovir alafenamide fumarate (tenofovir AF, TAF, Vemlidy)

The FDA approved Descovy in 2015 as a PrEP medication to reduce the risk of getting HIV and as an ARV for people with HIV infection. Descovy is manufactured by <u>Gilead Sciences</u>.

The component drugs in Descovy, emtricitabine and tenofovir AF, are <u>nucleoside reverse transcriptase</u> <u>inhibitors (NRTIs)</u>. NRTIs bind to and block reverse transcriptase (an HIV enzyme). HIV uses reverse transcriptase to convert its RNA into DNA (reverse transcription). Blocking reverse transcriptase and reverse transcription prevents HIV from replicating.

When used in combination with other ARVs to treat HIV infection, Descovy may help:

- Reduce the amount of HIV in your blood. This is called viral load.
- Increase the number of <u>CD4 cells</u> in your blood that help fight off other infections.

Reducing the amount of HIV and increasing CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting <u>opportunistic infections (OIs)</u> that can happen when your immune system is weak. <u>Read more about viral suppression.</u>

Descovy <u>does not cure</u> HIV infection or <u>AIDS</u>. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE DESCOVY?

Descovy is a prescription two-drug fixed-dose combination medication that may be used in two different ways. Descovy is used:

- to treat HIV infection in adults and children who weigh at least 55 pounds (25 kg), in combination with other ARVs
- as HIV PrEP to reduce the risk of getting HIV infection in adults and adolescents who weigh at least 77 pounds (35 kg)

The safety and effectiveness of Descovy for treatment of HIV infection has not been established in children who weigh less than 55 pounds (25 kg). The safety and effectiveness of Descovy as PrEP for reducing the risk of HIV infection has not been established in people who weigh less than 77 pounds (35 kg).

All people with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. Read more about U.S. ART guidelines.

Descovy provides two drugs in one pill. It can be more convenient to use Descovy than some other combinations of drugs that must be taken separately or at different times of the day. This could mean fewer missed doses and better control of HIV. **Descovy must be used in combination with other ARVs for the treatment of HIV infection.**

WHO SHOULD NOT TAKE DESCOVY?

Do not take Descovy if you are allergic to emtricitabine, tenofovir AF, or any of the ingredients in this drug.

Do not take Descovy if you are taking any of the following medicines. Taking Descovy with these medicines may affect how Descovy works. Descovy may cause serious or life-threatening side effects or death when used with these medicines:

- Seizure medicines: carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- Tuberculosis (TB) medicines: rifabutin, rifampin, rifapentine
- Herbal product: St. John's Wort (*Hypericum perforatum*)

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of these medicines in the past four weeks, talk to your healthcare provider or pharmacist before starting treatment with Descovy.

Do not take Descovy for HIV PrEP if you already have HIV or you do not know your HIV infection status. You must be HIV-negative to start Descovy. Descovy can only help reduce your risk of getting HIV infection before you are infected. You must get tested to make sure that you do not already have HIV infection before taking Descovy for PrEP. If you have HIV, you need to take other ARVs with Descovy to treat HIV infection. Descovy by itself is not a complete treatment for HIV. If you have HIV and take only Descovy, over time your HIV may become harder to treat.

Do not take Descovy for HIV PrEP if you were assigned female at birth (AFAB). Descovy for PrEP is not for use in AFAB people who are at risk of getting HIV infection from vaginal sex because its effectiveness has not been studied.

Descovy is not recommended in people with severe kidney disease or end-stage renal disease (ESRD).

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING DESCOVY?

Before you take Descovy, tell your healthcare provider about all of your medical conditions, and in particular if you:

- Have liver problems, including hepatitis B virus (HBV) infection
- Have kidney problems

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with Descovy. It is not known if Descovy can harm your unborn baby. There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. Read more about pregnancy and HIV.

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with Descovy. At least one of the medicines in Descovy (emtricitabine) can pass to your baby in your breastmilk. Do not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. Read more about HIV drug resistance.

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS DESCOVY TAKEN?

Descovy is taken by mouth as a tablet. Each Descovy tablet contains 200 mg of emtricitabine and 25 mg of tenofovir AF. The recommended dosage of Descovy for HIV treatment and PrEP is one tablet once daily.

If you take Descovy to treat HIV infection, you need to take Descovy with other HIV medicines. Your healthcare provider will tell you what medicines to take and how to take them.

Take Descovy at the same time each day with or without food. If you are on dialysis, take your daily dose of Descovy following dialysis.

