

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

DESCOVY® Tablets

(200 mg emtricitabine / 25 mg tenofovir alafenamide and 200 mg emtricitabine / 10 mg tenofovir alafenamide)
emtricitabine / tenofovir alafenamide

Consumer Medicine Information

What is in this leaflet

Read all of this leaflet carefully before you start taking this medicine.

This leaflet answers some of the common questions about DESCOVY tablets. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist about your medical condition or treatment. If you have further questions, please ask your doctor or your pharmacist.

This medicine has been prescribed for you personally and you should not pass it on to others.

It may harm them, even if their symptoms are the same as yours.

Medicines are sometimes prescribed for conditions that are not mentioned in this leaflet.

Keep this leaflet with your DESCOVY medicine.

You may need to read it again.

What is DESCOVY

How DESCOVY works

DESCOVY tablets consist of the following medicines:

- emtricitabine
- tenofovir alafenamide

These are combined in one tablet.

Emtricitabine and tenofovir alafenamide belong to a group of antiviral medicines known as nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs).

What is DESCOVY used for

- to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults and paediatric patients weighing ≥ 25 kg when taken in combination with other anti-HIV medicines;
- to reduce the risk of getting HIV-1 infection in at-risk adults and adolescents weighing ≥ 35 kg.

When DESCOVY is used to treat HIV-1 infection

DESCOVY helps block HIV-1 reverse transcriptase, a viral chemical (enzyme) in your body that is needed for HIV-1 to multiply.

DESCOVY lowers the amount of HIV in the blood (viral load).

DESCOVY may also help to increase the number of T cells (CD4+ cells), allowing your immune system to improve.

Lowering the amount of HIV in the blood lowers the chance of death or infections that happen when your immune system is weak (opportunistic infections).

HIV infection destroys CD4 T cells, which are important to the immune system. The immune system helps fight infection. After a large number of T cells are destroyed, acquired immune deficiency syndrome (AIDS) may develop.

DESCOVY is for people who do not have a resistant HIV virus to DESCOVY.

Use in Children

DESCOVY is used to treat HIV-1 infection in adults and children weighing ≥ 25 kg.

DESCOVY is used to reduce the risk of getting HIV-1 in adolescents weighing ≥ 35 kg.

DESCOVY has not been studied in children weighing less than 25 kg.

Does DESCOVY cure HIV or AIDS

DESCOVY does not cure HIV infection or AIDS.

The long-term effects of DESCOVY are not known at this time.

People taking DESCOVY may still get opportunistic infections or other conditions that happen with HIV infection.

Opportunistic infections are infections that develop because the immune system is weakened. Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium complex* (MAC) infection.

This medicine is only available from a pharmacist after it has been prescribed by a doctor who specialises in the treatment of HIV infection.

If you wish to continue receiving treatment with DESCOVY it is important you remain under the care of a hospital or doctor who specialises in the treatment of HIV infection.

Does DESCOVY reduce the risk of passing HIV to others

DESCOVY will substantially reduce the risk of passing HIV to others. However, a residual risk cannot be excluded.

Discuss with your doctor the precautions needed to avoid infecting other people.

For your health and the health of others, it is important to always practice safer sex by using a latex or polyurethane condom of other barrier to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Never re-use or share needles.

Before you take DESCOVY

When you must not take it

Together with your doctor, you need to decide whether DESCOVY is right for you.

Do not take DESCOVY if you are allergic to:

- emtricitabine
- tenofovir
- or any of the other ingredients of DESCOVY.

Do not take DESCOVY if you are already taking any other medicines that contain the same active ingredients.

The ingredients of DESCOVY are listed in the product description section of this leaflet.

Do not take DESCOVY if you take:

- tenofovir disoproxil fumarate (e.g. VIREAD)
- lamivudine (e.g. Combivir, Zeffix, Kivexa, Trizivir, Triumeq)
- carbamazepine (e.g. Tegretol)
- oxcarbazepine (e.g. Trileptal)
- phenobarbital or phenytoin (e.g. Dilantin)
- rifabutin (e.g. Mycobutin)
- rifampicin (e.g. Rifadin/Rimycin)
- rifapentine (e.g. Prifitin)
- St John's Wort or products containing St John's Wort
- tipranavir (e.g. Aptivus)
- boceprevir (e.g. Victrelis)

Do not take DESCOVY to treat your HIV infection if you are also taking adefovir dipivoxil to treat your hepatitis B virus (HBV) infection.

This is not a complete list of medicines that you should tell your doctor about.

