

Patient Information
DESCOVY® (des-KOH-vee)
(emtricitabine
and tenofovir alafenamide)
tablets

Important: Ask your healthcare provider or pharmacist about medicines that should not be taken with DESCOVY. For more information, see the section “What should I tell my healthcare provider before taking DESCOVY?”

Read this Patient Information before you start taking DESCOVY and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is the most important information I should know about DESCOVY?

DESCOVY can cause serious side effects, including:

- **Worsening of Hepatitis B virus infection. DESCOVY is not for use to treat chronic hepatitis B virus (HBV) infection. If you have hepatitis B virus (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.**
 - 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 HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking DESCOVY.

For more information about side effects, see the section “What are the possible side effects of DESCOVY?”

What is DESCOVY?

DESCOVY is a prescription medicine that is used together with other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) in people 12 years of age and older.

HIV-1 is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

DESCOVY is **not** for use to help reduce the risk of getting HIV-1 infection by sexual contact in adults at high risk.

DESCOVY contains the prescription medicines emtricitabine (EMTRIVA®) and tenofovir alafenamide.

It is not known if DESCOVY is safe and effective in children under 12 years of age or who weigh less than 77 lb.

DESCOVY when used together with other HIV-1 medicines to treat HIV-1 infection may help:

- Reduce the amount of HIV-1 in your blood. This is called “viral load”.
- Increase the number of CD4+ (T) cells in your blood that help fight off other infections.

Reducing the amount of HIV-1 and increasing the CD4+ (T) cells in your blood may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

DESCOVY does not cure HIV-1 infections or AIDS. You must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others.

- Do not share or re-use needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.

- Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Ask your healthcare provider if you have any questions about how to prevent passing HIV-1 to other people.

What should I tell my healthcare provider before taking DESCOVY?

Before taking DESCOVY, tell your healthcare provider if you:

- have liver problems, including hepatitis B virus infection
- have kidney problems
- have bone problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if DESCOVY can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking DESCOVY.

Pregnancy Registry: There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. Do not breastfeed if you take DESCOVY.
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - At least one of the medicines in DESCOVY can pass to your baby in your breast milk. It is not known if the other medicine in DESCOVY can pass into your breast milk.

Talk with your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines may interact with DESCOVY. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with DESCOVY.
- **Do not start a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take DESCOVY with other medicines.

How should I take DESCOVY?

- Take DESCOVY exactly as your healthcare provider tells you to take it. DESCOVY must be taken together with other HIV-1 medicines to treat HIV-1 infection.
- Take DESCOVY 1 time each day with or without food.
- Do not change your dose or stop taking DESCOVY without first talking with your healthcare provider. Stay under a healthcare provider's care when taking DESCOVY.
- Do not miss a dose of DESCOVY.
- If you take too much DESCOVY, call your healthcare provider or go to the nearest hospital emergency room right away.
- When your DESCOVY supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to DESCOVY and become harder to treat.

What are the possible side effects of DESCOVY?

DESCOVY may cause serious side effects, including:

- **See “What is the most important information I should know about DESCOVY?”**
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having any new symptoms after starting your HIV-1 medicine.
- **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 while you are taking DESCOVY. Your healthcare provider may tell you to stop taking DESCOVY if you develop new or worse kidney problems.
- **Too much lactic acid in your blood (lactic acidosis).** Too much lactic acid is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you get these symptoms: weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.
- **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 “tea-colored” urine, light-colored stools, loss of appetite for several days or longer, nausea, or stomach-area pain.
- **Bone problems** can happen in some people who take DESCOVY. Bone problems may include bone pain, softening or thinning (which may lead to fractures). Your healthcare provider may need to do tests to check your bones.

The most common side effect of DESCOVY is nausea.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of DESCOVY. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store DESCOVY?

- Store DESCOVY below 86 °F (30 °C).
- Keep DESCOVY in its original container.
- Keep the container tightly closed.

Keep DESCOVY and all medicines out of reach of children.

General information about the safe and effective use of DESCOVY.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use DESCOVY for a condition for which it was not prescribed. Do not give DESCOVY to other people, even if they have the same symptoms you have. It may harm them. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about DESCOVY that is written for health professionals. For more information, call 1-800-445-3235 or go to www.DESCOVY.com.

What are the ingredients in DESCOVY?

Active ingredients: emtricitabine and tenofovir alafenamide.

Inactive ingredients: croscarmellose sodium, magnesium stearate, and microcrystalline cellulose.

The tablets are film-coated with a coating material containing indigo carmine aluminum lake, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

Manufactured and distributed by: Gilead Sciences, Inc. Foster City, CA 94404

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This Patient Information has been approved by the U.S. Food and Drug Administration

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