Before taking Descovy for HIV PrEP:

- You must be HIV negative to start Descovy. You must get tested to make sure that you do not already have HIV infection.
- Do not take Descovy for HIV PrEP unless you are confirmed to be HIV negative.
- Some HIV tests can miss HIV infection in a person who has recently become infected. If you have flu-like symptoms, you could have recently become infected with HIV. Tell your healthcare provider if you had a flu-like illness within the last month before starting Descovy or at any time while taking Descovy. Symptoms of new HIV infection include:
 - Tiredness
 - Fever

- loint or muscle aches
- Headache
- Sore throat
- Vomiting or diarrhea
- Rash
- Night sweats
- Enlarged lymph nodes in the neck or groin

While you are taking Descovy for HIV PrEP:

- Descovy does not prevent other sexually transmitted infections (STIs). Practice <u>safer sex</u> by using a <u>condom</u> to reduce the risk of getting STIs.
- You must stay HIV negative to keep taking Descovy for HIV PrEP.
 - Know your HIV status and the HIV status of your partners.
 - Ask your partners with HIV if they are taking HIV medicines and have an undetectable viral load. An undetectable viral load is when the amount of virus in the blood is too low to be measured in a lab test. To maintain an undetectable viral load, your partners must keep taking HIV medicines every day. Your risk of getting HIV is lower if your partners with HIV are taking effective treatment.
 - Get tested for HIV at least every 3 months or when your healthcare provider tells you.
 - Get tested for other STIs such as syphilis, chlamydia, and gonorrhea. These infections make it easier for HIV to be transmitted.
 - If you think you were exposed to HIV, tell your healthcare provider right away. They may want to do more tests to be sure you are still HIV negative.
 - Get <u>information and support</u> to help reduce sexual risk behaviors.
 - Do not miss any doses of Descovy. Missing doses increases your risk of getting HIV infection.
- If you do become HIV positive, you need more medicine than Descovy alone to treat HIV. Descovy by itself is not a complete treatment for HIV.

WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary <u>side effects</u> such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effect of Descovy for HIV treatment is nausea. The most common side effect of Descovy for HIV PrEP is <u>diarrhea</u>.

Descovy can cause serious side effects including:

Worsening of HBV infection. Your healthcare provider will test you for HBV before starting treatment with Descovy. If you have HBV infection and take Descovy, your HBV may get worse (flareup) if you stop taking Descovy. A flare-up is when your HBV infection suddenly returns in a worse way than before. Do not stop taking Descovy without first talking to your healthcare provider. Do not run out of Descovy. Refill your prescription or talk to your healthcare provider before your Descovy is all gone. 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 HBV infection, or give you a medication to treat HBV. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking Descovy.

Immune Reconstitution Inflammatory Syndrome (IRIS). IRIS is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting treatment with Descovy.

New or worse kidney problems, including kidney failure. Your healthcare provider should do blood and urine tests to check your kidneys before you start and during treatment with Descovy. Your healthcare provider may tell you to stop taking Descovy if you develop new or worse kidney problems during treatment with Descovy.

Too much lactic acid in your blood (lactic acidosis). <u>Lactic acidosis</u> is a serious but rare medical emergency that can cause death. Tell your healthcare provider right away if you develop any of these symptoms:

- Weakness or being more tired than usual
- Being short of breath or fast breathing
- Cold or blue hands and feet
- Fast or abnormal heartbeat
- Unusual muscle pain
- Stomach pain with nausea and vomiting
- Feel dizzy or lightheaded

Severe liver problems. In rare cases, severe liver problems can happen that can lead to death. Tell your healthcare provider right away if you get these symptoms:

- Skin or the white part of your eyes turns yellow
- Dark or "tea-colored" urine
- Light-colored stools (bowel movements)
- Loss of appetite for several days or longer
- Nausea
- Stomach-area pain

These are not all the possible side effects of Descovy. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW DOES DESCOVY REACT WITH OTHER DRUGS?

All ARVs can <u>interact</u> with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take Descovy with other medicines.

See above for a list of medications that should not be taken with Descovy.

MORE INFORMATION

Visit the **Descovy website**.

Visit the <u>Descovy PrEP website</u>.

Visit the <u>Descovy healthcare professional website</u>.

Download the full <u>Prescribing Information</u>.

Download the <u>Important Facts</u> information sheet about Descovy for HIV treatment.

Download the Important Facts information sheet about Descovy for PrEP.

Apply for the Gilead Advancing Access Program.

Read more about PrEP at pleasePrEPme.org

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