For people using DESCOVY to reduce the risk of getting HIV-1 infection:

Do not take DESCOVY to help reduce your risk of getting HIV-1 if:

- you already have HIV-1 infection. If you are HIV-positive, you need to take other medicines with DESCOVY to treat HIV. DESCOVY by itself is not a complete treatment for HIV.
- you do not know your HIV-1 infection status. You may already be HIV-positive. You need to take other HIV-1 medicines with DESCOVY to treat HIV-1.
- Many HIV-1 tests can miss HIV-1 infection in a person who has recently become infected. If you have flu-like symptoms, you could have recently become infected with HIV-1. 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-1 infection include: tiredness, fever, joint or muscle aches, headache, sore throat, vomiting or diarrhoea, rash, night sweats or enlarged lymph nodes in the neck or groin.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have, or have had, any of the following medical conditions:

- kidney problems or are undergoing kidney dialysis treatment.
- liver problems, including hepatitis B or C virus infection.

Tell your doctor if you are pregnant, or likely to become pregnant during your course of medication.

We do not know if DESCOVY can harm your unborn child. You and your doctor will need to decide if DESCOVY is right for you.

Tell your doctor if you are breastfeeding, or likely to breastfeed during your course of medication.

You should not breastfeed if you are HIV-positive because of the chance of passing the HIV virus to your baby. At least one of the active substances in this medicine (emtricitabine) have been found in breast milk at low concentrations. It is not known if DESCOVY affects milk production or has effects on the breastfed child. Talk with your doctor about the best way to feed your baby.

Taking other medicines

Some medicines may affect the levels of DESCOVY or DESCOVY may affect the levels of other medicines in the body when they are taken at the same time as DESCOVY.

Your doctor may change your other medicines or change their doses. Other medicines, including herbal products may affect DESCOVY.

For this reason, it is very important to let your doctor or pharmacist know what medications, herbal supplements, or vitamins you are taking.

Know the medicines you take. Keep a list of medicines and show it to your doctor and pharmacist when you get a new medicine.

Your doctor and your pharmacist can tell you if you can take these medicines with DESCOVY.

Do not start any new medicines while you are taking DESCOVY without first talking with your doctor or pharmacist.

How to take DESCOVY

Take the exact amount of DESCOVY your doctor has prescribed for you.

Never change the dose on your own.

Do not stop this medicine unless your healthcare provider tells you to stop.

How much to take

The usual dose is one DESCOVY tablet orally, once daily.

Take DESCOVY with or without food.

If you forget to take it

It is important not to miss a dose of DESCOVY.

If you do miss a dose:

- **If you notice within 18 hours** of the time you usually take DESCOVY, you must take the tablet as soon as possible. Then take the next dose as usual.
- **If you notice 18 hours or more** after the time you usually take DESCOVY, then do not take the missed dose. Wait and take the next dose at your usual time.

Do not take a double dose to make up for a forgotten dose.

Continue with your regular dosing schedule.

When your DESCOVY supply starts to run low, get more from your doctor or pharmacy.

This is very important. If you are taking DESCOVY for HIV-1 treatment, 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. If you are taking DESCOVY to reduce your risk of getting HIV, you must take DESCOVY every day to protect yourself from getting HIV-1.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre: 131126 (Australia) and 0800 764 766 (New Zealand) or go to the Accident and Emergency department at your nearest hospital if you think you or anyone else may have taken too many DESCOVY tablets. Do this even if there are no signs of discomfort or poisoning. This may need urgent medical attention.

While you are taking DESCOVY

Things you must not do if taking it for HIV-1 Treatment

Do not breastfeed. See “Before you start to take it”

Avoid doing things that can spread HIV infection since DESCOVY does not stop you from passing the HIV infection to others.

- **Do not share needles or other injection equipment.**
- **Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.**
- **Do not have any kind of sex without protection.**

Always practice safer sex by using a latex or polyurethane condom or other barrier to reduce the chance of sexual contact with semen, vaginal secretions, or blood.

Do not take DESCOVY after the expiry or “use by” date (EXP) printed on the bottle.

If you take it after the expiry date has passed, it may not work as well.

Do not take DESCOVY if the packaging is torn or shows signs of tampering.

If you are taking DESCOVY to reduce your risk of getting HIV

You must stay HIV-negative to keep taking DESCOVY.

Things to be careful of

Be careful driving or operating machinery until you know how DESCOVY affects you.

If you are dizzy, have trouble concentrating, or are drowsy, avoid activities that may be dangerous, such as driving or operating machinery.

Side Effects

Like all medicines, DESCOVY can have side effects, although not everybody gets them. Some may be serious and need medical attention.

Check with your doctor as soon as possible if you have any problems while taking DESCOVY, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Serious side effects

Serious Liver Problems (hepatotoxicity)

If you have any of the following symptoms while taking your medication, tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital.

- your skin or the white part of your eyes turns yellow (jaundice)
- your urine turns dark
- your bowel movements (stools) turn light in colour
- you don't feel like eating food for several days or longer
- you feel sick to your stomach (nausea)
- you have lower stomach area (abdominal) pain

These side effects may be due to a condition called hepatotoxicity with liver enlargement (hepatomegaly) and fat deposits in the liver (steatosis) which sometimes occurs in patients taking anti-HIV medicines.

Hepatic Flares

If you have HBV infection you should not stop your DESCOVY treatment without first discussing this with your doctor. Your HBV may get worse (flare-up) if you stop taking DESCOVY. A “flare-up” or “hepatic flare” is when your HBV infection suddenly returns in a worse way than before. You may require medical exams and blood tests for several months after stopping treatment. You must discuss your HBV therapy with your doctor.

Signs and symptoms of inflammation

In some patients with advanced HIV infection (AIDS), signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response, which lets the body fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please tell your doctor immediately.

Lactic Acidosis

If you have any of the following symptoms after taking your medication, tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital.

- you feel very weak or tired
- you have unusual (not normal) muscle pain
- you have trouble breathing
- you have stomach pain with nausea and vomiting
- you feel cold, especially in your arms and legs
- you feel dizzy or light headed
- you have a fast or irregular heartbeat

These side effects may be due to a condition called lactic acidosis (build-up of an acid in the blood).

Lactic acidosis can be a medical emergency and may need to be treated in the hospital.

Allergy

Some people are allergic to medicines. If you have any of the following symptoms soon after taking your medicine, DO NOT TAKE ANY MORE DESCOVY and tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital:

- skin troubles such as lumpy skin rash or “hives”
- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- wheezing, chest pain or tightness
- fainting

These are very serious effects. If you have them, you may have a serious allergic reaction. You may need urgent medical attention or hospitalisation.

Hypersensitivity reactions are very rare.

Common side effects

The most common side effect of DESCOVY is nausea.

Other side effects include:

- diarrhea
- fatigue
- headaches
- abdominal pain
- indigestion
- flatulence
- rash
- vomiting
- abnormal dreams

Talk to your doctor or pharmacist if you don't understand anything in this list.

This is not a complete list of side effects possible with DESCOVY.

Ask your doctor or pharmacist for a more complete list of side effects of DESCOVY and all the medicines you will take.

After taking DESCOVY

Storage

Keep DESCOVY tablets where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store them.

Keep DESCOVY tablets in a cool, dry place where it stays below 30 °C.

Do not store DESCOVY or any other medicine in a bathroom or near a sink.

Do not leave DESCOVY in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep your DESCOVY tablets in the bottle with the cap tightly closed until you take them.

If you take DESCOVY tablets out of their pack they may not keep well.

Product Description

What the tablets look like

The 200/25 mg DESCOVY tablets are rectangular-shaped, film-coated and blue in colour.

Each tablet is debossed with “GSI” on one side and the number “225” on the other side.

The 200/10 mg DESCOVY tablets are rectangular-shaped, film-coated and gray in colour.

Each tablet is debossed with “GSI” on one side and the number “210” on the other side

DESCOVY tablets are supplied in bottles containing 30 tablets.

Ingredients

Each DESCOVY tablet contains the active ingredients:

- emtricitabine
- tenofovir alafenamide

Each DESCOVY tablet also contains the following inactive ingredients:

- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate

Film-coating (200/25 mg tablets):

- polyvinyl alcohol
- titanium dioxide
- polyethylene glycol
- talc
- indigo carmine aluminum lake

Film-coating (200/10 mg tablets):

- polyvinyl alcohol
- titanium dioxide
- polyethylene glycol
- talc
- iron oxide black

Sponsor

DESCOVY tablets are supplied in Australia by:

Gilead Sciences Pty Ltd
Level 6, 417 St Kilda Road
Melbourne, Victoria 3004

In New Zealand:

Gilead Sciences (NZ)
Grant Thornton New Zealand Limited
L4, 152 Fanshawe Street,
Auckland 1010
New Zealand

Date of preparation: 07 January 2021

DESCOVY 200/10 mg tablets AUST R
246093

DESCOVY 200/25 mg tablets AUST R
246092

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